

FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JULY 1, 2016, TO DECEMBER 31, 2016

PUBLISHED BY THE COMMISSION

VOLUME 162



Compiled by
The Office of the Secretary
Robert F. Swenson, Editor

**MEMBERS OF THE FEDERAL TRADE COMMISSION
DURING THE PERIOD
JULY 1, 2016 TO DECEMBER 31, 2016**

EDITH RAMIREZ, *Chairwoman*
Took oath of office April 5, 2010.

MAUREEN K. OHLHAUSEN, *Commissioner*
Took oath of office April 4, 2012.

TERRELL McSWEENY, *Commissioner*
Took oath of office April 28, 2014

DONALD S. CLARK, *Secretary*
Appointed August 28, 1988.

CONTENTS

Members of the Commission	ii
Table of Cases	iv
Findings, Opinions, and Orders	1
Interlocutory, Modifying, Vacating, and Miscellaneous Orders.....	1202
Responses to Petitions to Quash	1212
Table of Commodities.....	1218

TABLE OF CASES

VOLUME 162

<u>File or Docket #</u>	<u>Name</u>	<u>Page(s)</u>
A		
C-4584	ABS Consumer Products, LLC	27
9369	Advocate Health and Hospitals Corporation <i>(Interlocutory Order)</i>	1205, 1208
9369	Advocate Healthcare Network <i>(Interlocutory Order)</i>	1205, 1208
	Airgas, Inc. . <i>See American Air Liquide Holdings, Inc.</i>	
C-4589	Allergan plc	563
	Alvogen Pharma US, Inc. <i>See Mylan N.V.</i>	
C-4574	American Air Liquide Holdings, Inc.	141
C-4574	American Air Liquide Holdings, Inc. <i>(Divestiture)</i>	1202, 1211
	Argos USA LLC	<i>See Heidelbergcement AG</i>
C-4587	ASUSTeK Computer, Inc.	203
B		
C-4581	Ball Corporation	418
C-4585	Beyond Coastal	49
C		
9366	Cabell Huntington Hospital	60
9370	California Naturel, Inc.	1066
9370	California Naturel, Inc. <i>(Interlocutory Order)</i> ..	1210
9371	Canexus Corporation	373
162 3134	CellMark BioPharma LLC <i>(PTQ)</i>	1212
D		
C-4588	Delhaize Group NV/SA	945

TABLE OF CASES
continued

E

	EDEN BodyWorks	
 See ABS Consumer Products, LLC	
C-4583	Erickson Marketing Group Inc., The	15

F

	Fairchild Semiconductor International, Inc.	
 See ON Semiconductor Corporation	
C-4592	Fortiline, LLC	891

G

	General Motors Company See General Motors LLC	
C-4596	General Motors LLC	1099

H

C-4579	HeidelbergCement AG	504
C-4579	Heidelbergcement AG (Divestiture)	1207

I

	Indicus Pharma LLC	See Mylan N.V.
C-4586	Invibio Limited	97
C-4586	Invibio, Inc.	97
C-4579	Italcementi S.p.A.	504
C-4579	Italcementi S.p.A. (Divestiture)	1207

J

	Jim Koons Automotive Companies	
 See Jim Koons Management Company	
C-4598	Jim Koons Management Company	1150

K

C-4588	Koninklijke Ahold N.V.	945
--------	-------------------------------------	-----

L

	L' Air Liquide, S.A.	
 See American Air Liquide Holdings, Inc.	
9357	LabMD, Inc.	246
162 3133	Lexium International, LLC (PTQ)	1212
C-4597	Lithia Motors, Inc.	1126
	Littelfuse, Inc.	
 See ON Semiconductor Corporation	

M

C-4599	Mars Petcare US, Inc.	1172
	Matheson Tri-Gas, Inc.	
 See American Air Liquide Holdings, Inc.	
	Meda AB	See Mylan N.V.
C-4590	Mylan N.V.	798

N

9369	NorthShore University HealthSystem (<i>Interlocutory Order</i>)	1205, 1208
------	---	------------

O

C-4593	ON Semiconductor Corporation	910
--------	---	-----

P

9366	Pallottine Health Services, Inc.	60
9368	Penn State Hershey Medical Center, The	1015
9368	Penn State Hershey Medical Center, The (<i>Interlocutory Order</i>)	1203
9368	PinnacleHealth System	1015
9368	PinnacleHealth System (<i>Interlocutory Order</i>) ...	1203
	Plaid Social Labs, LLC	
 See Warner Bros. Home Entertainment Inc.	
C-4591	Practice Fusion, Inc.	397

TABLE OF CASES
continued

R

	Reliant Holdings, Ltd.	
 See American Air Liquide Holdings, Inc.	
C-4581	Rexam PLC	418
	Rocky Mountain Sunscreen	
 See Erickson Marketing Group Inc., The	

S

	Shikai	See Trans-India Products, Inc.
9366	St. Mary's Medical Center, Inc.	60
9371	Superior Plus Corp.	373

T

C-4589	Teva Pharmaceutical Industries Ltd.	563
C-4582	Trans-India Products, Inc.	1

V

C-4586	Victrex plc	97
--------	--------------------------	----

W

C-4595	Warner Bros. Home Entertainment Inc.	1040
	Warner Bros. Interactive Entertainment	
 See Warner Bros. Home Entertainment Inc.	

FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JULY 1, 2016, TO DECEMBER 31, 2016

IN THE MATTER OF

TRANS-INDIA PRODUCTS, INC.
D/B/A
SHIKAI

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4582; File No. 152 3265
Complaint, July 6, 2016 – Decision, July 6, 2016

This consent order addresses Trans-India Products, Inc.'s advertising for its hand and body lotion and shower gel products. The complaint alleges that the respondent violated Section 5(a) of the Federal Trade Commission Act by representing that its hand and body lotion and shower gel products are "all natural" even though they contain the synthetic ingredients Dimethicone, Ethylhexyl Glycerin, and Phenoxyethanol. The consent order prohibits any representation regarding whether any product is all natural or 100% natural; the extent to which such product contains any natural or synthetic ingredient or component; the ingredients or composition of such product; or the environmental or health benefits of such product, unless the representation is non-misleading.

Participants

For the *Commission*: Robert M. Frisby, Gregory Madden and John Andrew Singer.

For the *Respondent*: Pamela Steckroat Treadway, President, *pro se*.

COMPLAINT

The Federal Trade Commission, having reason to believe that Trans-India Products, Inc., has violated the provisions of the

Complaint

Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Trans-India Products, Inc., doing business as ShiKai, is a California corporation with its principal office or place of business at 3330-A Coffey Lane, Santa Rosa, California 95404, and a mailing address of Box 2866, Santa Rosa, California 95405.

2. Respondent has advertised, labeled, offered for sale, sold, and distributed products to consumers, including “All Natural Hand and Body Lotion” and “All Natural Moisturizing Shower Gel.”

3. The acts and practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent advertises the above products on the Internet. They retail for \$6.39 to \$6.59.

5. Respondent has disseminated or has caused to be disseminated advertisements for its Hand and Body Lotion and Moisturizing Shower Gel, including but not necessarily limited to the attached Exhibits A-C.

- a. The packaging for the Hand and Body Lotion states that it is an “All Natural Hand and Body Lotion.”

Exhibit A, Internet webpage www.walgreens.com/store/c/shikai-all-natural-hand-and-body-lotion-starfruit (August 2015).

- b. Respondent’s catalogue states that the Hand and Body Lotion contains:

wonderful rich ingredients: lots of aloe vera, wheatgerm & apricot oils, shea butter, and borage oil too. And they’re all natural.

Exhibit B, Internet webpage www.shikai.com/home/catalogue.pdf at p. 10 (August 2015).

Complaint

- c. The packaging for the Moisturizing Shower Gel states that it is an “All Natural Moisturizing Shower Gel.”

Exhibit C, Internet webpage www.vitacost.com/shikai-all-natural-moisturizing-showerhand-and-body-lotion-coconut-12-fl-oz (August 2015); Exhibit D, Internet webpage www.shikai.com/home/catalogue.pdf at p. 11 (August 2015).

Count I
False Claim

6. In connection with the advertising, labeling, promotion, offering for sale, or sale of its All Natural Hand and Body Lotion and All Natural Moisturizing Shower Gel, Respondent has represented, directly or indirectly, expressly or by implication, that these products are “all natural.”

7. In fact, All Natural Hand and Body Lotion and All Natural Moisturizing Shower Gel are not “all natural” because they contain or contained at least one synthetic ingredient. The All Natural Hand and Body Lotion contains or contained the synthetic ingredients Dimethicone, Ethylhexyl Glycerin, and Phenoxyethanol. The All Natural Moisturizing Shower Gel contains or contained the synthetic ingredients Ethylhexyl Glycerin and Phenoxyethanol. Therefore, the “all natural” representations set forth in Paragraph 6 are false or misleading.

Violations of Section 5(a)

8. The acts and practices of Respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this sixth day of July, 2016, has issued this Complaint against Respondent.

By the Commission.

Complaint

Exhibit A

The screenshot displays the Walgreens website interface for the product 'SHKcal All Natural Hand and Body Lotion'. At the top, the Walgreens logo and navigation tabs for Pharmacy, Health & Wellness, Contact Lenses, and Pet Care are visible. The product image shows a tube of lotion with a price tag of \$6.39. Below the image, there is a 'Description' section with text describing the lotion's benefits, such as being '100% All Natural' and 'Free of Parabens and Fragrance'. A 'Shipping' section indicates that shipping is free for orders over \$25. An 'Ingredients' section lists various natural oils and butters. At the bottom, there is a 'Reviews' section and a navigation menu with categories like Customer Service, Shipping, and Pharmacy Services.

Complaint

Exhibit B

PAMPER YOUR SKIN

Our fragrant body lotions smell really luscious and you'll love the way your skin feels, so soft and smooth with no slippery after-feel.

Each contains wonderful rich ingredients: lots of aloe vera, wheatgerm & apricot oils, shea butter, and borage oil too. And they're all natural!

Choose from 9 tantalizing fragrances: cooling Cucumber Melon, spicy Yuzu, sweet Gardenia and more.

SHIKAI® HAND & BODY LOTIONS



Complaint

Exhibit D

LUXURIATE IN A TUB OR SHOWER

Rich, scented bubbles smell wonderful, will clean gently, and moisturize your skin too!

That's right - these are not just ordinary shower gels. Pure colloidal oatmeal, aloe vera, and special moisturizers combine to soothe dry sensitive skin and relieve those itches.

Select from 9 alluring fragrances: mellow Vanilla, mysterious Sandalwood, tropical Coconut and more.

Have a sumptuous shower (or bath) and give your skin a treat as well.

SHIKAI® MOISTURIZING SHOWER GELS



Natural solutions that work.™

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C § 45 *et seq.*; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), a statement that respondent neither admits nor denies any of the allegations in the draft complaint except as specifically stated in the consent agreement, an admission by the respondent of facts necessary to establish jurisdiction for purposes of this action, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Trans-India Products, Inc., doing business as Shikai, is a corporation with its principal office or place of business at 3330-A Coffey Lane, Santa Rosa, California 95404, and a mailing address of Box 2866, Santa Rosa, California 95405.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the respondent, and the proceeding is in the public interest.

Decision and Order

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “respondent” and “Trans-India” shall mean Trans-India Products, Inc., a corporation doing business as Shikai, its successors and assigns, and its officers, agents, representatives, and employees.
- B. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not make any representation, expressly or by implication, including through the use of a product name, trademark, or trade name, about:

- A. whether such product is all natural or 100% natural;
- B. the extent to which such product contains any natural or synthetic ingredient or component;
- C. the ingredients or composition of such product; or
- D. the environmental or health benefits of such product,

unless the representation is non-misleading, including that, at the time such representation is made, the respondent possesses and relies upon competent and reliable evidence, which when appropriate based on the expertise of professionals in the relevant area must be competent and reliable scientific evidence, that is sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the

Decision and Order

entire body of relevant and reliable evidence, to substantiate that the representation is true. For the purposes of this Provision:

1. “competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results; and
2. “competent and reliable *scientific* evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

II.

IT IS FURTHER ORDERED that respondent Trans-India, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

Decision and Order

III.

IT IS FURTHER ORDERED that respondent Trans-India, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent must maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

IV.

IT IS FURTHER ORDERED that respondent Trans-India, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Trans-India Products, Inc., doing business as Shikai, Docket No. C-4582.

Decision and Order

V.

IT IS FURTHER ORDERED that respondent Trans-India, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VI.

This order shall terminate on July 6, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order as to Trans-India Products, Inc., doing business as Shikai (hereafter “respondent”).

The proposed consent order (“order”) has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the respondent’s advertising for its hand and body lotion and shower gel products. The Commission’s complaint alleges that the respondent violated Section 5(a) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45(a), by falsely representing that its hand and body lotion and shower gel products are “all natural.” It also alleges that the products are not “all natural” because the hand and body lotion contains the synthetic ingredients Dimethicone, Ethylhexyl Glycerin, and Phenoxyethanol and the shower gel contains the synthetic ingredients Ethylhexyl Glycerin and Phenoxyethanol.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. It also includes provisions to assist the Commission in monitoring and enforcing compliance with the order.

Part I prohibits any representation regarding whether any product is all natural or 100% natural; the extent to which such product contains any natural or synthetic ingredient or component; the ingredients or composition of such product; or the environmental or health benefits of such product, unless the representation is non-misleading. The respondent must have competent and reliable evidence, sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true. When appropriate, based on the expertise of professionals in the relevant

Analysis to Aid Public Comment

area, the substantiation must be competent and reliable scientific evidence. “Competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results. “Competent and reliable scientific evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

Parts II through V require the respondent to: (1) keep records of advertisements and substantiation relevant to representations covered by Part I; (2) deliver a copy of the order to principals, officers, directors, and managers, and to employees, agents, and representatives having responsibilities with respect to the subject matter of the order; (3) notify the Commission of changes in corporate structure that might affect compliance obligations; and (4) file compliance reports with the Commission.

Part VI provides that, with exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order’s terms in any way.

Complaint

IN THE MATTER OF

**THE ERICKSON MARKETING GROUP INC.
D/B/A
ROCKY MOUNTAIN SUNSCREEN**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4583; File No. 152 3268
Complaint, July 6, 2016 – Decision, July 6, 2016*

This consent order addresses The Erickson Marketing Group Inc.'s advertising for its sunscreen products. The complaint alleges that the respondent violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing that its sunscreen products are "all natural" when they contain the synthetic ingredients Dimethicone, Polyethylene, Butyloctyl Salicylate, and Neopentyl Glycol Diethylhexanoate. The consent order prohibits any representation regarding whether any product is all natural or 100% natural; the extent to which such product contains any natural or synthetic ingredient or component; the ingredients or composition of such product; or the environmental or health benefits of such product, unless the representation is non-misleading.

Participants

For the *Commission*: Robert M. Frisby, Gregory Madden, and John Andrew Singer.

For the *Respondent*: David C. Erickson, President, *pro se*.

COMPLAINT

The Federal Trade Commission, having reason to believe that The Erickson Marketing Group Inc., a corporation, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent The Erickson Marketing Group Inc., also doing business as Rocky Mountain Sunscreen, is a Colorado corporation with its principal office or place of business at 14700 W.66th Place, Suite 2, Arvada, Colorado 80004.

Complaint

2. Respondent has advertised, labeled, offered for sale, sold, and distributed products to consumers, including Face Stick SPF 60 All Natural Sunscreen and Face Stick SPF 60 Kids All Natural Sunscreen. These sunscreen products are “drugs” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

3. The acts and practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent advertises Face Stick SPF 60 All Natural Sunscreen and Face Stick SPF 60 Kids All Natural Sunscreen on the Internet. These products retail for \$7.99.

5. Respondent has disseminated or has caused to be disseminated advertisements for Face Stick SPF 60 All Natural Sunscreen and Face Stick SPF 60 Kids All Natural Sunscreen, including but not necessarily limited to the attached Exhibit A. These materials contain the following statements:

Natural Face Stick

- a. True to form, Rocky Mountain Sunscreen offers superior protection in an all natural formula with their Natural Face Stick --- available for both kids and adults. This *natural sunscreen* option helps get protection in the areas more difficult to apply liquid sunscreen, like on the nose and ears.
- b. This all natural sunscreen Face Stick provides SPF 60 protection and its ingredients include zinc oxide and titanium dioxide, two of the most effective blockers of harmful UVA rays. This product is extraordinarily effective and is ideal for those with sensitive skin. The Face Stick for kids is a must have for child care centers, day camps, and even moms on the go, as its easy, smooth application ensures that little faces are protected and there’s no tears from sunscreen in the eyes or hair.

Complaint

- c. This all *natural sunscreen* Face Stick is very effective, yet safe for everyday use. It is non-irritating, non-greasy, and non-comedogenic. It is also free of fragrances, nut oils, and Vitamin A (retinyl palmitate). And, just like all the sunscreen options from Rocky Mountain Sunscreen, it can stand up to the elements, such as sweat, chlorine, and more. SPF 60 All Natural Kids Face Stick Sunscreen is also ideal for active youngsters for any type of summertime activity they may enjoy.

(Exhibit A, Internet webpage www.rmsunscreen.com (May 2015) (emphasis in original)).

**Count I
False Claim**

6. In connection with the advertising, labeling, promotion, offering for sale, or sale of Face Stick SPF 60 All Natural Sunscreen and Face Stick SPF 60 Kids All Natural Sunscreen, Respondent has represented, directly or indirectly, expressly or by implication, including through the name of the product, that Face Stick SPF 60 All Natural Sunscreen and Face Stick SPF 60 Kids All Natural Sunscreen are “all natural.”

7. In fact, Face Stick SPF 60 All Natural Sunscreen and Face Stick SPF 60 Kids All Natural Sunscreen are not “all natural” because they contain the synthetic ingredients Dimethicone, Polyethylene, Butyloctyl Salicylate, and Neopentyl Glycol Diethylhexanoate. Therefore, the “all natural” representation set forth in Paragraph 6 is false or misleading.

Violations of Sections 5 and 12

8. The acts and practices of Respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

Complaint

THEREFORE, the Federal Trade Commission this sixth day of July, 2016 has issued this Complaint against Respondent.

By the Commission.

Complaint

Exhibit A

all Natural Sunscreen Face Stick: Kids and Adults

The screenshot shows the Rocky Mountain Sunscreen website. At the top, there is a navigation bar with links for Home, Why RMS?, Skin & Sun, and FAQs. A search bar is also present. The main header features the Rocky Mountain Sunscreen logo and the tagline "Inspired by Altitude For superior protection in any environment." Below the header, there is a navigation menu with links for Home, Why RMS?, Skin & Sun, and FAQs. The main content area is titled "Natural Face Stick" and contains the following text:

True to form, Rocky Mountain Sunscreen offers superior protection in an all natural formula with their Natural Face Stick—available for both kids and adults. This natural sunscreen option helps get protection in the areas more difficult to apply liquid sunscreen, like on the nose and ears.

This all natural sunscreen Face Stick provides SPF 60 protection and its ingredients include zinc oxide and titanium dioxide, two of the most effective blockers of harmful UVA rays. This product is extraordinarily effective and is ideal for those with sensitive skin. The Face Stick for Kids is a must have for child care centers, day camps, and even moms on the go, as its easy, smooth application ensures that little faces are protected and there's no tears from sunscreen in the eyes or hair.

This all natural sunscreen Face Stick is very effective, yet safe for everyday use. It is non-irritating, non-greasy, and non-comedogenic. It is also free from fragrances, nut oils, and Vitamin A (retinyl palmitate). And, just like all the sunscreen options from Rocky Mountain Sunscreen, it can stand up to the elements, such as sweat, chlorine, and more. **SPF 60 All Natural Kids Face Stick Sunscreen** is also ideal for active youngsters for any type of summertime activity they may enjoy.

Get your all natural face sticks for fast and effective face protection. And browse the site to shop for all your sunscreen needs, from bulk gallons to travel size bottles to lip balm and hand sanitizer. We have you covered when you want to get out in the sun.

Displaying products 1 - 2 of 2 results

Showing 30 items | Sort: Default

The product listings show two items:

- Face Stick SPF 60 All Natural Sunscreen**: Price: \$7.99, 5 stars rating, Add to Cart, More Info.
- Face Stick SPF 60 Kids All Natural Sunscreen**: Price: \$7.99, 5 stars rating, Add to Cart, More Info.

The sidebar on the left contains the following categories:

- Shop Sunscreen by SPF
 - SPF 30
 - SPF 30 All Natural
 - SPF 50
 - SPF 60
 - SPF 70
- Shop Sunscreen by Size
 - Travel Size
 - Refillable Bottles
 - Quarts
 - Gallons
- Specialty Products
 - Lip Balm
 - Sunburn Relief
 - Hand Sanitizer
 - Insect Repellent
 - Wedding Favors (Custom)
- Spray Sunscreen
 - Natural Face Stick
 - Kids Sunscreen
- Bulk Pump Dispensers
- Event Packages
- ON SALE TODAY
- What's with the Purple Mountains?
- Custom Lip Balm
- View All Products

At the bottom of the sidebar, there is a "MORE INFO" section with links to:

- Schools / Childcare
- Outdoor / Gov't Workers
- Wholesale Dealer Site
- FDA New 2012 Regulations
- Sunscreen Safety Concerns
- Partners / Athletes
- Media & Press
- Find a Retailer
- Our Guarantee (returns)
- Privacy
- Shipping Details

http://www.rmssunscreen.com/NaturalSunscreen.aspx[5/22/2015 2:25:29 PM]

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C § 45 *et seq.*; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), a statement that respondent neither admits nor denies any of the allegations in the draft complaint except as specifically stated in the consent agreement, an admission by the respondent of facts necessary to establish jurisdiction for purposes of this action, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent The Erickson Marketing Group Inc., also doing business as Rocky Mountain Sunscreen, is a Colorado corporation with its principal office or place of business at 14700 W. 66th Place, Suite 2, Arvada, Colorado 80004.

Decision and Order

2. The Commission has jurisdiction over the subject matter of this proceeding and over the respondent, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “respondent” shall mean The Erickson Marketing Group Inc., a corporation, also doing business as Rocky Mountain Sunscreen, its successors and assigns, and its officers, agents, representatives, and employees.
- B. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not make any representation, expressly or by implication, including through the use of a product name, trademark, or trade name, about:

- A. whether such product is all natural or 100% natural;
- B. the extent to which such product contains any natural or synthetic ingredient or component;
- C. the ingredients or composition of such product; or
- D. the environmental or health benefits of such product,

unless the representation is non-misleading, including that, at the time such representation is made, the respondent possesses and relies upon competent and reliable evidence, which when

Decision and Order

appropriate based on the expertise of professionals in the relevant area must be competent and reliable scientific evidence, that is sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true. For the purposes of this Provision:

1. “competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results; and
2. “competent and reliable *scientific* evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

II.

IT IS FURTHER ORDERED that respondent The Erickson Marketing Group Inc., and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the

Decision and Order

representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

III.

IT IS FURTHER ORDERED that respondent The Erickson Marketing Group Inc., and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent must maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

IV.

IT IS FURTHER ORDERED that respondent The Erickson Marketing Group Inc., and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement,

Decision and Order

Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re The Erickson Marketing Group Inc., Docket No. C-4583.

V.

IT IS FURTHER ORDERED that Respondent The Erickson Marketing Group Inc., and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VI.

This order shall terminate on July 6, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the

Analysis to Aid Public Comment

later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order as to The Erickson Marketing Group Inc., d/b/a Rocky Mountain Sunscreen (hereafter “respondent”).

The proposed consent order (“order”) has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the respondent’s advertising for its sunscreen products. The Commission’s complaint alleges that the respondent violated Sections 5(a) and 12 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. §§ 45(a) and 52, by falsely representing that its sunscreen products are “all natural.” It also alleges that the sunscreen products are not “all natural” because they contain the synthetic ingredients Dimethicone, Polyethylene, Butyloctyl Salicylate, and Neopentyl Glycol Diethylhexanoate.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. It also includes provisions to assist the Commission in monitoring and enforcing compliance with the order.

Analysis to Aid Public Comment

Part I prohibits any representation regarding whether any product is all natural or 100% natural; the extent to which such product contains any natural or synthetic ingredient or component; the ingredients or composition of such product; or the environmental or health benefits of such product, unless the representation is non-misleading. The respondent must have competent and reliable evidence, sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true. When appropriate, based on the expertise of professionals in the relevant area, the substantiation must be competent and reliable scientific evidence. “Competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results. “Competent and reliable scientific evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

Parts II through V require the respondent to: (1) keep records of advertisements and substantiation relevant to representations covered by Part I; (2) deliver a copy of the order to principals, officers, directors, and managers, and to employees, agents, and representatives having responsibilities with respect to the subject matter of the order; (3) notify the Commission of changes in corporate structure that might affect compliance obligations; and (4) file compliance reports with the Commission.

Part VI provides that, with exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order’s terms in any way.

Complaint

IN THE MATTER OF

ABS CONSUMER PRODUCTS, LLC
D/B/A
EDEN BODYWORKS

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4584; File No. 152 3269
Complaint, July 6, 2016 – Decision, July 6, 2016

This consent order addresses ABS Consumer Products, LLC's advertising for its shampoo, conditioner, and other hair care products. The complaint alleges that the respondent violated Section 5(a) of the Federal Trade Commission Act by representing that their products are "all natural" when they contain one or more synthetic ingredients. The consent order prohibits any representation regarding whether any product is all natural or 100% natural; the extent to which such product contains any natural or synthetic ingredient or component; the ingredients or composition of such product; or the environmental or health benefits of such product, unless the representation is non-misleading.

Participants

For the *Commission: Robert M. Frisby, Gregory Madden, and John Andrew Singer.*

For the *Respondent: Darrell N. Phillips, Pietrangelo Cook PLC; and Kevin Swinton, solo practioner.*

COMPLAINT

The Federal Trade Commission, having reason to believe that ABS Consumer Products, LLC, a limited liability company, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent ABS Consumer Products, LLC, also doing business as EDEN BodyWorks, is a limited liability company with its principal office or place of business at 3634 Park Avenue, Memphis, Tennessee 38111.

Complaint

2. Respondent has advertised, labeled, offered for sale, sold, and distributed products to consumers, including Coconut Shea All Natural Curl Defining Cream, Coconut Shea All Natural Leave In Conditioner, Coconut Shea Styling Elixir, Jojoba Monoi Moisturizing Shampoo, and Jojoba Monoi Revitalizing Conditioner.

3. The acts and practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent advertises the above products on the Internet. They retail for \$8.47 to \$8.99.

5. Respondent has disseminated or has caused to be disseminated advertisements for Coconut Shea All Natural Curl Defining Cream, Coconut Shea All Natural Leave In Conditioner, Coconut Shea Styling Elixir, Jojoba Monoi Moisturizing Shampoo, and Jojoba Monoi Revitalizing Conditioner, including but not necessarily limited to the attached Exhibits A-C. These materials contain the following statements:

Coconut Shea All Natural Curl Defining Cream

Discover EDEN for yourself. EDEN BodyWorks Coconut Shea All Natural Curl Defining Cream is a humidity-resistant formulation designed to refine and separate curls and waves.

(Exhibit A, Internet webpages www.walmart.com/ip/EDEN-BodyWorks-Coconut-Shea-All-Natural-Curl-Defining-Cream (April and May 2015))

Coconut Shea All Natural Leave In Conditioner

Discover EDEN for yourself. EDEN BodyWorks Shea All Natural Leave In Conditioner is a daily conditioning treatment formulated with one of nature’s best moisturizers, coconut oil, to penetrate and revitalize tresses. It’s blended with shea butter to seal in moisture.

Complaint

(Exhibit B, Internet webpage www.walmart.com/ip/EDEN-BodyWorks-Coconut-Shea-All-Natural-Leave-In-Conditioner (May 2015))

**Coconut Shea
All Natural Styling Elixir**

**Jojoba Monoi
All Natural Shampoo**

**Jojoba Monoi
All Natural Conditioner**

(Exhibit C, product labels displayed on Internet webpages at www.edenbodyworks.com (May 2015))

**Count I
False Claim**

6. In connection with the advertising, labeling, promotion, offering for sale, or sale of Coconut Shea All Natural Curl Defining Cream, Coconut Shea All Natural Leave In Conditioner, Coconut Shea Styling Elixir, Jojoba Monoi Moisturizing Shampoo, and Jojoba Monoi Revitalizing Conditioner, Respondent has represented, directly or indirectly, expressly or by implication, including through the name of the first two products, that these products are “all natural.”

7. In fact, the above products are not “all natural” because they contain at least one synthetic ingredient. Coconut Shea All Natural Curl Defining Cream contains the synthetic ingredient Polyquaternium-7. Coconut Shea All Natural Leave In Conditioner contains the synthetic ingredients Polyquaternium-7 and Polyquaternium-37. Coconut Shea Styling Elixir contains the synthetic ingredients Polyquaternium-37, Polyquaternium-11, Phenoxyethanol, and Caprylyl Glycol. Jojoba Monoi Moisturizing Shampoo and Jojoba Monoi Revitalizing Conditioner contain the synthetic ingredients Phenoxyethanol and Caprylyl Glycol. Therefore, the “all natural” representation set forth in Paragraph 6 is false or misleading.

Complaint

Violations of Section 5

8. The acts and practices of Respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this sixth day of July, 2016, has issued this Complaint against Respondent.

By the Commission.

Complaint

Exhibit A

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme, 16 fl oz - Walmart.com



All Departments My Local Store Value of the Day Tips & Ideas FREE SHIPPING on orders of \$50 or more

Beauty Hair Care Hair Treatments

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme, 16 fl oz

8 reviews Q&A By: Eden BodyWorks Walmart #: 552442543



Product pricing and purchase options:

\$8.47 52.99 / fl oz

FREE shipping on orders \$50 + FREE pickup

Quantity:

Complaint

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme, 16 fl oz - Walmart.com







[Add to list](#)

Sold by **Walmart.com**

- Designed to refine and separate curls and waves
- Infuses moisture to strengthen hair

[More about this item...](#)

Customers also bought these products

					
\$8 47 EDEN BodyWorks... (5)	\$8 47 EDEN BodyWorks... (7)	\$8 47 EDEN BodyWorks... (4)	\$8 47 EDEN BodyWorks... (3)	\$8 99 EDEN BodyWorks... Was \$9.99 You save \$0.68 (4)	\$9 47 EDEN B



Rollback Roundup THOUSANDS of NEW ITEMS just added! [Save Now](#)

About this item

Discover EDEN for yourself. EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme is a humidity-resistant formulation designed to refine and separate curls and waves. It infuses moisture to strengthen hair, provides frizz control, and optimizes style definition.

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme:

- Designed to refine and separate curls and waves
- Infuses moisture to strengthen hair
- Provides frizz control
- Optimizes style definition
- Medium hold

Complaint

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme, 16 fl oz - Walmart.com

Ingredients:

Water, Cocos Nucifera (Coconut) Oil, Vegetable Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice, Cetyl Alcohol, Stearyl Alcohol, Persea Gratissima (Avocado) Oil, Butyrospermum Parkii (Shea) Butter, Cetyl Esters, Glyceryl Dilaurate, Steareth-20, Polyquaternium-7, Cocos Nucifera (Coconut) Milk, Simmondsia Chinensis (Jojoba) Seed Oil, Limnanthes Alba (Meadowfoam) Seed Oil, Lactobacillus/Tomato Fruit Ferment Extract, Oryza Sativa (Rice Extract, Keratin Amino Acids, Acyl Coenzyme A Desaturase, Cetrimeronium Chloride, Glycerin, Tocopheryl Acetate (Vitamin E), Hydrolyzed Silk, Panthenyl Hydroxypropyl Steardimonium Chloride, Fragrance, Dehydroacetic Acid, Benzyl Alcohol.

Directions:

Directions: Apply to dry or damp hair. Finger comb product through the hair until the level of curl definition desired is reached. Diffuse or air dry, as needed.

For external use only. Avoid contact with eyes.


[Read less](#) <

Specifications


Model No.:	12-520
Shipping Weight (In pounds):	1.1
Product In Inches (L x W x H):	3.562 x 3.562 x 3.375
Assembled In Country of Origin:	USA
Origin of Components:	USA
Walmart No.:	552442643

Advertisement

Explore related products



Brand: Eden BodyWorks



Hair Coconut Oils

Advertisement

Sponsored Products

Complaint

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme, 16 fl oz - Walmart.c... Page 1 of 6


All Search Hello, Sign In My Account

[About this item](#) [Customer reviews](#) [Item recommendations](#) [Policies](#)

Beauty Hair Care Hair Treatments

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme, 16 fl oz

8 reviews Q&A By: Eden BodyWorks Walmart #: 503442613



\$8.47 at Clinton 12.94 / fl oz

FREE pickup

Quantity: 1 + [Add to cart](#)

[Add to registry](#) [Add to list](#)

Sold by Walmart store

Shipping Not available **FREE pickup** As soon as today

Designed to refine and separate curls and waves
Infuses moisture to strengthen hair

[More about this item...](#)

Customers also considered

				
\$8.47	\$9.47	\$8.47	\$5.74	\$5.97
EDEN BodyWorks Cooc	EDEN BodyWorks Jojoba	EDEN BodyWorks Jojoba	OGX Moroccan Argan C	Cantu Shea Butter For
(5)	(19)	(4)	(50)	(4)

 **Top values** on the latest styling tools [Shop Now](#) 

Complaint

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme, 16 fl oz - Walmart.c... Page 2 of 6

[All](#)
Hello, Sign in
My Account

About this item [Customer reviews](#) [Item recommendations](#) [Policies](#)
 About this item Explore related products

Discover EDEN for yourself. EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme is a humidity-resistant formulation designed to refine and separate curls and waves. It infuses moisture to strengthen hair, provides frizz control, and optimizes style definition.

EDEN BodyWorks Coconut Shea All Natural Curl Defining Creme:

- Designed to refine and separate curls and waves
- Infuses moisture to strengthen hair
- Provides frizz control
- Optimizes style definition
- Medium hold

Ingredients:

Water, Cocos Nucifera (Coconut) Oil, Vegetable Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice, Cetyl Alcohol, Stearyl Alcohol, Persea Gratissima (Avocado) Oil, Butyrospermum Parkii (Shea) Butter, Cetyl Esters, Glyceryl Dilaurate, Steareth-20, Polyquaternium-7, Cocos Nucifera (Coconut) Milk, Simmondsia Chinensis (Johoba) Seed Oil, Limnanthes Alba (Meadowfoam) Seed Oil, Lactobacillus/Tomato Fruit Ferment Extract, Oryza Sativa (Rice) Extract, Keratin Amino Acids, Acyl Coenzyme A Desaturase, Cetrimonium Chloride, Glycerin, Tocopheryl Acetate (Vitamin E), Hydrolyzed Silk, Panthenyl Hydroxypropyl Steardimonium Chloride, Fragrance, Dehydroacetic Acid, Benzyl Alcohol.

Directions:

Directions: Apply to dry or damp hair. Finger comb product through the hair until the level of curl definition desired is reached. Diffuse or air dry, as needed.

For external use only. Avoid contact with eyes.

Brand: Eden BodyWorks

Hair Coconut Oils

Hair Regrowth Products

Hair Growth Oils

Advertisement

Fast Pass

Specifications

Model No.:	12-520
Shipping Weight (in pounds):	1.1
Product in Inches (L x W x H):	3.562 x 3.562 x 3.375
Assembled in Country of Origin:	USA
Origin of Components:	USA
Walmart No.:	652442643

Sponsored Products

Complaint

Exhibit B

EDEN BodyWorks Coconut Shea All Natural Leave In Conditioner, 8 ... <http://www.walmart.com/ip/EDEN-BodyWorks-Coconut-Shea-All-Na...>

Beauty & Hair Care > Conditioners

Customers also considered

 \$8.47	 \$8.47	 \$8.47	 \$8.47	 \$8.99
---	---	---	---	--

EDEN BodyWorks Coconut Shea All Natural Leave In Conditioner, 8 fl oz

7.9/10 (44) By Eden BodyWorks Walmart #33440547



\$8.47 ~~\$16.94~~

FREE shipping on orders \$35+ or FREE pickup

Quantity: 1

Sell by Walmart.com

Shipping: Curbside pickup

A daily conditioning treatment to penetrate and seal hair
travels deeper with shea butter to seal in moisture
[Learn about this item.](#)

Check out these related products

 \$2.98	 \$9.47	 \$3.48	 \$8.47	 \$8.49
---	---	---	---	--

Top values on the latest styling tools [Shop Now](#)

[About this item](#) [Customer reviews](#) [Item recommendations](#) [Policies](#)

Complaint

EDEN BodyWorks Coconut Shea All Natural Leave In Conditioner, 8 ... <http://www.walmart.com/ip/EDEN-BodyWorks-Coconut-Shea-All-Na...>

Home

Walmart.com

My Account

ABOUT THIS ITEM

Discover EDEN for yourself. EDEN BodyWorks Coconut Shea All Natural Leave In Conditioner is a daily conditioning treatment formulated with one of nature's best moisturizers, coconut oil, to penetrate and revitalize tresses. It's blended with shea butter to seal in moisture.

EDEN BodyWorks Coconut Shea All Natural Leave In Conditioner

- A daily conditioning treatment to penetrate and revitalize tresses
- Blended with shea butter to seal in moisture
- Sulfate-free formula
- Safe for color treated, chemically treated, curly, or straight hair

Ingredients:

Water, Aloe Barbadensis (Aloe Vera) Leaf Juice, Cocos Nucifera (Coconut) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Carthamus Tinctorius (Safflower) Seed Oil, Persea Gratissima (Avocado) Oil, Polysesterium-17, Tocopheryl Acetate (Vitamin E), Dicaprylate/Dicaprate, Peg-10 Shea Butter, Glycerin, Gellan Gum Chloride, Hydrolyzed Keratin, Pottassium Hydroxymethyl Sulfonate Chloride, Sodium PCA, Polyquaternium-7, Fragrance (Parfum), Ipp-1 Tridecyl-6, Dihydroxyacetic Acid, Benzyl Alcohol.

Read more

Cancel return by mail
Due to federal restrictions, this item cannot be returned by mail. See our return policy for more information.

Specifications

Model No:	12-450
Shipping Weight (in pounds):	6.8
Product in inches (L x W x H):	1.825 x 1.825 x 7.325
Assembled in Country of Origin:	USA
Origin of Components:	USA
Walmart P/N:	552442947

Customer reviews

5 stars	7
4 stars	0
3 stars	0
2 stars	0
1 star	0

7 reviews | 5 out of 5

100%
Would recommend to a friend

[Write a review](#)

Sort by: **Most helpful**

Excellent line of products, Highly recommended! 11/25/2013

by Carlie

These products do wonders for natural African American hair. I have tried all items in the Coconut Shea line some of the Jojoba Moist and Peppermint Lives. They do not fail to please, and provide moisture, shine, body and a healthy appearance to the hair. I will repurchase again and again. The products also last for quite a while as a little goes a long way, even with a maintenance reproduct used. [View more reviews](#)

Would recommend to a friend? Yes

Age: 35 - 44

Ownership: 2 - 7 weeks

Gender: Female

Usage: Every day

✓ Verified purchase

Love this! 1/2/2014

by Chaeba

I love all Eden body works hair products because they natural and very moisturizing.

Would recommend to a friend? Yes

Age: 35 - 44

Complaint

Exhibit C

Coconut Shea Styling Elixir | EDEN BodyWorks



CONTACT US 877-578-EDEN LOG IN CREATE AN ACCOUNT CART (0)



- ABOUT US
- PRODUCTS
- HAIR STORIES
- EVENTS
- BUZZ
- WHERE TO BUY

what it is how to use ingredients reviews



COCONUT SHEA STYLING ELIXIR

Water (Aqua), Cocos Nucifera (Coconut) Oil, Aloe Barbadensis (Aloe Vera) Leaf Juice, Sorbitol, PEG-50 Shea Butter, Polyquaternium-37, Propylene Glycol Dicaprylate/Dicaprate, Polyquaternium-14, Cocos Nucifera (Coconut) Milk Panthenol, PPG-1 Trideceth-6, Fragrance (Parfum), Phenoxyethanol, Caprylyl Glycol, Sorbic Acid

Price: \$8.99 Qty: [Add to Cart](#)

Other Products In This Collection

WRITE A REVIEW
READ ALL REVIEWS



Connect

Join the Conversation

Events



1h

MORE EVENTS

Complaint

Jojoba Monoi Moisturizing Shampoo | EDEN BodyWorks



CONTACT US 877-578-EDEN LOG IN CREATE AN ACCOUNT CART (0)



- ABOUT
- US
- PRODUCTS
- HAIR
- STORIES
- EVENTS
- BUZZ
- WHERE TO BUY

what it is how to use ingredients reviews

JOJOBA MONOI MOISTURIZING SHAMPOO

Ingredients: Water (Aqua), Cocoamidopropyl Betaine, Sodium Lauryl Sulfoacetate, Disodium Laureth Sulfosuccinate, PEG-150 Distearate, Coco Nut Oil, Tiare Flower, Simmondsia Chinensis (Jojoba) Seed Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Tocopheryl Acetate (Vitamin E), Aloe Barbadensis Leaf Extract, Panthenol, Disodium EDTA, Cocamidopropyl Oxide, Citric Acid, PPG-20 Methyl Glucose Ether, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid

Price: \$8.99 Qty: [Add to Cart](#)
 Size: 8 oz.

Other Products In This Collection



[WRITE A REVIEW](#)
[READ ALL REVIEWS](#)

Decision and Order

Jojoba Monoi Revitalizing Conditioner | EDEN BodyWorks



CONTACT US 877-578-EDEN LOG IN CREATE AN ACCOUNT CART (0)



- ABOUT US
- PRODUCTS
- HAIR
- STORIES
- EVENTS
- BUZZ
- WHERE TO BUY



what it is how to use ingredients reviews

JOJOBA MONOI REVITALIZING CONDITIONER

Ingredients: Water (Aqua), Cetyl Alcohol, Stearyl Alcohol, Behentrimonium Methosulfate, Coco Nut Oil, Tiare Flower, Simmondsia Chinensis (Jojoba) Seed Oil, Daucus Carota Sativa (Carrot) Seed Oil, Anthemis Nobilis (Camomile) Flower Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Tocopheryl Acetate (Vitamin E), Aloe Barbadensis Leaf Extract, Hydroxyethylcellulose, Disodium EDTA, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid

Price: \$8.99 Qty: [Add to Cart](#)
Size: 8 oz.

Other Products In This Collection



[WRITE A REVIEW](#)
[READ ALL REVIEWS](#)

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C § 45 *et seq.*; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), a statement that respondent neither admits nor denies any of the allegations in the draft complaint except as specifically stated in the consent agreement, an admission by the respondent of facts necessary to establish jurisdiction for purposes of this action, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent ABS Consumer Products, LLC, also doing business as EDEN BodyWorks, is a limited liability company with its principal office or place of business at 3634 Park Avenue, Memphis, Tennessee 38111.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the respondent, and the proceeding is in the public interest.

Decision and Order

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “respondent” shall mean ABS Consumer Products, LLC, a limited liability company, also doing business as EDEN BodyWorks, its successors and assigns, and its officers, agents, representatives, and employees.
- B. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not make any representation, expressly or by implication, including through the use of a product name, trademark, or trade name, about:

- A. whether such product is all natural or 100% natural;
- B. the extent to which such product contains any natural or synthetic ingredient or component;
- C. the ingredients or composition of such product; or
- D. the environmental or health benefits of such product,

unless the representation is non-misleading, including that, at the time such representation is made, the respondent possesses and relies upon competent and reliable evidence, which when appropriate based on the expertise of professionals in the relevant area must be competent and reliable scientific evidence, that is sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the

Decision and Order

entire body of relevant and reliable evidence, to substantiate that the representation is true. For the purposes of this Provision:

1. “competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results; and
2. “competent and reliable *scientific* evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

II.

IT IS FURTHER ORDERED that respondent ABS Consumer Products, LLC, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

Decision and Order

III.

IT IS FURTHER ORDERED that respondent ABS Consumer Products, LLC, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent must maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

IV.

IT IS FURTHER ORDERED that respondent ABS Consumer Products, LLC, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the limited liability company that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor company; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the company name or address. *Provided, however,* that, with respect to any proposed change in the company about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW,

Decision and Order

Washington, DC 20580. The subject line must begin: In re ABS Consumer Products, LLC, Docket No. C-4584.

V.

IT IS FURTHER ORDERED that ABS Consumer Products, LLC, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VI.

This order shall terminate on July 6, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Analysis to Aid Public Comment

By the Commission.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order as to ABS Consumer Products, LLC, d/b/a EDEN BodyWorks (hereafter “respondent”).

The proposed consent order (“order”) has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the respondent’s advertising for its shampoo, conditioner, and other hair care products. The Commission’s complaint alleges that the respondent violated Section 5(a) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45(a), by falsely representing that these products are “all natural.” It also alleges that these products are not “all natural” because they contain one or more synthetic ingredients. Specifically, Coconut Shea All Natural Curl Defining Cream contains the synthetic ingredient Polyquaternium-7. Coconut Shea All Natural Leave In Conditioner contains the synthetic ingredients Polyquaternium-7 and Polyquaternium-37. Coconut Shea Styling Elixir contains the synthetic ingredients Polyquaternium-37, Polyquaternium-11, Phenoxyethanol, and Caprylyl Glycol. Jojoba Monoi Moisturizing Shampoo and Jojoba Monoi Revitalizing Conditioner contain the synthetic ingredients Phenoxyethanol and Caprylyl Glycol.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. It also

Analysis to Aid Public Comment

includes provisions to assist the Commission in monitoring and enforcing compliance with the order.

Part I prohibits any representation regarding whether any product is all natural or 100% natural; the extent to which such product contains any natural or synthetic ingredient or component; the ingredients or composition of such product; or the environmental or health benefits of such product, unless the representation is non-misleading. The respondent must have competent and reliable evidence, sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true. When appropriate, based on the expertise of professionals in the relevant area, the substantiation must be competent and reliable scientific evidence. “Competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results. “Competent and reliable scientific evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

Parts II through V require the respondent to: (1) keep records of advertisements and substantiation relevant to representations covered by Part I; (2) deliver a copy of the order to principals, officers, directors, and managers, and to employees, agents, and representatives having responsibilities with respect to the subject matter of the order; (3) notify the Commission of changes in corporate structure that might affect compliance obligations; and (4) file compliance reports with the Commission.

Part VI provides that, with exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official

Analysis to Aid Public Comment

interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

BEYOND COASTAL

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4585; File No. 162 3001

Complaint, July 6, 2016 – Decision, July 6, 2016

This consent order addresses Beyond Coastal's advertising for its sunscreen product. The complaint alleges that the respondent violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing that its sunscreen product is "all natural" even though the sunscreen product is not "all natural" because it contains the synthetic ingredients Dimethicone and Caprylyl Glycol. The consent order prohibits any representation regarding whether any product is all natural or 100% natural; the extent to which such product contains any natural or synthetic ingredient or component; the ingredients or composition of such product; or the environmental or health benefits of such product, unless the representation is non-misleading.

Participants

For the *Commission: Robert M. Frisby, Gregory Madden, and John Andrew Singer.*

For the *Respondent: Sterling McMurrin, President, pro se.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Beyond Coastal, a limited liability company, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Beyond Coastal is a Utah limited liability company with its principal office or place of business at 2424 South 2570 West, Salt Lake City, Utah 84119.
2. Respondent has advertised, labeled, offered for sale, sold, and distributed products to consumers, including Natural Sunscreen SPF 30. This sunscreen product is a "drug" within the

Complaint

meaning of Sections 12 and 15 of the Federal Trade Commission Act.

3. The acts and practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent advertises Natural Sunscreen SPF 30 on the Internet. This product retails for \$6.99.

5. Respondent has disseminated or has caused to be disseminated advertisements for Natural Sunscreen SPF 30, including but not necessarily limited to the attached Exhibit A.

- a. Beyond Coastal’s “Natural Sunscreen SPF 30” webpage states the product is a:

100% natural sunscreen

Exhibit A, Internet webpage www.beyondcoastal.com/category/natural-formulas/natural-sunscreen-spf-30 (September 2015).

Count I
False Claim

6. In connection with the advertising, labeling, promotion, offering for sale, or sale of Natural Sunscreen SPF 30, Respondent has represented, directly or indirectly, expressly or by implication, that the product is a “100% natural” sunscreen.

7. In fact, Sunscreen SPF 30 is not “100% natural” because it contains or contained the synthetic ingredients Dimethicone and Caprylyl Glycol. Therefore, the “100% natural” representation set forth in Paragraph 6 is false or misleading.

Violations of Sections 5(a) and 12

8. The acts and practices of Respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in

Complaint

violation of Sections 5(a) and 12 of the Federal Trade Commission Act.


THEREFORE, the Federal Trade Commission this sixth day of July, 2016, has issued this Complaint against Respondent.

By the Commission.

Complaint

Exhibit A

PROTECTS • NOURISHES • REPAIRS • HYDRATES




Natural and Active Sun Care Products
Free U.S. shipping for orders over \$25

[SHOP PRODUCTS](#) | [HOW WE DO IT](#) | [SUN PROTECTION](#) | [COMMUNITY](#) | [RESPONSIBILITY](#) | [WELCOME TO BCB](#)

Call us: 1-877-565-3372
 2000 South 201st Street
 Suite 100, CH, 98478-1111
 Call Center (Closed 11/1/2014)

Beyond Coastal Sun Care Products • Natural Formula Sunscreen • Natural Sunscreen SPF 30



SKU: 15483

Natural Sunscreen SPF 30

Listed as one of the "Top Sunscreens" in the Environmental Working Group's Skin Deep sunscreen guide.

Our healthy, 100% natural sunscreen provides shelter from UVA rays with zinc oxide and titanium dioxide. SPF 30 effectively blocks 97% of UVA rays, which cause wrinkles. This ultraviolet-absorber for the whole family is non-toxic and water resistant.

Our active ingredients aren't just empty filler. Beyond Coastal's Natural Sunscreen nourishes, repairs, and hydrates your skin with zinc oxide, Shea butter, and vitamin C.

Size	1.0L	2.0-oz	4.0L	8.0L
Price	\$9.99	\$13.99	\$19.99	\$33.99

Qty: <input type="text" value="1"/>	MRP: \$13.99
-------------------------------------	--------------

[Add to Cart](#)

DETAILS

- Broad spectrum UVA/UVB protection (SPF of 30/30)
- Zinc oxide and titanium dioxide provide all natural protection
- Nourishes your skin with grape seed extract, jojoba oil, and coconut oil
- Non-comedogenic & free of toxins
- Water resistant
- Great sunscreen for keeping babies from tanning
- Gluten Free, Cruelty Free, Fragrance Free
- Chlorophyll-Free, Parabens-Free

INGREDIENTS

<p>Protects</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Active Ingredients</td> <td style="width: 30%;">Function</td> <td style="width: 30%;">EWG Rating</td> </tr> <tr> <td>Titanium Dioxide (5%)</td> <td>UV-A/UV-B Natural Sunscreen</td> <td>1</td> </tr> <tr> <td>Zinc Oxide (5%)</td> <td>UV-A/UV-B Natural Sunscreen</td> <td>2</td> </tr> </table> <p>Hydrates</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Active Ingredients</td> <td style="width: 30%;">Function</td> <td style="width: 30%;">EWG Rating</td> </tr> <tr> <td>Levulinic Acid</td> <td>Anti-inflammatory, Immune booster</td> <td>0</td> </tr> <tr> <td>Algae Extract</td> <td>Antioxidant, Fights Free Radicals</td> <td>0</td> </tr> <tr> <td>Natural Vitamin E</td> <td>Antioxidant, Fights Free Radicals</td> <td>2</td> </tr> <tr> <td>Shea Butter Ethyl Ether</td> <td>Antioxidant, Soothing Skin</td> <td>1</td> </tr> <tr> <td>Coconut Seed Butter</td> <td>Anti-aging, Skin Rejuvenation</td> <td>0</td> </tr> <tr> <td>Vitamin C</td> <td>Antioxidant, Fights Free Radicals</td> <td>0</td> </tr> <tr> <td>Coconut Seed Extract</td> <td>Anti-Fat Burner, Protein and Soothing</td> <td>0</td> </tr> </table> <p>Other</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Inactive Ingredients</td> <td style="width: 30%;">Function</td> <td style="width: 30%;">EWG Rating</td> </tr> <tr> <td>Ceramide Alcohols</td> <td>Moisturizing Agent</td> <td>1</td> </tr> <tr> <td>Cholesterol</td> <td>Skin Softener</td> <td>1</td> </tr> <tr> <td>Glycerin Stearate</td> <td>Skin Softener</td> <td>0</td> </tr> <tr> <td>Polybutene-6</td> <td>Emulsifying Agent</td> <td>0</td> </tr> <tr> <td>Arachidyl Alcohol</td> <td>Skin Softener</td> <td>1</td> </tr> <tr> <td>Behenyl Alcohol</td> <td>Skin Softener</td> <td>1</td> </tr> <tr> <td>Isopropyl Myristate</td> <td>Thickener</td> <td>0</td> </tr> <tr> <td>Polyhydroxyethyl Acrylate</td> <td>Anti-microbial preservative</td> <td>0</td> </tr> <tr> <td>Lauryl Sulfate</td> <td>Anti-microbial preservative, Moisturizer</td> <td>0</td> </tr> <tr> <td>Caprylyl Glycol</td> <td>Anti-microbial preservative, Moisturizer</td> <td>0</td> </tr> <tr> <td>Potassium Sorbate</td> <td>Anti-microbial preservative</td> <td>0</td> </tr> <tr> <td>Phenoxy Ethanol</td> <td>Anti-microbial preservative</td> <td>0</td> </tr> <tr> <td>Glucy Acid</td> <td>Anti-microbial preservative</td> <td>0</td> </tr> <tr> <td>Sodium Stearate</td> <td></td> <td>1</td> </tr> </table>	Active Ingredients	Function	EWG Rating	Titanium Dioxide (5%)	UV-A/UV-B Natural Sunscreen	1	Zinc Oxide (5%)	UV-A/UV-B Natural Sunscreen	2	Active Ingredients	Function	EWG Rating	Levulinic Acid	Anti-inflammatory, Immune booster	0	Algae Extract	Antioxidant, Fights Free Radicals	0	Natural Vitamin E	Antioxidant, Fights Free Radicals	2	Shea Butter Ethyl Ether	Antioxidant, Soothing Skin	1	Coconut Seed Butter	Anti-aging, Skin Rejuvenation	0	Vitamin C	Antioxidant, Fights Free Radicals	0	Coconut Seed Extract	Anti-Fat Burner, Protein and Soothing	0	Inactive Ingredients	Function	EWG Rating	Ceramide Alcohols	Moisturizing Agent	1	Cholesterol	Skin Softener	1	Glycerin Stearate	Skin Softener	0	Polybutene-6	Emulsifying Agent	0	Arachidyl Alcohol	Skin Softener	1	Behenyl Alcohol	Skin Softener	1	Isopropyl Myristate	Thickener	0	Polyhydroxyethyl Acrylate	Anti-microbial preservative	0	Lauryl Sulfate	Anti-microbial preservative, Moisturizer	0	Caprylyl Glycol	Anti-microbial preservative, Moisturizer	0	Potassium Sorbate	Anti-microbial preservative	0	Phenoxy Ethanol	Anti-microbial preservative	0	Glucy Acid	Anti-microbial preservative	0	Sodium Stearate		1	<p>Nourishes</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Active Ingredients</td> <td style="width: 30%;">Function</td> <td style="width: 30%;">EWG Rating</td> </tr> <tr> <td>Croton Oil</td> <td>Skin Softener</td> <td>2</td> </tr> <tr> <td>Aliso Wax</td> <td>Chemical Stabilizer, Buffering, Skin Softener</td> <td>0</td> </tr> <tr> <td>Shea Butter</td> <td>UVB Protection, Anti-aging, Moisturizer</td> <td>0</td> </tr> <tr> <td>Jojoba Seed Oil</td> <td>Anti-aging, IRD Protection, Moisturizer</td> <td>0</td> </tr> <tr> <td>Shea Myr Oil</td> <td>Anti-aging, Soothing Skin, Moisturizer</td> <td>0</td> </tr> </table> <p>Repairs</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Active Ingredients</td> <td style="width: 30%;">Function</td> <td style="width: 30%;">EWG Rating</td> </tr> <tr> <td>Shearwater</td> <td>Hydrates</td> <td>0</td> </tr> <tr> <td>Oxybenzone</td> <td>Monoamine Oxidase Inhibitor</td> <td>1</td> </tr> </table>	Active Ingredients	Function	EWG Rating	Croton Oil	Skin Softener	2	Aliso Wax	Chemical Stabilizer, Buffering, Skin Softener	0	Shea Butter	UVB Protection, Anti-aging, Moisturizer	0	Jojoba Seed Oil	Anti-aging, IRD Protection, Moisturizer	0	Shea Myr Oil	Anti-aging, Soothing Skin, Moisturizer	0	Active Ingredients	Function	EWG Rating	Shearwater	Hydrates	0	Oxybenzone	Monoamine Oxidase Inhibitor	1
Active Ingredients	Function	EWG Rating																																																																																																								
Titanium Dioxide (5%)	UV-A/UV-B Natural Sunscreen	1																																																																																																								
Zinc Oxide (5%)	UV-A/UV-B Natural Sunscreen	2																																																																																																								
Active Ingredients	Function	EWG Rating																																																																																																								
Levulinic Acid	Anti-inflammatory, Immune booster	0																																																																																																								
Algae Extract	Antioxidant, Fights Free Radicals	0																																																																																																								
Natural Vitamin E	Antioxidant, Fights Free Radicals	2																																																																																																								
Shea Butter Ethyl Ether	Antioxidant, Soothing Skin	1																																																																																																								
Coconut Seed Butter	Anti-aging, Skin Rejuvenation	0																																																																																																								
Vitamin C	Antioxidant, Fights Free Radicals	0																																																																																																								
Coconut Seed Extract	Anti-Fat Burner, Protein and Soothing	0																																																																																																								
Inactive Ingredients	Function	EWG Rating																																																																																																								
Ceramide Alcohols	Moisturizing Agent	1																																																																																																								
Cholesterol	Skin Softener	1																																																																																																								
Glycerin Stearate	Skin Softener	0																																																																																																								
Polybutene-6	Emulsifying Agent	0																																																																																																								
Arachidyl Alcohol	Skin Softener	1																																																																																																								
Behenyl Alcohol	Skin Softener	1																																																																																																								
Isopropyl Myristate	Thickener	0																																																																																																								
Polyhydroxyethyl Acrylate	Anti-microbial preservative	0																																																																																																								
Lauryl Sulfate	Anti-microbial preservative, Moisturizer	0																																																																																																								
Caprylyl Glycol	Anti-microbial preservative, Moisturizer	0																																																																																																								
Potassium Sorbate	Anti-microbial preservative	0																																																																																																								
Phenoxy Ethanol	Anti-microbial preservative	0																																																																																																								
Glucy Acid	Anti-microbial preservative	0																																																																																																								
Sodium Stearate		1																																																																																																								
Active Ingredients	Function	EWG Rating																																																																																																								
Croton Oil	Skin Softener	2																																																																																																								
Aliso Wax	Chemical Stabilizer, Buffering, Skin Softener	0																																																																																																								
Shea Butter	UVB Protection, Anti-aging, Moisturizer	0																																																																																																								
Jojoba Seed Oil	Anti-aging, IRD Protection, Moisturizer	0																																																																																																								
Shea Myr Oil	Anti-aging, Soothing Skin, Moisturizer	0																																																																																																								
Active Ingredients	Function	EWG Rating																																																																																																								
Shearwater	Hydrates	0																																																																																																								
Oxybenzone	Monoamine Oxidase Inhibitor	1																																																																																																								

Write a Review

To write a review, you must log in to your Beyond Coastal customer account — or you can connect via Facebook.

[Log In](#)

Reviews

Review by **Nick C.** April 2013

5/5 Stars

I've tried other natural sunscreens and this one puts in 50 much more. It's also water resistant for 80 minutes when most of the other natural sunscreens are only for 40 minutes. Great product!

[Privacy Policy](#) | [Shipping Policy](#) | [Returns Policy](#) | [Contact Us](#)

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C § 45 *et seq.*; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), a statement that respondent neither admits nor denies any of the allegations in the draft complaint except as specifically stated in the consent agreement, an admission by the respondent of facts necessary to establish jurisdiction for purposes of this action, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days, and having duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Beyond Coastal is a limited liability company with its principal office or place of business at 2424 South 2570 West, Salt Lake City, Utah 84119.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the respondent, and the proceeding is in the public interest.

Decision and Order

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “respondent” shall mean Beyond Coastal, a limited liability company, its successors and assigns, and its officers, members, agents, representatives, and employees.
- B. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not make any representation, expressly or by implication, including through the use of a product name, trademark, or trade name, about:

- A. whether such product is all natural or 100% natural;
- B. the extent to which such product contains any natural or synthetic ingredient or component;
- C. the ingredients or composition of such product; or
- D. the environmental or health benefits of such product,

unless the representation is non-misleading, including that, at the time such representation is made, the respondent possesses and relies upon competent and reliable evidence, which when appropriate based on the expertise of professionals in the relevant area must be competent and reliable scientific evidence, that is sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the

Decision and Order

entire body of relevant and reliable evidence, to substantiate that the representation is true. For the purposes of this Provision:

1. “competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results; and
2. “competent and reliable *scientific* evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

II.

IT IS FURTHER ORDERED that respondent Beyond Coastal, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

Decision and Order

III.

IT IS FURTHER ORDERED that respondent Beyond Coastal, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent must maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

IV.

IT IS FURTHER ORDERED that respondent Beyond Coastal, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Beyond Coastal, Docket No. C-4585.

Decision and Order

V.

IT IS FURTHER ORDERED that respondent Beyond Coastal, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VI.

This order shall terminate on July 6, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order as to Beyond Coastal (hereafter “respondent”).

The proposed consent order (“order”) has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the respondent’s advertising for its sunscreen product. The Commission’s complaint alleges that the respondent violated Sections 5(a) and 12 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. §§ 45(a) and 52, by falsely representing that its sunscreen product is “all natural.” It also alleges that the sunscreen product is not “all natural” because it contains the synthetic ingredients Dimethicone and Caprylyl Glycol.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. It also includes provisions to assist the Commission in monitoring and enforcing compliance with the order.

Part I prohibits any representation regarding whether any product is all natural or 100% natural; the extent to which such product contains any natural or synthetic ingredient or component; the ingredients or composition of such product; or the environmental or health benefits of such product, unless the representation is non-misleading. The respondent must have competent and reliable evidence, sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true. When appropriate, based on the expertise of professionals in the relevant area, the substantiation must be competent and reliable scientific evidence. “Competent and reliable evidence” means tests,

Analysis to Aid Public Comment

analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results. “Competent and reliable scientific evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

Parts II through V require the respondent to: (1) keep records of advertisements and substantiation relevant to representations covered by Part I; (2) deliver a copy of the order to principals, officers, directors, and managers, and to employees, agents, and representatives having responsibilities with respect to the subject matter of the order; (3) notify the Commission of changes in corporate structure that might affect compliance obligations; and (4) file compliance reports with the Commission.

Part VI provides that, with exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order’s terms in any way.

Complaint

IN THE MATTER OF

CABELL HUNTINGTON HOSPITAL, INC.;
PALLOTTINE HEALTH SERVICES, INC.;
AND
ST. MARY’S MEDICAL CENTER, INC.COMPLAINT AND FINAL ORDER IN REGARD TO ALLEGED
VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION
ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. 9366; File No. 141 0218
Complaint, November 5, 2015 – Decision, July 6, 2016

This case addresses the acquisition by Cabell Huntington Hospital, Inc. of St. Mary’s Medical Center, Inc. The complaint alleges that the transaction violates Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act by significantly reducing competition in the markets for general acute care inpatient hospital services and outpatient surgical services in Huntington, West Virginia. The order dismisses the Complaint because the West Virginia Health Care Authority issued its written decision approving the Cooperative Agreement.

Participants

For the *Commission: Elizabeth Arens, Jeanine Balbach, Lucas Ballet, Stephanie R. Cummings, Melissa Davenport, , Svetlana Gans, Elisa Kantor, Michael Perry, Marc Schneider, Sam Sheinberg, and Michelle Yost Hale.*

For the *Respondents: Ken Field, Jones Day and Jeff Brennan, McDermott Will & Emery LLP; David Simon, and H. Holden Brooks, Foley & Lardner LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (“FTC Act”), and by virtue of the authority vested in it by the Act, the Federal Trade Commission (“Commission”), having reason to believe that Respondents Cabell Huntington Hospital, Inc. (“Cabell”), Pallottine Health Services, Inc. (“PHS”), and St. Mary’s Medical Center, Inc. (“St. Mary’s”), having executed an agreement pursuant to which Cabell will become the sole

Complaint

member, and thereby acquire all the assets, of St. Mary's (the "Definitive Agreement") in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, which if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

I**NATURE OF THE CASE**

1. Cabell's proposed acquisition of St. Mary's (the "Acquisition") is likely to substantially lessen competition for healthcare services in Huntington, West Virginia, and its surrounding communities. The Acquisition would lead to increased healthcare costs for local residents and reduce the merging parties' incentives to maintain and improve quality of care. If allowed to proceed, the Acquisition would create a dominant firm with a near monopoly over general acute care (or "GAC") inpatient hospital services and outpatient surgical services in and around Huntington.

2. Cabell and St. Mary's are general acute care hospitals located only three miles apart in Huntington, and they directly compete with one another to provide inpatient and outpatient services. As the only two hospitals in Huntington, Cabell and St. Mary's have a long history of close competition that has yielded numerous price and quality benefits for consumers.

3. As Cabell's CFO emphasized in 2013, St. Mary's is Cabell's "main competitor for all but our exclusive services," which are limited to three service lines: neonatal ICU, pediatric ICU, and burn. Other documents from the two hospitals, their consultants, and ratings agencies consistently describe Cabell and St. Mary's not only as "competitors," but also as each other's "main," "primary," or "strongest" "competitors," and "long-standing rival[s]." Respondents' own merger consultant testified that Cabell and St. Mary's have been "head-to-head competitors

Complaint

for a very long period of time,” which is consistent with testimony from health plan and other industry executives that “Cabell Huntington and St. Mary’s are each other’s closest competitors for inpatient and outpatient services.”

4. Especially in recent years, Cabell and St. Mary’s have competed on the pricing of their healthcare services, vying for inclusion in commercial health plan networks and attempting to “meet and/or beat” the other’s prices for individual services. Cabell and St. Mary’s have also competed vigorously on non-price dimensions, working to improve performance on quality measures, expand service lines, invest in new technology, and otherwise improve hospital quality to attract patients from one another. If consummated, the Acquisition would eliminate this intense competition to the detriment of local employers and residents.

5. That Cabell and St. Mary’s are intense, close competitors also is evidenced by their efforts to coordinate their actions to lessen the competition between them. During its investigation of the proposed Acquisition, the Commission discovered that Cabell and St. Mary’s have engaged in conduct to limit their head-to-head competition through explicit and tacit coordination in the form of joint contracting with health plans, secret territorial agreements not to advertise against one another, and a “gentlemen’s agreement” to allocate service lines between them. Of particular significance, Cabell, St. Mary’s, and other regional hospitals negotiated health plan contracts jointly through a so-called physician hospital organization (“PHO”) for nearly 10 years. Although this so-called PHO is now inactive, contracts that resulted from these negotiations remain in place, and Cabell and St. Mary’s have continued to share information about prospective health plan negotiations.

6. The Acquisition is likely to substantially lessen competition in two relevant markets in which Cabell and St. Mary’s compete to offer services: (1) general acute care inpatient hospital services sold and provided to commercial health plans and their members, respectively; and (2) outpatient surgical services sold and provided to commercial health plans and their members, respectively. The relevant geographic market in which

Complaint

to analyze the effects of the Acquisition is no broader than the four counties surrounding Huntington—Cabell, Wayne, and Lincoln counties in West Virginia, and Lawrence County, Ohio (the “Four-County Huntington Area”). Cabell and St. Mary’s each routinely identify these same four counties as their Primary Service Area (“PSA”).

7. Post-Acquisition, the combined entity would account for more than 75% of the discharges in the Four-County Huntington Area for general acute care inpatient services. Similarly, the combined entity would command a high share of the market for outpatient surgical services in the Four-County Huntington Area. These very high market shares and the corresponding concentration levels render the Acquisition presumptively unlawful—by a wide margin—under the relevant case law and the U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (“Merger Guidelines”).

8. Respondents recognize that the Acquisition will result in extraordinary concentration levels. St. Mary’s CEO wrote in April 2015 that, post-merger, “SMMC and CHH collectively will control almost 90% of the market.” Similarly, according to their own ordinary-course documents, Cabell’s and St. Mary’s *individual* market shares in their PSA have ranged in recent years from 35% to over 40% *for each hospital*. According to these same documents, the next-closest hospital, King’s Daughters Medical Center (“King’s Daughters”), which is approximately a 25-minute drive across state lines into Kentucky, maintains a much smaller market share in Cabell and St. Mary’s PSA. No other hospital holds more than a 5% market share in the PSA.

9. The West Virginia Health Care Authority’s (“WVHCA”) rate review system would not prevent anticompetitive harm from the Acquisition. The WVHCA principally reviews and approves (or disapproves) a hospital’s list prices, or “charges,” as opposed to the prices, or “rates,” negotiated between the hospitals and health plans. Because these negotiated rates are below the list prices/charges, the limit on charges represents a ceiling on negotiated rates but does not preclude a significant increase in those negotiated rates. Furthermore, the WVHCA’s rate review system does not protect competition on non-price dimensions,

Complaint

such as quality and service. This rate review scheme is not an adequate substitute for competition.

10. In an attempt to avoid an antitrust challenge to the Acquisition, Cabell and St. Mary's entered into two agreements, conditional on consummation of the Acquisition, that purport to limit the combined entity's conduct for five to seven years: (1) a Letter of Agreement ("LOA") [REDACTED] and (2) an Assurance of Voluntary Compliance ("AVC") between Respondents and the Attorney General of West Virginia. Neither of these temporary agreements would sufficiently protect consumers. Principally consisting of price controls shown by economic theory and evidence to be ineffective, the two agreements would not replace the benefits of competition lost through the Acquisition.

11. Entry or expansion by other providers of the relevant services is unlikely to occur, much less in a manner timely, likely, or sufficient to deter or counteract the loss of price and non-price competition in the near future. Significant barriers to entry, including substantial up-front costs, regulatory restrictions, and the Four-County Huntington Area's demographic profile, make new healthcare providers unlikely to enter the relevant markets.

12. Finally, Respondents' efficiencies and quality claims are largely not verifiable or merger-specific, and any cognizable claims are insufficient to offset the significant competitive harm from the Acquisition.

13. Respondents cannot consummate the Acquisition until they first receive a Certificate of Need ("CON") from the WVHCA and then receive approval from the Catholic Church. Respondents have advised the Commission that, because their CON application is subject to a contested proceeding that may involve significant discovery, the CON process may not be completed for at least several months from now. Additionally, Respondents have advised the Commission that obtaining approval from the Catholic Church may take an additional six to eight weeks following CON approval.

Complaint

II.

BACKGROUND

A.

Jurisdiction

14. Respondents, and each of their relevant operating entities and parent entities are, and at all relevant times have been, engaged in commerce or in activities affecting “commerce” as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

15. The Acquisition constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

B.

Respondents

16. Respondent Cabell is a not-for-profit, 303-bed hospital incorporated under and by virtue of the laws of West Virginia. Cabell is headquartered at 1340 Hal Greer Boulevard, Huntington, West Virginia, 25701. During the fiscal year ending September 30, 2014, Cabell earned \$439 million in revenue.

17. In addition to its main hospital, Cabell owns and operates the 72-bed Hoops Family Children’s Hospital, an outpatient surgery center, and, together with the Marshall University Joan C. Edwards School of Medicine (“Marshall”), the Edwards Comprehensive Cancer Center. Pursuant to a management agreement, Cabell also manages Pleasant Valley Hospital, a 201-bed community hospital located 50 miles northeast of Huntington. Cabell employs approximately ■ physicians and leases approximately ■ physicians from Marshall. Cabell serves as a teaching hospital for Marshall medical students and residents.

18. Respondent PHS is a non-profit organization incorporated under and by virtue of the laws of West Virginia. PHS is run by the Pallottine Missionary Sisters, who are headquartered in

Complaint

Florissant, Missouri, and is located in Huntington, West Virginia. PHS owns two hospitals, St. Joseph's Hospital ("St. Joseph's") in Buckhannon, West Virginia, and St. Mary's.

19. Respondent St. Mary's is a not-for-profit, 393-bed Catholic hospital incorporated under and by virtue of the laws of West Virginia. St. Mary's is headquartered at 2900 First Avenue, Huntington, West Virginia, 25702. During the fiscal year ending September 30, 2014, St. Mary's earned \$401 million in revenue.

20. In addition to its main hospital, St. Mary's manages and has a [REDACTED] ownership interest in Three Gables Surgery Center in Proctorville, Ohio. St. Mary's also owns and operates a small emergency room, outpatient laboratory, and imaging center in Ironton, Ohio. St. Mary's employs approximately [REDACTED] physicians. St. Mary's also serves as a teaching hospital for Marshall medical students and residents.

C.**The Proposed Acquisition**

21. In the spring of 2013, PHS began to take steps toward the sale of St. Mary's and St. Joseph's. PHS planned to use a request for proposal ("RFP") process that involved identifying potential buyers and asking them to submit bids.

22. In January 2014, Cabell submitted a Letter of Intent for the purchase of St. Mary's. PHS declined the Letter of Intent in favor of pursuing the RFP process. In May 2014, Cabell and [REDACTED] other hospital systems, including not-for-profit, for-profit, and Catholic systems, submitted bids to purchase St. Mary's.

23. In June 2014, PHS began discussions with Cabell about drafting a memorandum of understanding for the sale of St. Mary's to Cabell.

24. On August 1, 2014, Cabell and PHS signed a Term Sheet for the sale of St. Mary's. On November 7, 2014, Respondents signed a Definitive Agreement whereby Cabell would become the sole member and ultimate parent entity of St. Mary's.

Complaint

25. Prior to closing the transaction, Cabell must obtain a CON from the WVHCA for the purchase of St. Mary's. Cabell's CON application, filed on April 30, 2015, has been opposed by a local employer. Although the WVHCA was scheduled to hold a hearing on Cabell's application on November 18, 2015, the WVHCA recently continued the hearing, at Cabell's request, for an indefinite period.

26. Respondents also must obtain approval of the Acquisition from the Catholic Church, which Respondents may receive only after obtaining a CON from the WVHCA. Respondents have advised the Commission that this approval may take an additional six to eight weeks.

III.

THE RELEVANT SERVICE MARKETS

27. The first relevant service market in which to analyze the proposed Acquisition is general acute care inpatient hospital services sold and provided to commercial health plans and their members, respectively. This service market consists of the broad cluster of medical and surgical diagnostic and treatment services offered by both Cabell and St. Mary's that typically require an overnight hospital stay. It includes all inpatient services offered by both Cabell and St. Mary's.

28. Although the Acquisition's likely effect on competition could be analyzed separately for each individual inpatient service, it is appropriate to evaluate the likely effects through an analysis of the cluster of GAC inpatient hospital services because each of these services is offered to residents of the Four-County Huntington Area under similar competitive conditions, by similar market participants. Thus, grouping the hundreds of individual GAC inpatient hospital services into a cluster for analytical convenience enables the efficient evaluation of competitive effects with "no loss of analytic power."

29. The second relevant service market is outpatient surgical services sold and provided to commercial health plans and their members, respectively. Outpatient surgical services consist of the

Complaint

cluster of general surgery procedures offered by Cabell and St. Mary's that do not require an overnight hospital stay. Outpatient surgical services are a separate relevant market and warrant separate analysis from inpatient services because they are offered by a different set of providers under different competitive conditions. In addition, health plans and patients generally do not substitute outpatient services for inpatient services in the face of a price increase; rather, the decision to provide care on an inpatient or outpatient basis is a clinical decision made by the patient's physician.

30. Although the Acquisition's effect on each outpatient surgical service could be analyzed separately, treatment of outpatient surgical services as a cluster market is appropriate because of the similar competitive conditions that characterize outpatient surgical services in the Four-County Huntington Area.

IV.**THE RELEVANT GEOGRAPHIC MARKET**

31. For both relevant service markets, the relevant geographic market in which to analyze the effects of the Acquisition is no broader than the Four-County Huntington Area, which consists of Cabell, Wayne, and Lincoln counties in West Virginia, and Lawrence County, Ohio. Cabell and St. Mary's routinely analyze this area—which they call their “Primary Service Area”—to evaluate market shares in the ordinary course of business.

32. The appropriate geographic market is determined by identifying the geographic boundaries within which a hypothetical monopolist for the services at issue could profitably impose a small but significant and non-transitory increase in price.

33. Residents of the Four-County Huntington Area strongly prefer to obtain GAC inpatient hospital services and outpatient services locally. Patients choose to seek care close to their homes or workplaces for their own convenience and that of their friends and families.

Complaint

34. Indeed, Cabell's regulatory filings show that an overwhelming percentage of patients in Cabell and Wayne counties seek inpatient care in Cabell County—that is, at Cabell or St. Mary's.

35. Hospitals outside of the Four-County Huntington Area do not regard themselves as, and are not, meaningful competitors of Cabell or St. Mary's for GAC inpatient hospital services or outpatient surgical services in the Four-County Huntington Area.

36. Because residents of the Four-County Huntington Area clearly prefer to obtain GAC inpatient hospital services and outpatient surgical services in the Four-County Huntington Area, a health plan that had neither Cabell nor St. Mary's in its network would be unattractive to consumers in the area. Health plans have stated that a network lacking both Cabell and St. Mary's would be so unattractive as to not be viable. Accordingly, in response to a small but significant price increase in GAC inpatient hospital services at a merged Cabell/St. Mary's, a health plan serving patients in the Four-County Huntington Area would not attempt to market a network that excluded those two hospitals. Because a majority of patients within the Four-County Huntington Area do not view providers outside of that area as practicable alternatives, the merged hospital system could profitably impose a small but significant price increase in the Four-County Huntington Area. The same competitive dynamic exists for outpatient surgical services.

V.

**MARKET STRUCTURE AND THE ACQUISITION'S
PRESUMPTIVE ILLEGALITY**

37. Following the Acquisition, Cabell would own the only general acute care hospitals within the Four-County Huntington Area, and it would hold a dominant share of the market for general acute care inpatient hospital services. The only other hospital that serves more than a negligible percentage of Four-County Huntington Area residents is King's Daughters, in Ashland, Kentucky. The few other hospitals that serve residents

Complaint

in the relevant market are even farther away and have minimal shares.

38. Cabell's post-Acquisition market share for general acute care inpatient hospital services would be over 75%, as measured by share of inpatient admissions of patients residing in the Four-County Huntington Area. This market share far surpasses levels held to be presumptively unlawful by the U.S. Supreme Court and numerous other courts, including those in recent hospital merger cases.

39. The Herfindahl-Hirschman Index ("HHI") is a well-accepted method used to measure market concentration, as reflected in the Merger Guidelines. A merger or acquisition is presumed likely to create or enhance market power, and thus is presumed illegal, when the post-merger HHI exceeds 2,500 points and the merger or acquisition increases the HHI by more than 200 points. Here, the market concentration levels far exceed these thresholds, with a post-Acquisition HHI in the general acute care inpatient hospital services market of over 5,800, and an increase in HHI of over 2,800 points.

40. The market shares and HHI figures for the general acute care inpatient hospital services market for 2013, the most recent year for which state data were available, are summarized in the following table. These figures are conservatively calculated; they attribute market share to all hospitals accounting for admissions of patients residing in the Four-County Huntington Area, regardless of whether the hospital is physically located in the Four-County Huntington Area.

GENERAL ACUTE CARE INPATIENT HOSPITAL SERVICES		
Provider	Market Share	Post-Acquisition
Cabell Huntington Hospital	40.8%	75.4%
St. Mary's Medical Center	34.6%	

Complaint

King’s Daughters Medical Center	9.8%	9.8%
Our Lady of Bellefonte Hospital	4.4%	4.4%
Charleston Area Medical Center	4.0%	4.0%
Other	6.4%	6.4%
HHI	2,999	5,824
Change in HHI	+2,825	

41. As the above table reflects, no hospital other than the merging parties and King’s Daughters serves more than 5% of patients in the Four-County Huntington Area.

42. For outpatient surgical services, Cabell and St. Mary’s are again the most significant providers in the Four-County Huntington Area. The only other outpatient surgical facility located in the relevant market is Three Gables Surgery Center (“Three Gables”) in Proctorville, Ohio, about a 12-minute drive from Huntington. Three Gables is a multi-specialty surgical facility focusing on orthopedic, gastroenterological, and ENT procedures. Three Gables predominantly performs outpatient procedures and has only eight inpatient beds for the small number of its cases that require an overnight stay. St. Mary’s holds the management contract for Three Gables and negotiates health plan contracts on its behalf, and Three Gables’ CEO is a St. Mary’s employee. Pursuant to the management contract, St. Mary’s also has a [REDACTED] ownership interest in Three Gables. Even if Three Gables is treated as an independent competitor despite St. Mary’s significant involvement, the Acquisition would result in a high combined market share, a highly concentrated market, and a significant increase in concentration for outpatient surgical services.

43. Under the relevant case law and the Merger Guidelines, the Acquisition is presumptively unlawful by a wide margin, as it

Complaint

would significantly increase concentration in markets that are already highly concentrated.

VI.**ANTICOMPETITIVE EFFECTS****A.****Hospital Competition Yields Lower Prices and Higher Quality**

44. Competition between hospitals occurs in two distinct but related stages. First, hospitals compete for inclusion in commercial health plans' provider networks. Second, in-network hospitals compete to attract patients, including health plan members.

45. In the first stage of hospital competition, hospitals compete to be included in health plan networks. To become an in-network provider, a hospital negotiates with a health plan and, if mutually agreeable terms can be reached, enters into a contract. Reimbursement rates (i.e., prices), which the hospital charges for services rendered to a health plan's members, are a central contract term that is negotiated.

46. In-network status benefits a hospital by giving it preferential access to the health plan's members. Health plan members typically pay far less to access in-network hospitals than out-of-network hospitals. Thus, all else being equal, an in-network hospital will attract more patients from a particular health plan than an out-of-network hospital. This dynamic motivates hospitals to offer lower rates to health plans to win inclusion in their networks.

47. From the health plan's perspective, having hospitals in-network is beneficial because it enables the health plan to create a healthcare provider network in a particular geographic area that is attractive to current and prospective members, typically local employers and their employees.

Complaint

48. A critical determinant of the relative bargaining positions of a hospital and a health plan during contract negotiations is whether other, nearby comparable hospitals are available to the health plan and its members as alternatives in the event of a negotiating impasse. The presence of alternative hospitals limits a hospital's bargaining leverage and thus constrains its ability to obtain higher reimbursement rates from health plans. The more attractive these alternative hospitals are to a health plan's members in a local area, the greater the constraint on that hospital's bargaining leverage. Where there are few or no meaningful alternatives, a hospital will have greater bargaining leverage to demand and obtain higher reimbursement rates.

49. A merger between hospitals that are close substitutes in the eyes of health plans and their members therefore tends to lead to increased bargaining leverage for the merged entity and, as a result, higher negotiated rates, because it eliminates an available alternative for health plans. This increase in leverage is greater when the merging hospitals are closer substitutes for (competitors to) each other.

50. Increases in the reimbursement rates negotiated between a hospital and a health plan significantly impact the health plan's members. "Self-insured" employers rely on a health plan for access to its provider network and negotiated rates, but these employers pay the cost of their employees' healthcare claims directly and thus bear the full and immediate burden of any rate increases in the healthcare services used by their employees. "Fully-insured" employers pay premiums to health plans—and employees pay premiums, co-pays, and deductibles—in exchange for the health plan assuming financial responsibility for paying hospital costs generated by the employees' use of hospital services. When hospital rates increase, health plans pass on these increases to their fully-insured customers in the form of higher premiums, co-pays, and deductibles.

51. In the second stage of hospital competition, hospitals compete to attract patients to their facilities. Because health plan members often face similar out-of-pocket cost for in-network hospitals, hospitals in the same network compete to attract patients on non-price features—that is, by offering better quality

Complaint

of care, amenities, convenience, and patient satisfaction than their competitors. Hospitals also compete on these non-price dimensions to attract patients covered by Medicare and Medicaid, and other patients without commercial insurance. A merger of competing hospitals eliminates that non-price competition and reduces their incentive to improve and maintain quality.

52. Although West Virginia has a healthcare regulatory system that includes rate review, hospital competition retains a central role in promoting lower prices and higher quality of care. West Virginia's rate review system creates a ceiling on hospital charges and rates, but it is not a replacement for competition in yielding lower prices, and it does not protect against reductions in non-price competition.

53. The WVHCA reviews and approves a hospital's average charge per inpatient discharge and average charge per outpatient visit, both of which are based on the charges listed in the hospital's chargemaster (price list). The WVHCA calculates average charges annually and applies a methodology to determine a hospital's permitted increase in its average charges for the coming year. Notably, those charges are list prices, not the actual reimbursement rates negotiated by health plans, which are lower.

54. Although the WVHCA also reviews negotiated reimbursement rates that health plans have agreed to pay hospitals, the primary goal of this review is to ensure that the discounted reimbursement rate "does not constitute an amount below the actual cost to the hospital" and thus does not threaten the hospital's financial viability. Contract reimbursement rates rarely have been rejected by the WVHCA, and never have been rejected on the basis that the negotiated discount was too small or that a price increase reflected an undue exercise of a hospital's market power.

55. Because all of Cabell's and St. Mary's health plan commercial contracts establish negotiated reimbursement rates below the chargemaster levels, the WVHCA's rate review system does not foreclose higher prices to health plans and their members post-Acquisition. In other words, rate review may impose an upper limit, but negotiated rates have room to increase before they

Complaint

hit that ceiling. Moreover, the WVHCA's rate review does nothing to protect against the loss of quality and service competition.

B.**The Acquisition Would Eliminate Price Competition**

56. As a result of their proximity and service offerings, Cabell and St. Mary's are intense competitors and close substitutes for each other in the eyes of health plans and patients in the Four-County Huntington Area. As a health plan executive succinctly stated, [REDACTED]

[REDACTED] The Acquisition would end the hospitals' significant and beneficial incentive to compete on price.

57. A standard economic analysis of the closeness of competition known as diversion analysis, which is based on data about where patients receive hospital services, confirms that Cabell and St. Mary's are very close competitors. In fact, they are each other's closest competitors, by a wide margin. Diversion analyses show that, if Cabell were no longer available to patients, about half of its patients would seek GAC inpatient hospital services at St. Mary's. Similarly, if St. Mary's were no longer available, about half of its patients would seek GAC inpatient hospital services at Cabell. Diversions from Cabell or St. Mary's to other hospitals are significantly smaller.

58. In particular, Cabell and St. Mary's compete for inclusion in health plan networks. For example, writing about a health plan seeking to enter the market, Cabell's CFO stated, "if St. Mary's ends up in their network and not us, we can expect a tongue lashing [from Cabell's CEO]."

59. To win inclusion in health plan networks, Cabell and St. Mary's compete, including on price. Numerous ordinary course of business documents show each hospital carefully monitoring and responding to the other's health plan negotiations, charges, and costs. Indeed, Cabell and St. Mary's track the outcomes of each other's health plan negotiations and try to match or beat the

Complaint

other's terms, viewing any negotiated rate advantage over the other as "very helpful."

60. Likewise, health plans have played Cabell and St. Mary's off each other to obtain lower reimbursement rates or more favorable terms. For example, ██████████ negotiated a fixed-rate reimbursement structure (which health plans favor because it provides more rate certainty than a discount-off-charges reimbursement structure) in its contract with ██████████ and then leveraged that outcome to negotiate a fixed-rate reimbursement structure with ██████████.

61. In addition, in 2009 or 2010, ██████████ excluded ██████████ from its Medicare Advantage network. ██████████ was only willing to include ██████████ in this network if ██████████ provided a substantial discount to bring payments closer to ██████████ levels. After it refused, ██████████ faced complaints from doctors frustrated by the local ██████████ members who turned to ██████████ instead of paying more to use ██████████ as an out-of-network hospital. In 2011, as a direct result of this competition from ██████████, ██████████ relented, agreeing to give ██████████ the discount it had originally sought in return for inclusion in ██████████ Medicare Advantage network.

62. Similarly, in 2010, ██████████ threatened to demote ██████████ to a "second-tier" hospital in its network because ██████████ had higher prices than ██████████. Demotion to the second tier would have subjected ██████████ members to higher out-of-pocket costs when using ██████████. Concerned that ██████████ members would divert to ██████████, ██████████ responded by offering ██████████ an additional ██████████ discount on large claims in return for maintaining its first-tier status. After ██████████ rejected this proposal due to concerns about administrative costs, ██████████ convinced ██████████ to keep ██████████ in the first tier by persuading ██████████ that, when certain adjustments were made, ██████████ prices were comparable to ██████████.

63. As these examples show, absent the Acquisition health plans can negotiate lower rates by threatening either to exclude Cabell or St. Mary's from their networks or to assign either

Complaint

hospital to a less preferential tier, because the other hospital serves as a close alternative for patients.

64. The Acquisition would eliminate health plans' ability to use competition between Cabell and St. Mary's to negotiate better rates. Because of local residents' strong preference for in-network access to at least one Huntington hospital, health plans could not develop an attractive network that included neither hospital, and Cabell would therefore have increased bargaining leverage with health plans post-Acquisition.

65. Cabell knows that a merger with a competing hospital would increase its bargaining leverage. In a presentation on hospital affiliations, Cabell's CFO identified "Negotiating Power" with "Third party payers" as the first "main reason[]" to affiliate.

66. Health plans have also confirmed that the Acquisition would enhance Cabell's bargaining leverage. Multiple health plans have expressed concerns that the combined Cabell/St. Mary's will have the ability to increase rates. As one health plan executive declared, [REDACTED]

Likewise, [REDACTED]

informed Cabell that [REDACTED]

employee similarly reported [REDACTED]

67. The Acquisition would also eliminate competition to contain list prices and costs. Cabell and St. Mary's closely track each other's list prices. For example, in July 2014, Cabell's CFO explained, "We have a [REDACTED] compared to St. Mary's (higher) for the same DRG's. This is of concern in terms of competitiveness in the future with payers." With respect to the pricing of individual services, St. Mary's deliberately sets its charges lower than Cabell's for many services, and Cabell has lowered its charges on multiple services to match St. Mary's. At times, this competition threatened to become a "downward spiral," as Cabell's CFO put it, with St. Mary's "discount[ing] to meet and/or beat" Cabell's prices.

Complaint

68. With respect to cost, Cabell was aware that its higher cost structure, due primarily to higher employee salaries and benefits, placed it at a competitive disadvantage vis-à-vis St. Mary's. Cabell examines St. Mary's salaries and benefits at least once a year. After St. Mary's froze its defined benefit retirement plan, Cabell made plans to do the same. Cabell has received complaints from patients and employers about its higher prices relative to those at St. Mary's and other facilities in the region. After one such complaint, Cabell's CFO wrote, in January 2014, "I believe we have three years at best to get our costs in line with St. Mary's."

69. Aware that the vigorous competition between them forces lower list prices and larger discounts for health plans, and creates pressure to reduce costs, Cabell and St. Mary's have made periodic efforts to limit competition between them.

70. In 1994, Cabell and St. Mary's, along with local physicians, formed a so-called PHO named Tri-State Health Partners, Inc. ("Tri-State"). Two small hospitals in the region, Pleasant Valley Hospital and Williamson Memorial Hospital, subsequently joined Tri-State. Through Tri-State, Cabell and St. Mary's jointly negotiated contracts with multiple health plans, including [REDACTED] and [REDACTED]. These contracts—which are evergreen, meaning that they have no termination date and automatically renew—have identical, low discounts (5% off charges) for both Cabell and St. Mary's.

71. In or about 2003, Tri-State ceased to function and was "administratively dissolved" by the state for failure to file annual reports. Nonetheless, and despite the absence of any clinical integration or other efficiencies that might have once justified the PHO (if such integration or efficiencies ever did exist), Cabell and St. Mary's maintained Tri-State as a "shell" corporation, which kept their favorable, jointly negotiated health plan contracts in place. As a Cabell employee wrote in 2012, "Tri-State Health Partners has ceased ongoing operations. The entity has zero employees, zero revenues and . . . has also been administratively dissolved by the State. My understanding is that the only reason Articles of Dissolution have not been filed is to ensure that a few

Complaint

PPO network contracts entered into roughly ten-fifteen years ago remain in place.”

72. To this day, contracts negotiated through Tri-State remain in effect for Cabell and St. Mary’s with [REDACTED], and other area health plans, despite efforts by health plans to renegotiate the contract terms.

73. In 2013, as competition between them intensified, St. Mary’s and Cabell had multiple meetings in an effort to “resurrect” Tri-State and “look for opportunities for this PHO with other contracts.” Cabell and St. Mary’s also communicated with each other in recent years about their individual negotiations, including prospective rates and contract termination, with certain health plans.

74. In addition, prior to 2009, the hospitals maintained a “friendly agreement” whereby each hospital agreed not to put up billboards in the other’s “backyard.” In 2009, St. Mary’s broke this agreement by placing a billboard near Cabell. Cabell responded with the “‘nuclear option,’ buying up as many available billboards in [St. Mary’s] backyard as we could.” In 2011-2012, the hospitals reached a new agreement to allocate billboard locations, and, in 2013-2014, they continued their pattern of negotiation and competitive retaliation on advertising.

75. Evidence also suggests that Cabell and St. Mary’s coordinated by allocating certain high-end service lines. A healthcare marketing firm retained by St. Mary’s wrote in 2013 that the hospitals had maintained a “gentlemen’s agreement,” which allocated services that each hospital would “own” within the market. Pursuant to this understanding, St. Mary’s key services included cardiac care and cancer services. According to this document, the “competitive market” between Cabell and St. Mary’s ended this “mutual understanding,” and Cabell became “very aggressive in growing these services.” The events described by this document are consistent with the facts, including Cabell’s opening of the Edwards Comprehensive Cancer Center in 2006 and Cabell’s 2013 receipt of Certificate of Need approval to offer primary percutaneous coronary intervention (“PCI”), a cardiac catheterization service.

Complaint

76. The Acquisition would fulfill and make permanent Cabell and St. Mary's efforts to coordinate, depriving consumers of the competitive benefits from any reduction or cessation of these efforts.

C.**The Acquisition Would Eliminate Quality and Service Competition**

77. Cabell and St. Mary's compete vigorously on non-price dimensions, particularly patient service and clinical quality, and patients benefit substantially from this competition. As St. Mary's CEO acknowledged, competition among hospitals creates "incentives for investing dollars into their operations to provide and improve quality to expand services for patients." Competition between these two hospitals has brought advances in services and quality for residents of the Four-County Huntington Area.

78. Documents and testimony reveal that, prior to announcing the Acquisition, Cabell and St. Mary's were each striving to seize patient volume and market share from the other—and feared the other hospital was doing the same. Documents show that the hospitals viewed each other as "competitive threats" in areas including emergency services, surgery, and cancer care.

79. Cabell and St. Mary's compare their quality and patient satisfaction metrics to one another's. For example, after a quality-ranking company released new, "disturbing" results showing that St. Mary's had scored much higher than Cabell on six service lines, Cabell's Director of Strategic Marketing sent an email to other executives asking, "Is this something we should look into from a quality perspective?" Similarly, St. Mary's benchmarked quality measures, such as average emergency room wait times and patient perceptions of cleanliness, responsiveness, staff and physician communication, pain management, and other factors, against Cabell.

80. Documents comparing emergency room (or "ER") services reflect Cabell's and St. Mary's close competition on

Complaint

quality. A St. Mary's executive boasted that patients' transition from the ER to inpatient beds was "seamless," while "one very big issue at CHH is that [patients] would sit for hours." In light of reports that Cabell had low ER volumes and was losing ER market share to St. Mary's, Cabell's VP of Marketing asked, [REDACTED]

Cabell also [REDACTED]

[REDACTED] which St. Mary's executives understood as "yet another move to impact EMS volumes to CHH [Cabell Huntington Hospital] vs. SMMC." St. Mary's has also explored improvements to better compete with Cabell, including a [REDACTED]

81. In addition, Cabell and St. Mary's closely monitor each other's service line and quality-themed advertisements. For example, after a St. Mary's advertisement touted the superiority of its high-definition da Vinci robotic surgical system technology, Cabell's Marketing Director began "working on three different CHH da Vinci newspaper ads to strike back," which would "hammer hard on the lack of da Vinci experience of St. Mary's surgeons." In turn, St. Mary's objected to a Cabell advertisement stating that "more people turn to the Medical Oncology team at the Edwards Comprehensive Cancer Center for Cancer Treatment than any other program in the region" on the grounds that St. Mary's treats more cancer patients than Cabell. Cabell then expressed concern internally that, to retaliate, St. Mary's would "produce a commercial saying that [St. Mary's] ER volume is nearly double ours." Cabell's and St. Mary's responses to each other's quality advertisements reflect the hospitals' intense head-to-head competition on service and quality, and also discipline them to back up their quality claims.

82. Competition has also driven Respondents to offer new technologies and service lines. For example, after St. Mary's purchased a new da Vinci robot for surgical services, Cabell was concerned about losing surgical patients because of its older, limited-capacity da Vinci model. In response, Cabell expanded

Complaint

its da Vinci services and acquired two new da Vinci models. Da Vinci robots benefit patients by permitting “much less invasive” surgery.

83. Cardiac services are an area of traditional strength for St. Mary’s. In 2013, however, Cabell overcame St. Mary’s opposition to obtain CON approval to offer emergency PCI cardiac catheterization services. Before Cabell received this CON, patients at Cabell requiring PCI services had been transferred to St. Mary’s. Over the past several years, Cabell has developed plans to further expand and enhance its cardiac program, [REDACTED]

84. Cabell has also increased competition with St. Mary’s for cancer services, another traditional strength of St. Mary’s. In 2006, Cabell opened the Edwards Comprehensive Cancer Center, and its market share for cancer services increased at St. Mary’s expense. Consistent with this strategy of targeting St. Mary’s service lines of traditional strength, recent Cabell documents identify cancer and cardiovascular as two “strategic service lines” for which Cabell has been looking to increase volumes.

85. The elimination of this vigorous and beneficial quality competition between Cabell and St. Mary’s would affect all patients who use these hospitals, including commercially insured, Medicare, Medicaid, and self-pay patients. Post-Acquisition, the hospitals would no longer be spurred by each other to improve the quality of their services, add service lines, obtain new technologies, recruit new physicians, and increase patient safety, comfort, and convenience. Already, these effects from the pending Acquisition can be seen: St. Mary’s has put on hold plans to build [REDACTED]

Complaint

D.**Temporary Conduct Remedies Would Not Prevent Competitive Harm or Replicate Market Competition**

86. In an acknowledgment that the proposed Acquisition would produce anticompetitive effects, Respondents attempted to create temporary conduct remedies through Cabell's entry into the LOA [REDACTED] and the AVC with the West Virginia Attorney General.

87. In November 2014, Cabell agreed to the LOA with

[REDACTED] informed Cabell that

[REDACTED] The LOA, which is expressly contingent on consummation of the Acquisition, [REDACTED]

88. In the AVC, which was signed in July 2015, Cabell and St. Mary's committed to certain terms temporarily governing the merged entity's conduct post-Acquisition. Among other things, the AVC purports to impose certain limits with respect to hospital charges, operating margins, termination of evergreen health plan contracts, and opposition to certain CON applications. Each of these commitments expires seven years after the Acquisition is consummated.

89. For mergers that may substantially lessen competition, the Supreme Court, other courts, and the federal antitrust agencies strongly prefer "structural" remedies, such as pre-merger injunctions and post-merger divestitures, to preserve competition rather than "conduct" remedies, which rely on courts or enforcement authorities to police post-merger behavior. For example, just this year, in *Commonwealth v. Partners Healthcare System, Inc.*, a Massachusetts court rejected a settlement agreement, similar to but far more detailed than the AVC,

Complaint

between merging hospitals and the state attorney general. The court explained that such a conduct remedy “permits consolidation and then attempts to limit the consequences that flow from that by imposing certain restrictions on the defendant’s behavior” and thus “require[s] constant and costly monitoring.” The court further stated that “the remedies that are proposed are temporary and limited in scope—like putting a band-aid on a gaping wound that will only continue to bleed (perhaps even more profusely) once the band-aid is taken off.” The same is true here.

90. First, neither the LOA nor the AVC restores the competition that the Acquisition would eliminate. They simply, and ineffectively, seek to limit the harm that results from the substantial lessening of competition.

91. Even if the LOA and AVC closed off all potential avenues for price increases to consumers during their terms—which they do not—they do not preserve quality competition between Cabell and St. Mary’s. In fact, it is likely that any temporary mitigation of price increases during the effective dates of the LOA and AVC would result in greater non-price harm, as the merged firm exercises its market power to limit quality and service improvements.

92. Nor does the AVC protect health plans that would seek to renegotiate their agreements to obtain better terms from Cabell and St. Mary’s. The provision restricting termination of evergreen contracts preserves agreements that were negotiated by Cabell and St. Mary’s jointly through Tri-State and contain terms favorable to the hospitals. Post-Acquisition, the health plans would be negotiating against a combined Cabell/St. Mary’s—the only hospital provider in the Four-County Huntington Area—and therefore could not take advantage of competition to negotiate more favorable terms.

93. Finally, the AVC and the LOA would terminate no later than seven years from the Acquisition, at which time the combined Cabell/St. Mary’s would be able to use its enhanced bargaining leverage to demand higher prices without any constraint imposed by the AVC and the LOA.

Complaint

94. Because other regional hospitals are distant and insufficient substitutes for Cabell and St. Mary's for the majority of patients in the Four-County Huntington Area, health plans would be compelled to pay higher prices after the expiration of the AVC and LOA.

VII.

ENTRY BARRIERS

95. Neither entry by new healthcare providers into the relevant service markets nor expansion by existing market participants would deter or counteract the serious competitive harm likely to result from the Acquisition.

96. New hospital entry in the Four-County Huntington Area would not be likely, timely, or sufficient to deter or offset the Acquisition's harmful effects. Construction and operation of a new general acute care hospital involves major capital investment and serious financial risk and would take many years from the initial planning stage to opening.

97. It is also unlikely that sufficient demand exists for a new GAC inpatient hospital in the Four-County Huntington Area. The Four-County Huntington Area is an economically challenged region with flat population growth and high percentages of Medicare and Medicaid patients, making it unattractive for new hospital development.

98. West Virginia's CON regulations, administered by the WVHCA, pose an additional significant barrier to entry. West Virginia requires that "all health care providers, unless otherwise exempt, must obtain a CON before (1) adding or expanding health care services, (2) exceeding the capital expenditure threshold of \$3,112,828, (3) obtaining major medical equipment valued at \$3,112,828 or more, or (4) developing or acquiring new health care facilities." Under this regulatory regime, enhancing competition is not necessarily grounds for approving new healthcare services; instead, the aim is to develop new institutional health services in an "orderly, economical" manner that "avoid[s] unnecessary duplication." According to the

Complaint

WVHCA, “currently, there is no demand for additional beds in the Huntington area.” Thus, West Virginia is unlikely to approve entry that would duplicate services provided by the merged entity.

99. Indeed, West Virginia’s CON regulations have repeatedly thwarted the development of competitive healthcare services in the Four-County Huntington Area. For example, the WVHCA denied a Huntington physician group’s application to acquire an MRI; as a result, the group was compelled to enter into a joint venture with St. Mary’s to obtain the equipment. The WVHCA also denied Cabell’s application to provide fixed open-bore MRI services, which were offered by St. Mary’s.

100. Other GAC hospitals in the communities surrounding the Four-County Huntington Area have no plans to enter or expand into Huntington. In addition, King’s Daughters’ financial struggles following a Department of Justice investigation create a further reason why that hospital is unlikely to expand into the Four-County Huntington Area.

101. Entry of outpatient surgical services providers also would not be likely, timely, or sufficient to deter or offset the Acquisition’s harmful effects. Opening an outpatient surgery center requires considerable time and capital investment, as the opening of Three Gables in 2000 demonstrates. It took four years for Three Gables to open, including two years of planning and two years of construction, and the owners [REDACTED]. In addition, West Virginia’s CON laws apply to outpatient facilities and services. No company or group of physicians has declared plans to open a new outpatient surgical center in the Four-County Huntington Area.

VIII.**EFFICIENCIES**

102. Efficiencies that could outweigh the Acquisition’s likely significant harm to competition are lacking here.

103. [REDACTED]

Complaint

[REDACTED]

[REDACTED] These asserted savings have not been substantiated and face multiple practical obstacles.

104. Nor are the claimed cost savings merger-specific. There are significant, unexplored savings opportunities available to Cabell and St. Mary's independently, without the Acquisition, and St. Mary's could also achieve savings through a less competitively-harmful acquisition by one of the multiple alternative bidders in the 2014 RFP.

105. Even if a portion of the claimed efficiencies were to be realized, they would be offset by the costs of integrating the two hospitals,

[REDACTED]

[REDACTED] Post-Acquisition,

[REDACTED] this expense would offset any cognizable savings.

106. Respondents also claim that the Acquisition will lead to quality enhancement opportunities, but these claims are likewise unsubstantiated and largely lack merger-specificity. Respondents assert that the merged entity will realize volume-related improvements in the quality of care through the consolidation of certain clinical service lines. Respondents' analysis on this issue is conclusory and does not account for the fact that the procedures with demonstrated volume-outcome relationships are already largely consolidated at one or the other hospital, and that certain key services may not be consolidated. Respondents also project quality improvements from "standardization" across the two facilities and the building of a "bridge" between the two hospitals' electronic health records systems to render them interoperable. Neither of these initiatives has been substantiated, and neither is merger-specific.

Complaint

IX.**VIOLATION****COUNT I – ILLEGAL AGREEMENT**

107. The allegations of Paragraphs 1 through 106 above are incorporated by reference as though fully set forth herein.

108. The Definitive Agreement constitutes an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

COUNT II – ILLEGAL ACQUISITION

109. The allegations of Paragraphs 1 through 106 above are incorporated by reference as though fully set forth.

110. The Acquisition, if consummated, may substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the 5th day of April, 2016, at 10 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C., 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in

Complaint

which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C., 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

Complaint

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Acquisition challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Acquisition is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant markets, with the ability to offer such products and services as Cabell and St. Mary's were offering and planning to offer prior to the Acquisition.
2. A prohibition against any transaction between Cabell and St. Mary's that combines their businesses in the relevant markets, except as may be approved by the Commission.
3. A requirement that, within four months, Cabell and St. Mary's will, individually and without sharing information or otherwise coordinating with one another, renegotiate each still-effective health plan contract that was negotiated through Tri-State Health Partners.
4. A requirement that, for a period of time, Cabell and St. Mary's provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other company operating in the relevant markets.
5. A requirement to file periodic compliance reports with the Commission.
6. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to restore St. Mary's as a viable, independent competitor in the relevant markets.

Final Order

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this fifth day of November, 2015.

By the Commission.

**ORDER RETURNING MATTER TO ADJUDICATION
AND DISMISSING COMPLAINT**

On March 24, 2016, the Commission withdrew this matter from adjudication for thirty days. On April 22, 2016, the withdrawal from adjudication was extended until 11:59 p.m. EDT on the 14th calendar day after the West Virginia Health Care Authority (“WVHCA”) issued its written decision, pursuant to Section 16-29B-28(e)(3) of the Code of West Virginia, regarding the Application of Cooperative Agreement (Acquisition of St. Mary’s Medical Center) filed by Respondent Cabell on March 25, 2016. On June 22, 2016, the WVHCA issued its written decision approving the Cooperative Agreement.

For the reasons outlined in the Statement of the Commission issued concurrently with this Order, the Commission has now determined to return this matter to adjudication for the sole purpose of dismissing the Complaint. Accordingly,

IT IS ORDERED that this matter be, and it hereby is, returned to adjudication;

and

IT IS FURTHER ORDERED that the Complaint in this matter be, and it hereby is, dismissed without prejudice.

By the Commission.

Statement of the Commission

Statement of the Federal Trade Commission

In November 2015, the Commission issued an administrative complaint challenging Cabell Huntington Hospital's proposed acquisition of St. Mary's Medical Center, the only two hospitals in Huntington, West Virginia. The Commission had reason to believe that the acquisition would create a near-monopoly over general acute care inpatient hospital services and outpatient surgical services in the four-county region surrounding Huntington. As alleged in the complaint, this near-monopoly is likely to increase prices and degrade quality of care.

Although our concerns about this transaction remain, the Commission has determined to dismiss the administrative complaint without prejudice. We do so in light of the passage of West Virginia Senate Bill 597 ("SB 597") and the West Virginia Health Care Authority's decision to approve Cabell's cooperative agreement with St. Mary's, with which the West Virginia Attorney General concurred.

This case presents another example of healthcare providers attempting to use state legislation to shield potentially anticompetitive combinations from antitrust enforcement. The Commission believes that state cooperative agreement laws such as SB 597 are likely to harm communities through higher healthcare prices and lower healthcare quality.

Cooperative agreement laws, which seek to replace federal (and sometimes state) antitrust enforcement and judicial review under the antitrust laws with state regulation and supervision of healthcare provider combinations, undervalue the important role that competition plays in the healthcare sector. In general, vigorous competition benefits consumers through lower prices, higher quality goods and services, greater access to goods and services, and innovation. Empirical research demonstrates this holds true in healthcare provider markets as well. As a recently published economic review article notes, "the message from this literature is clear ..., mergers between rival hospitals are likely to raise the price of inpatient care and these effects are larger in

Statement of the Commission

concentrated markets.”¹ A recent economic working paper confirms this conclusion.² Further, these price increases are likely to be passed on to consumers through higher insurance premiums, deductibles, and copays; reduced coverage; or lower wages.³ Finally, the weight of the existing evidence shows that competition improves clinical hospital quality and lowers mortality rates.⁴

Proponents of cooperative agreement laws claim that antitrust enforcement undermines the policy goals of the Affordable Care Act to improve quality and lower costs through greater coordination among healthcare providers. This is fundamentally incorrect. The ACA did not repeal the antitrust laws, and it certainly does not condone mergers that substantially lessen competition.⁵ In many cases, healthcare providers can advance

1 Martin Gaynor et al., *The Industrial Organization of Health Care Markets*, 53 J. ECON. LIT. 235, 262 (2015); *see also* Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation: Update*, Robert Wood Johnson Found. (June 2012), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261.

2 Zack Cooper et al., *The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured* (Nat'l Bur. of Econ. Research, Working Paper No. 21815, 2015), <http://www.nber.org/papers/w21815.pdf>.

3 For empirical evidence on the impact on premiums and wages, see, e.g., *id.*; Erin Trish & Bradley Herring, *How Do Health Insurer Market Concentration and Bargaining Power With Hospitals Affect Health Insurance Premiums?*, 42 J. HEALTH ECON. 104, 112 (2015); Katherine Baicker & Amitabh Chandra, *The Labor Market Effects of Rising Health Insurance Premiums*, 24 J. LABOR ECON. 609–34 (2006).

4 *See* Gaynor et al., *supra* note 1, at 249 (“[T]he evidence indicates that increases in competition improve hospital quality.”); *see also* Martin Gaynor et al., *Death by Market Power: Reform, Competition, and Patient Outcomes in the National Health Service*, 5 AM. ECON. J.: ECONOMIC POLICY 134 (2013); Zack Cooper et al., *Does Hospital Competition Save Lives? Evidence from the English NHS Patient Choice Reforms*, 121 ECON. J. 228 (2011); Nathan Wilson, *Market Structure as a Determinant of Patient Care Quality*, 2 AM. J. HEALTH ECON. 241 (2016).

5 In fact, the ACA final program rules specifically recognize antitrust enforcement’s role in ensuring competition in provider markets. U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., Medicare Program, Medicare Shared Savings Program: Accountable Care Organizations,

Statement of the Commission

the goal of delivering clinically integrated care either on their own or through mergers or other collaborations that raise little or no antitrust concern. Indeed, the Federal Trade Commission and the Antitrust Division of the Department of Justice have issued extensive guidance to providers seeking to collaborate within the bounds of the antitrust laws.⁶ In short, antitrust enforcement is consistent with – not an impediment to – the goals of the ACA.

Proponents of hospital mergers often argue, citing the policy goals of the ACA encouraging greater coordination of care, that a merger is necessary to improve quality and lower costs. Proponents claim those potential benefits as procompetitive efficiencies justifying mergers or collaborations that otherwise may raise antitrust concerns. We understand that coordination of care has the potential to further key goals of healthcare reform and consider those benefits when evaluating a provider merger. The FTC's and the Department of Justice's Horizontal Merger Guidelines expressly recognize that mergers may "result in lower prices, improved quality, enhanced service, or new products," and that these possible benefits must be evaluated and weighed against potential anticompetitive harm.⁷ Claimed benefits, however, are only cognizable if they are merger-specific. Many of the purported benefits of hospital mergers – including coordination of patient care, sharing information through

42 C.F.R. § 425 (2011), 76 Fed. Reg. 67,826 (Nov. 2, 2011), <https://www.gpo.gov/fdsys/pkg/FR-2011-11-02/html/2011-27461.htm>.

6 *See, e.g.*, Fed. Trade Comm'n & U.S. Dep't of Justice, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67,026 (Oct. 28, 2011), <https://www.gpo.gov/fdsys/pkg/FR-2011-10-28/pdf/2011-27944.pdf>; Fed. Trade Comm'n & U.S. Dep't of Justice, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS (2000), https://www.ftc.gov/sites/default/files/documents/public_events/joint-venture-hearings-antitrust-guidelines-collaboration-among-competitors/ftcdojguidelines-2.pdf; U.S. Dep't of Justice & Fed. Trade Comm'n, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996), <https://www.ftc.gov/sites/default/files/documents/reports/revised-federal-trade-commission-justice-department-policy-statements-health-care-anitrust/hlth3s.pdf>.

7 U.S. Dep't of Justice & Fed. Trade Comm'n, HORIZONTAL MERGER GUIDELINES 29–31 (2010), <https://www.ftc.gov/sites/default/files/attachments/merger-review/100819hmg.pdf>.

Statement of the Commission

electronic medical records, population health management, risk-based contracting, standardizing care, and joint purchasing – can often be achieved through alternative means that do not impair competition. Ultimately, the Commission challenges few hospital mergers and only does so after thorough investigation indicates, as alleged in this case, that the combination is likely to result in a loss of competition that is not outweighed by improvements in quality and cost efficiencies.

Cooperative agreements that replace antitrust enforcement with state regulatory regimes often protect likely anticompetitive transactions that impose harms far exceeding their benefits. These laws and any accompanying promises providers may make, no matter how well-intentioned or sophisticated, are unlikely to replicate the manifold benefits of competition. For this reason, the Commission has consistently recommended that states not implement such laws.⁸

Serious questions also remain about what happens if the parties to a cooperative agreement fail to achieve the level of benefits promised to state authorities and their local communities. Because healthcare provider mergers are difficult to unwind, there is no easy remedy if a cooperative agreement fails to deliver its promised benefits. In all likelihood, the benefits of competition will be lost, and patients, employers, and communities will suffer the consequences of higher-cost and lower-quality healthcare.

Finally, we emphasize that we will continue to vigorously investigate and, where appropriate, challenge anticompetitive mergers in the courts and, if necessary, through state cooperative agreement processes. Our decision to dismiss the complaint without prejudice does not necessarily mean that we will do the

⁸ See, e.g., Fed. Trade Comm'n Staff Comment Before the Ala. State Senate Re: House Bill 241 and Senate Bill 243 (May 2, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-alabama-state-senate-regarding-alabama-house-bill-241-senate-bill-243/160504commentalabama.pdf; Fed. Trade Comm'n Staff Comment to W.Va. House of Delegates Re: Senate Bill 597 (Mar. 9, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-west-virginia-house-delegates-regarding-sb-597-competitive-implications-provisions/160310westvirginia.pdf.

Statement of the Commission

same in other cases in which a cooperative agreement is sought or approved.

Complaint

IN THE MATTER OF

**VICTREX PLC,
INVIBIO LIMITED,
AND
INVIBIO, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4586; File No. 141 0042
Complaint, July 13, 2016 – Decision, July 13, 2016*

This consent order addresses Victrex plc's, Invibio, Inc.'s and Invibio Ltd.'s use of exclusive supply contracts. The complaint alleges that respondents violated of Section 5 of the Federal Trade Commission Act by using exclusive supply contracts to maintain monopoly power in the market for implant-grade polyetheretherketone ("PEEK"). The consent order requires Invibio to cease and desist from enforcing most exclusivity terms in current supply contracts and generally prohibits Invibio from requiring exclusivity in future contracts. The order also prevents Invibio from adopting other mechanisms, such as market-share discounts or retroactive volume discounts, to maintain its monopoly power.

Participants

For the *Commission: Dana Abrahamsen, Wes Carson, Mika Ikeda, Kristin Shaffer, and Charlotte Slaiman.*

For the *Respondents: Barbara Sicalides, Pepper Hamilton LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41, et seq., and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Victrex plc, Invibio, Inc., and Invibio Limited (hereinafter collectively referred to as "Invibio" or "Respondents") have violated the provisions of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding

Complaint

by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

NATURE OF THE CASE

1. Invibio is the dominant supplier of implant-grade polyetheretherketone (“PEEK” or “implant-grade PEEK”), a specialty polymer used by medical device makers to construct spinal, orthopedic, and other human implants.

2. Invibio’s only competitors in the sale of implant-grade PEEK are Solvay Specialty Polymers LLC (“Solvay”) and Evonik Corporation (“Evonik”). Solvay and Evonik each began to sell PEEK after Invibio had established market dominance, offering prices significantly below the prices charged by Invibio.

3. Invibio supplies PEEK to medical device makers primarily pursuant to long-term supply contracts. Both before and after entry by Solvay and Evonik, Invibio included exclusivity terms in these contracts. Invibio employed various strategies to coerce or induce device makers to accede to exclusivity terms, including threatening to discontinue PEEK supply or to withhold access to regulatory support.

4. Invibio’s insistence on exclusivity terms has been a deliberate and successful strategy to hinder its competitors and to maintain its monopoly power. In 2014, years after entry by Solvay and Evonik, and despite Solvay’s and Evonik’s lower prices, Invibio still accounted for over 90 percent of PEEK sales worldwide. A substantial majority of these sales have been foreclosed from Solvay and Evonik due to the exclusivity terms in Invibio’s long-term supply contracts.

5. Due to Invibio’s conduct, Solvay and Evonik have been hampered in their efforts to compete against Invibio, including in developing valuable customer relationships that would bolster the entrants’ reputations, and in realizing sufficient returns to justify further investment in the business. For their part, purchasers of PEEK have been deprived of a meaningful choice among suppliers and have been denied the full benefits of competition.

Complaint

RESPONDENTS

6. Respondent Victrex plc (“Victrex”) is headquartered in the United Kingdom and its shares are traded on the London Stock Exchange. Its principal place of business is located at Technology Centre, Hillhouse International, Thornton Cleveleys, Lancashire FY5 4QD, England.

7. Respondent Invibio Limited is a wholly-owned subsidiary of Victrex and its principal place of business is located at Technology Centre, Hillhouse International, Thornton Cleveleys, Lancashire FY5 4QD, England.

8. Respondent Invibio, Inc. is a wholly-owned subsidiary of Victrex and is a corporation organized, existing, and doing business under and by virtue of the laws of Delaware, with its main office and principal place of business located at 300 Conshohocken State Road, Suite 120, West Conshohocken, Pennsylvania 19428.

JURISDICTION

9. At all times relevant herein, each Respondent has been, and is now, a corporation, as “corporation” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

10. The acts and practices of each Respondent, including the acts and practices alleged herein, are in commerce or affect commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

INDUSTRY BACKGROUND

11. PEEK is a high-performance polymer used in a number of applications. A predecessor company to Victrex developed industrial-grade PEEK in the late 1970s. Industrial-grade PEEK is now used in a number of industries, including aerospace, automotive, and energy.

12. Respondents later developed implant-grade PEEK, which is manufactured under conditions that assure its purity. The

Complaint

principal use of implant-grade PEEK is in medical devices used in spinal interbody fusion, a procedure used to treat degenerative spinal disorders and similar conditions. Spinal interbody fusion devices and other medical devices that use PEEK must be cleared by the United States Food and Drug Administration (“FDA”) and by regulatory authorities in other countries.

13. As of the late 1990s, spinal interbody fusion devices were made primarily of titanium and other metals, along with autograft (a patient’s own bone) or allograft (cadaver bone). Around this time, medical device makers sought alternative implant materials.

14. In or about 1999, Invibio began to market a grade of PEEK suitable for implants. When Invibio launched implant-grade PEEK, it was the only supplier of this grade of PEEK. Invibio soon found willing buyers for its product.

15. When Invibio began marketing implant-grade PEEK, the company entered into supply contracts with its medical device maker customers. Many of these contracts included an exclusivity term of some kind. These terms generally required that the customer use Invibio PEEK for all PEEK-containing medical devices, for a broad category of devices, or for a list of identified devices.

16. When Invibio was the only PEEK supplier, its exclusivity terms went unchallenged by customers. This dynamic started to change in the late 2000s, when medical device makers became aware of competing suppliers.

COMPETITIVE ENTRY

17. In 2006, Solvay, a large chemical company, acquired assets to facilitate its entry into the sale of industrial-grade PEEK. Solvay also sold non-PEEK polymers to medical device makers. Device makers (customers of Invibio) informed Solvay that they desired another implant-grade PEEK supplier in order to inject competition into the market, including price and product development competition. In response to this encouragement from device makers, Solvay expanded into implant-grade PEEK.

Complaint

18. The FDA cleared the first spinal implant device using Solvay PEEK in 2010.

19. In 2005, Evonik, also a large chemical company, began producing industrial-grade PEEK. Like Solvay, Evonik supplied non-PEEK polymers to medical device makers. As with Solvay, device makers encouraged Evonik to produce implant-grade PEEK. In response to this encouragement, Evonik expanded into implant-grade PEEK.

20. The FDA cleared the first spinal implant device using Evonik PEEK in 2013.

21. Solvay and Evonik have offered to sell PEEK at prices significantly lower than the prices charged by Invibio. Invibio was aware of this price gap.

INVIBIO'S USE OF EXCLUSIVITY TO IMPEDE COMPETITORS

22. Invibio decided to adopt a strategy of expanding the scope and coverage of exclusivity terms in PEEK supply contracts to prevent Solvay and Evonik from developing into effective competitors. Invibio was concerned that if it did not block rivals, it would be forced to engage in painful price competition with Solvay and Evonik.

23. Invibio recognized that it was particularly important to lock up the largest and most sophisticated medical device makers with exclusive contracts, as doing so would prevent Solvay and Evonik from achieving success at these device makers and then building on that success with other customers. If Solvay's or Evonik's PEEK were used successfully by leading medical device makers, this would validate the rival in the eyes of other device makers, thereby enhancing competition in the market.

24. Invibio implemented its exclusivity strategy through negotiations with existing and potential customers. During these negotiations, Invibio sought to broaden its exclusivity terms in several ways, including by: (1) inserting more explicit exclusivity provisions into supply contracts; (2) expanding the scope of and

Complaint

limiting the exceptions to exclusivity requirements; and (3) employing restrictive contract terms that impeded customers' ability to switch to an alternative PEEK supplier for existing products even upon contract expiration.

25. For their part, after entry by Solvay and Evonik, a number of PEEK purchasers sought to negotiate supply terms with Invibio that did not require exclusivity. These device makers wanted to arrange a second source of PEEK supply in order to reduce the risk of a supply interruption and to obtain lower prices.

26. Invibio responded by insisting on exclusivity terms. Invibio's message was that if customers were going to use Invibio PEEK, they must use only Invibio PEEK.

27. Because device makers could not quickly obtain regulatory clearance to use a new source of PEEK for all of their devices, device makers generally had no choice but to sign an exclusive contract with Invibio.

28. Invibio enforced its position by threatening to withhold needed supply or regulatory support and, where necessary, offering minor inducements in exchange for exclusivity.

29. Invibio's threats in support of its exclusivity demands took several forms. For example, Invibio threatened to cut off PEEK supply for all of a device maker's existing products. Invibio also threatened not to sell Invibio's new brands of PEEK to a device maker unless the device maker agreed to buy Invibio's main brand of PEEK on an exclusive basis. And Invibio threatened to withhold access to Invibio's FDA Master File and other regulatory support if device makers did not agree to exclusivity.

30. Other device makers, while not explicitly threatened by Invibio, were too fearful of a supply interruption or other retaliatory tactics to resist Invibio's demand for exclusivity.

31. Where necessary, Invibio was prepared to provide a small price discount or other benefit in exchange for exclusivity. Invibio recognized that limited discounts were a small price to pay for the

Complaint

benefit of cutting off Solvay and Evonik from key customer accounts.

32. As a result of Invibio's efforts, nearly all medical device makers that purchase PEEK from Invibio do so under contracts containing some form of exclusivity. These exclusivity terms take one of three forms: (1) requiring that the customer use Invibio PEEK for all PEEK-containing medical devices; (2) requiring that the customer use Invibio PEEK for a broad category of PEEK-containing devices; or (3) requiring that the customer use Invibio PEEK for a list of identified PEEK-containing devices—with the list often including nearly every device in the customer's portfolio. Whatever the form, these exclusivity terms have prevented medical device makers from sourcing significant volumes of PEEK from Invibio's rivals.

INVIBIO'S MONOPOLY POWER

33. Invibio has exercised and continues to exercise monopoly power with respect to implant-grade PEEK.

34. Invibio has been able to price its PEEK substantially higher than competing versions of PEEK and to hamper competitors through its exclusive contracting practices.

35. Additionally, Invibio has maintained a high share of a relevant market with substantial barriers to entry.

36. The relevant product market is no larger than implant-grade PEEK: that is, PEEK that has been used in at least one device cleared by the United States Food and Drug Administration.

37. Other materials used in spinal and other implants are not close enough substitutes to prevent a monopolist supplier of PEEK from profitably raising PEEK prices. The choice of an implant device is typically determined by the physician rather than by the patient. Such selection is based in substantial part upon the characteristics of the implant material. PEEK has unique characteristics compared to other implant materials, including as to radiolucence, machinability, and elasticity. Physicians are

Complaint

unlikely to alter implant device selection patterns in response to a small but significant and non-transitory increase in PEEK prices. Device makers also are unlikely to alter PEEK purchasing patterns in response to a small but significant and non-transitory increase in PEEK prices.

38. Because implant-grade PEEK can be and is manufactured throughout the world, the relevant geographic market is worldwide.

39. There are three competitors in the worldwide market for implant-grade PEEK: Invibio, Solvay, and Evonik. Invibio has consistently maintained a market share of approximately 90 percent or greater.

40. The relevant market has significant barriers to entry and significant barriers to expansion. Such barriers include: (i) significant capital outlays needed to develop the capacity to manufacture PEEK; (ii) testing time and costs to develop new grades of PEEK; and (iii) regulatory requirements. In addition to these structural barriers, Invibio's exclusivity practices have created an additional barrier to entry and expansion by shrinking the volume of sales available to would-be rivals.

41. The experiences of Solvay and Evonik after entering the relevant market confirm the durability of Invibio's monopoly power. In 2014, years after Solvay and then Evonik announced plans to enter the market, the combined market share of Solvay and Evonik was less than 10 percent.

ANTICOMPETITIVE EFFECTS OF INVIBIO'S EXCLUSIVE CONTRACTS

42. Invibio has maintained its monopoly power through the use of exclusive supply contracts. Invibio's conduct has harmed competition by enabling Invibio to maintain supracompetitive prices, by reducing consumer choice, and by impeding rivals from becoming effective competitors.

43. Invibio used its monopoly power to maintain high prices for PEEK. Although Solvay and Evonik have offered significantly

Complaint

lower prices for PEEK, the typical Invibio customer did not see any significant price decrease after entry by Solvay and Evonik. Even in the rare instances in which customers received a price discount in exchange for exclusivity, the customers still paid more for Invibio PEEK than they would have paid for PEEK supplied by Solvay or Evonik.

44. Invibio used its monopoly power to impede device makers from contracting with alternative suppliers of PEEK. Medical device makers prefer to have multiple sources of PEEK for risk mitigation and other commercial benefits. Solvay and Evonik offer an alternative to Invibio, one that many device makers are eager to explore. Invibio's exclusive contracts, however, prevent device makers from doing so. Absent Invibio's exclusivity requirement, a significant number of device makers would contract with these alternative suppliers to secure lower-priced PEEK and to mitigate risk.

45. Invibio used its monopoly power to impede Solvay and Evonik from developing into fully effective rivals. Invibio's exclusive contracts have foreclosed from competitors a substantial portion of the worldwide PEEK market, including key customer accounts that would validate the entrants' reputations.

46. Invibio succeeded in its plan to hamper its rivals' growth with exclusive contracts. Solvay and Evonik have been forced to focus sales efforts on small device makers without exclusive contracts with Invibio. Due to the pervasiveness of Invibio's exclusivity terms, each firm has missed sales targets. Without sufficient returns to justify further investment in the business, including in next generation technologies, there is a significant risk that continued enforcement of Invibio's exclusive contracts would cause Solvay and Evonik to become even less effective competitors in the future.

47. The acts and practices of Respondents as alleged herein have had the purpose, capacity, tendency, and effect of restraining competition unreasonably and of maintaining Invibio's monopoly power.

Decision and Order

48. There are no legitimate procompetitive efficiencies that justify Invibio's conduct or that outweigh the substantial anticompetitive effects thereof.

49. Any legitimate objectives of Invibio's conduct as alleged herein could have been achieved through significantly less restrictive means.

VIOLATION OF FTC ACT

50. The allegations in all of the paragraphs above are re-alleged and incorporated by reference as though fully set forth herein.

51. Invibio has willfully engaged in anticompetitive and exclusionary acts and practices to enhance or maintain its monopoly power. These acts and practices constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirteenth day of July, 2016, issues its complaint against Respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of Victrex plc, Invibio Limited, and Invibio, Inc. (hereinafter collectively referred to as "Respondents"), and Respondents having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission

Decision and Order

for its consideration and which, if issued, would charge Respondents with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of the Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having found reason to believe that Respondents have violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Decision and Order (“Order”):

1. Respondent Victrex plc is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its office and principal place of business located at Victrex Technology Centre, Hillhouse International, Thornton Cleveleys, Lancashire FY5 4QD.
2. Respondent Invibio Limited is a wholly-owned subsidiary of Victrex plc and is a corporation organized, existing and doing business under and by virtue of the laws of the United Kingdom, with its office and principal place of business located at

Decision and Order

Victrex Technology Centre Hillhouse International,
Thornton, Cleveleys, Lancashire FY5 4QD.

3. Respondent Invibio, Inc. is a wholly-owned subsidiary of Victrex plc and is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 300 Conshohocken State Rd, Suite 120, West Conshohocken, Pennsylvania 19428.
4. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and over Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

THE PARTIES

- A. “Victrex” means Victrex plc, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Victrex plc, including without limitation Invibio Limited and Invibio, Inc.; and the respective directors, officers, employees, agents, consultants, representatives, successors, and assigns of each.
- B. “Invibio Limited” means Invibio Limited, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Invibio Limited including without limitation Invibio, Inc.; and the respective directors, officers, employees, agents, consultants, representatives, successors, and assigns of each.

Decision and Order

- C. “Invibio, Inc.” means Invibio, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Invibio, Inc.; and the respective directors, officers, employees, agents, consultants, representatives, successors, and assigns of each.
- D. “Respondents” means Victrex, Invibio Limited, and Invibio, Inc.
- E. “Commission” means the Federal Trade Commission.

OTHER DEFINITIONS

- F. “Antitrust Compliance Program” means the program to ensure compliance with this Order and with the Antitrust Laws, as required by Paragraph III of this Order.
- G. “Antitrust Laws” means the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et. seq.*, the Sherman Act, 15 U.S.C. § 1 *et. seq.*, and the Clayton Act, 15 U.S.C. § 12 *et. seq.*
- H. “Competing PEEK” means any PEEK manufactured or sold by any Person other than the Respondents.
- I. “Competing PEEK Supplier” means any Person other than Respondents that manufactures, markets, sells, offers to sell, or seeks to sell Competing PEEK.
- J. “Custom Component” means a Customer-specific component of a Customer Product or near net shape that (i) is composed of PEEK; (ii) is manufactured by Respondents to the specifications of, and at the request of, a single Customer; (iii) is the only component or near net shape of the same specifications sold to any Customer; (iv) requires for its manufacture the development and maintenance of tooling by Respondents; and (v) requires the development and

Decision and Order

maintenance by Respondents of a validation report for use by the Customer with the FDA.

- K. “Customer” means any Person who purchases, seeks to purchase, or otherwise takes delivery or receives, PEEK from one or more Respondents for use in any Customer Product sold or cleared for use in the United States, regardless of where the PEEK is manufactured or sold, regardless of where the Customer Product is manufactured, and regardless of whether the Customer also purchases PEEK for use in Customer Products sold outside of the United States. For the avoidance of doubt, “Customer” does not include any Person who purchases or seeks to purchase PEEK from one or more Respondents solely for use in Customer Products that are not manufactured in or imported into the United States.
- L. “Customer Product” means any medical device, implant, medical instrument, or similar item intended for use inside of or in contact with a human body that contains PEEK and is sold, offered for sale, or distributed by a Customer. For the avoidance of doubt, Customer Product includes Custom Components and Jointly Developed Products. For the further avoidance of doubt, other than Custom Components and Jointly Developed Products, products with different part numbers, SKUs, or other differentiating identifiers are distinct Customer Products, even if they have identical indications for use.
- M. “Dual Source” or “Dual Sourcing” means selling, offering for sale, or distributing two or more units of a Customer Product, some of which are manufactured from Respondents’ PEEK and some of which are manufactured from Competing PEEK.
- N. “Exclusivity,” “Exclusive,” or “Exclusively” means any requirement, whether formal or informal, that a Customer purchase or use only Respondents’ PEEK in

Decision and Order

all or any individual or group of Customer Products, or any other requirement that a Customer refrain from purchasing or using, or limit its purchase or use of, any Competing PEEK in one or more Customer Products. For the avoidance of doubt, “Exclusivity,” “Exclusive,” or “Exclusively” includes any limitations on Dual Sourcing.

- O. “Executive and Sales Staff” means the President, all Vice-Presidents, the Chief Financial Officer, and members of the Executive Committees of each Respondent (or their equivalent positions regardless of job title); and the officers, directors, and employees, and contractors of each Respondent whose duties relate primarily to the marketing, promotion, or sale of PEEK to Customers.

- P. “Extraordinary Support” is a subset of Product Support provided by Respondents to a Customer that (i) is requested by a Customer; (ii) is not made generally available to other Customers; and (iii) is needed to enable a Customer to introduce a new Customer Product. For the avoidance of doubt, the following activities are not Extraordinary Support: (i) granting a Customer a right to reference Respondents’ FDA Master File(s) before, during, and after FDA review and clearance of a Customer Product; (ii) maintaining biocompatibility data regarding Respondents’ PEEK; (iii) generating, maintaining, and updating Respondents’ FDA Master File(s) in accordance with standard practice and regulatory requirements; (iv) providing Respondents’ data, test results, or other information in response to questions or requests from the FDA or any other regulatory body regarding Respondents’ PEEK; (v) providing technical support associated with using Respondents’ PEEK in a Customer Product; (vi) examining, identifying, and developing solutions related to any problems or complaints associated with the application to or performance of Respondents’ PEEK; and (vii)

Decision and Order

providing information to enable Dual Sourcing of PEEK.

- Q. “FDA” means the U.S. Food and Drug Administration.
- R. “Jointly Developed Product” means a new Customer Product containing PEEK that is developed jointly by Respondents and the Customer, the development of which resulted from a contribution of significant capital, intellectual property rights, labor, or other things of value by both Respondents and the Customer.
- S. “Legacy Contract” means any agreement or contract for the sale and purchase of Respondents’ PEEK in effect as of February 1, 2016, and any subsequent renewal or extension of the agreement or contract, so long as: (i) the term of such renewal or extension does not extend beyond one (1) year after this Order is issued and (ii) such renewal or extension is terminable by the Customer upon thirty (30) days’ notice.
- T. “Mutual Exclusivity” means an agreement in writing and executed by both Respondent(s) and the Customer that, for a specified and concurrent period of time, (i) a Customer purchases or uses only Respondents’ PEEK in a specified Custom Component or specified Jointly Developed Product; and (ii) Respondents do not manufacture, market, sell, or offer to sell the specified Custom Component or specified Jointly Developed Product other than to such Customer.
- U. “New Contract” means any agreement or contract for the sale and purchase of Respondents’ PEEK that is entered into after February 1, 2016.
- V. “PEEK” means polyetheretherketone of any grade or form (including, but not limited to, granules, rods, near net shapes, and components) used or intended for continuous or discontinuous use in a medical device, implant, medical instrument, or similar item intended

Decision and Order

for use inside of or in contact with a human body for longer than 24 hours.

- W. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or governmental entity, and any subsidiary, division, group, or affiliate thereof.
- X. “Product Support” means any service, assistance, or other support provided by Respondents to a Customer, including but not limited to support related to (i) a Customer’s regulatory filings involving Respondents’ PEEK; (ii) technical support related to the performance of Respondents’ PEEK; or (iii) the qualification or validation process associated with using Respondents’ PEEK in a Customer Product.
- Y. “Respondents’ PEEK” means any PEEK manufactured, marketed, or sold by the Respondents.
- Z. “Sales Term” means the retail or wholesale price, resale price, purchase price, price list, credit term, delivery term, service term, including but not limited to any price reduction, rebate, promotional assistance, or other incentive that provides pecuniary value to a Customer, or any other contract term defining, setting forth, or relating to the money or compensation paid by a Customer to Respondents, or the service, delivery, credit, or other terms provided by Respondents to a Customer, in connection with the purchase or sale of any of Respondents’ PEEK.
- AA. “Unit Payments” mean any payments owed to Respondents that are calculated based on the number of units of Customer Products sold or manufactured by or on behalf of the Customer.

Decision and Order

II.

IT IS FURTHER ORDERED that, acting directly or indirectly, or through any corporate or other device, in or affecting commerce, as “commerce” is defined by the Federal Trade Commission Act, in connection with the development, production, manufacture, marketing, promotion, purchase or sale of PEEK:

- A. Respondents shall cease and desist from inviting, entering into, implementing, continuing, enforcing, or attempting thereto, any condition, policy, practice, agreement, contract, contract term, or understanding or any other requirement that has the effect of achieving Exclusivity with a Customer. Examples of practices prohibited under this Paragraph include but are not limited to:
1. Requiring a Customer to purchase from Respondents all of the Customer’s PEEK requirements;
 2. Requiring a Customer to purchase from Respondents all of the Customer’s PEEK requirements for a particular category or group of Customer Products;
 3. Requiring a Customer to purchase from Respondents all of the Customer’s PEEK requirements for a particular Customer Product, including but not limited to:
 - a. Requiring a Customer to purchase from Respondents all of the Customer’s PEEK requirements for any Customer Product for which Respondents have granted the Customer a right to reference one or more of Respondents’ FDA Master Files during FDA review and clearance of the Customer Product; or

Decision and Order

- b. Requiring a Customer to purchase from Respondents all of the Customer's PEEK requirements for any Customer Product for which the Customer obtained FDA clearance using Respondents' PEEK;
4. Conditioning the availability or applicability of a flat or lump sum payment of monies or any other item(s) of pecuniary value from Respondents (including but not limited to Sales Terms or Product Support) on Exclusivity;
5. Conditioning the sale or availability of one type of PEEK on a Customer's commitment to purchase all of its requirements for another type of PEEK;
6. Conditioning the availability of Sales Terms or Product Support on a Customer not testing or seeking FDA clearance for any Customer Product using Competing PEEK, or otherwise preventing or impeding a Customer from testing or seeking FDA clearance for any Customer Product using Competing PEEK;
7. Charging Unit Payments on units of Customer Products not made with Respondents' PEEK; and
8. Prohibiting, restraining, limiting or impeding the ability of a Customer to Dual Source any Customer Product, including by:
 - a. requiring a Customer to reference Respondents' brand name or trademark in the Customer's labeling and marketing materials (except as required by law);
 - b. restricting the amount of Respondents' PEEK that a Customer is allowed to purchase and maintain in its inventory; or

Decision and Order

- c. requiring that a Customer return Respondents' PEEK that is purchased but not already incorporated into a Customer Product after expiration of a contract or other agreement with the Customer.
- B. Respondents shall cease and desist from discriminating against, penalizing, or otherwise retaliating against any Customer for the reason, in whole or in part, that the Customer engages in, or intends to engage in, the research, development, testing, manufacture, production, distribution, purchase, marketing, promotion, or sale of any Customer Product using a Competing PEEK, or otherwise refuses to enter into or continue any condition, agreement, contract, understanding, or other requirement that imposes Exclusivity. Examples of practices prohibited under this Paragraph include but are not limited to the following, when the result, in whole or in part, of prohibited discrimination or retaliation for use of Competing PEEK or refusal to accede to Exclusivity:
1. Terminating, suspending, delaying, or threatening or proposing thereto, sales of Respondents' PEEK to the Customer, either generally or with respect to particular forms or grades of PEEK;
 2. Denying, or threatening or proposing to deny, the Customer access to Respondents' FDA Master File;
 3. Auditing the Customer's purchases or sales of Competing PEEK;
 4. Withdrawing or modifying, or threatening or proposing thereto, favorable Sales Terms or Product Support to the Customer;
 5. Providing, or threatening or proposing thereto, less favorable Sales Terms or Product Support to the Customer;

Decision and Order

6. Withholding from the Customer any form or grade of Respondents' PEEK;
7. Refusing to deal with the Customer on terms and conditions generally available to other Customers; and
8. Notwithstanding the existence or non-existence of any severability or other provisions in Respondents' agreement(s) or contract(s) with any Customer(s), terminating, suspending, or requiring renegotiation of any term of any agreement or contract for the purchase and sale of Respondents' PEEK, as a result of the Exclusivity terms or other terms inconsistent with this Order being waived, invalid, illegal, or unenforceable.

For the avoidance of doubt, it shall not constitute, in and of itself, a violation of this Order for Respondents to engage in the conduct described in Paragraph II.B(1-7) above, when such conduct results from independent and verifiable business reasons unrelated to a Customer's use of Competing PEEK or refusal to accede to Exclusivity.

- C. As to any New Contract, Respondents shall not invite, enter into, implement, enforce, or attempt thereto, any condition, policy, practice, agreement, contract, contract term, understanding, or any other requirement that:
 1. Requires a Customer to purchase or use minimum amounts (by units, revenue, product group, Customer Product, proportion, or any other measure) of Respondents' PEEK;
 2. Conditions any Sales Term, Product Support, or the availability of a particular type of PEEK on the Customer purchasing or using Respondents' PEEK for a specified proportion or percentage of the Customer's requirements for all Customer

Decision and Order

Products, for a group of Customer Products, or for a particular Customer Product; or

3. Provides a retroactive discount as a flat or lump-sum payment of monies (or any other item(s) of pecuniary value) if the Customer's sales or purchases of Respondents' PEEK reach a specified threshold (in units, revenues, or any other measure), or otherwise reduces the price of one unit of Respondents' PEEK because of the purchase or sale of an additional unit. For example, Respondents may not offer or provide a discount of X% on all Respondents' PEEK if sales exceed Y kilograms. For the avoidance of doubt, Respondents may offer a discount that is volume-based, above average variable cost, and not retroactive, *i.e.*, a discount of X% on those sales in excess of Y kilograms.

Provided, however, that it shall not be a violation of this Paragraph II.C for Respondents to provide discounts, rebates, or other price or non-price incentives to purchase Respondents' PEEK that are designed to meet competition, if Respondents determine in good faith that one or more Competing PEEK Suppliers are offering terms of sale for Competing PEEK that Respondents need to match in order to win contested business. For the avoidance of doubt, under no circumstances may Respondents tie any such incentives to Exclusivity.

- D. Notwithstanding any other provision of this Order, it shall not constitute a violation of this Order for Respondents to condition the provision of Extraordinary Support for a Customer Product or Customer Products on a requirement that a Customer purchase or use Respondents' PEEK for a specified volume or percentage of the Customer's annual PEEK requirements for the Customer Product(s) receiving the Extraordinary Support ("minimum purchase requirement"), so long as:

Decision and Order

1. the minimum purchase requirement is no more than 30% of the Customer's PEEK requirements (in units, revenues, or any other measure, over any period of time) for the identified Customer Product(s) that receive(s) the Extraordinary Support; and
 2. the minimum purchase requirement period for any Customer Product for which Extraordinary Support is provided shall not extend beyond three (3) years in length after the date of FDA approval for sale of that Customer Product(s).
- E. Notwithstanding any other provision of this Order, it shall not constitute a violation of this Order for Respondents to maintain or enter into a contract or agreement with a Customer providing for Mutual Exclusivity (i) for the research, development, manufacture, marketing, or sale of a Jointly Developed Product, or (ii) for the sale of a Custom Component, provided that:
1. the Mutual Exclusivity requirement applies only to the Jointly Developed Product or the Custom Component, as applicable, and is not tied to the availability of other products containing PEEK or other forms, grades, or types of PEEK;
 2. for any Jointly Developed Product, the Mutual Exclusivity term does not extend beyond five (5) years in length after the date of the first FDA approval for sale of the Jointly Developed Product;
 3. for any Custom Component, the Mutual Exclusivity term does not extend beyond three (3) years from (i) the date of first FDA approval for sale of the Customer Product(s) within which the Custom Component is incorporated, or (ii) if the Custom Component is incorporated into a Customer Product previously approved by the FDA, the first commercial sale of the Custom

Decision and Order

Component following completion of the validation master plan; and

4. Respondents' sales allowed under this Paragraph II.E do not exceed thirty (30) percent of all PEEK sales by Respondents in any twelve-month period, as measured either in units or in revenues.

F. Notwithstanding any other provision of this Order, if:

1. Respondents timely deliver the Order and Exhibits B and C to a Customer with an applicable Legacy Contract as required by Paragraph III(G); and
2. the Customer has not indicated that it will comply with the terms of Exhibit C by counter-signing and delivering Exhibit C to Respondents,

it shall not constitute a violation of this Order for Respondents to (i) enforce existing Exclusivity terms in a Legacy Contract, but only as applied to Customer Products for which the Customer has made a submission for regulatory clearance as of the date this Order is issued, or (ii) enforce terms under a Legacy Contract that prohibit Dual Sourcing of any Customer Product.

Provided, however, that as to any Customer that has counter-signed and delivered Exhibit C to Respondents, Respondents shall submit to the Commission written notice of any communication from any Respondent to the Customer that the Customer has breached the terms set forth in Exhibit C. Respondents shall submit any such notice to the Commission at least sixty (60) days prior to exercising any right of termination resulting from the alleged breach, during which time the Customer shall be given the opportunity to cure the alleged breach.

Decision and Order

III.

IT IS FURTHER ORDERED that Respondents shall design, maintain, and operate an Antitrust Compliance Program that sets forth the policies and procedures Respondents have implemented to comply with this Order and with the Antitrust Laws. So long as Respondents are under common ownership, they may operate under a single Antitrust Compliance Program. This program shall include, but not be limited to:

- A. Respondents' designation and retention for the duration of the Order of an antitrust compliance officer or director to supervise the design, maintenance, and operation of this program;
- B. Training regarding Respondents' obligations under this Order and the Antitrust Laws for Respondents' Executive and Sales Staff to occur:
 - 1. Within thirty (30) days after this Order becomes final, or for any subsequently hired Executive and Sales Staff, within thirty (30) days of their employment start date; and
 - 2. At least annually to all Executive and Sales Staff of Respondents.
- C. Policies and procedures for employees and representatives of Respondents to ask questions about, and report violations of, this Order and the Antitrust Laws confidentially and without fear of retaliation of any kind;
- D. Policies and procedures for disciplining employees and representatives of Respondents for failure to comply with this Order and the Antitrust Laws;
- E. The retention of documents and records sufficient to record Respondents' compliance with its obligations under this Paragraph III of this Order, including but not limited to records showing that employees and

Decision and Order

representatives of Respondents have received all trainings required under this Order during the preceding two (2) years;

- F. Distribution of a copy of this Order and Exhibit A to this Order to all Executive and Sales Staff:
1. Within thirty (30) days of the date this Order is issued;
 2. Annually within thirty (30) days of the anniversary of the date this Order is issued until the Order terminates; and
 3. Within thirty (30) days of any Person first becoming a member of Executive and Sales Staff.
- G. Within ten (10) days of the date this Order is issued, delivery to each Customer that has a current contract with any Respondent, of a copy of: (1) this Order; and (2) as applicable, either: (a) for a Customer with a contract that includes Exclusivity terms, Exhibits B and C; or (b) for a Customer with a contract that does not include Exclusivity terms, Exhibit D. Delivery under this Paragraph III.G shall be made (i) to the Customer's President, CEO, chief legal counsel, or senior executive overseeing PEEK purchasing; and (ii) to Respondents' primary contact with the Customer for contract negotiations.

IV.**IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the date this Order is issued, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the it has complied, is complying, and will comply with this Order. So long as Respondents are under common ownership, their reports may be filed jointly. For the

Decision and Order

period covered by this report, the reports shall include, but not be limited to:

1. The name, title, business address, e-mail address, and business telephone number of the officer(s) or director(s) designated by each Respondent to design, maintain, and operate its Antitrust Compliance Program; and
 2. For each Customer to whom Respondents sent Exhibits B and C or Exhibit D, as applicable, provide the following information: name, address, telephone number, addressee(s), date(s) of delivery, and identification of whether the Customer received Exhibits B and C or Exhibit D.
- B. Ninety (90) days after the date this Order is issued, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it has complied, is complying, and will comply with this Order. So long as Respondents are under common ownership, their reports may be filed jointly. For the period covered by this report, the reports shall include, but not be limited to:
1. The name, title, business address, e-mail address, and business telephone number of the officer(s) or director(s) designated by each Respondent to design, maintain, and operate its Antitrust Compliance Program; and
 2. For each Customer to whom Respondents sent Exhibits B and C, provide the following information: name, address, telephone number, addressee(s), date(s) of delivery, and whether such Customer has returned a signed copy of Exhibit C.
- C. One (1) year after the date this Order is issued, and annually for the following four (4) years on the anniversary of the date this Order is issued, as well as

Decision and Order

at any other such times as the Commission may require, each Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order. So long as Respondents are under common ownership, their reports may be filed jointly. For the periods covered by these reports, these reports shall include, but not be limited to:

1. The name, title, business address, e-mail address, and business telephone number of the officer(s) or director(s) designated by Respondents to design, maintain, and operate Respondents' Antitrust Compliance Program; and
2. For each Customer to whom Respondents sent Exhibits B and C, the following information: name, address, telephone number, addressee(s), and date(s) of delivery, and whether such customer has returned a signed copy of Exhibit C.
3. For any contract or agreement permitted under Paragraph II.E of this Order that was not included in a prior written report, the following information: Customer with whom the contract or agreement was entered, date the contract or agreement was entered, term of the contract or agreement, a brief description of the Jointly Developed Product or Custom Component that is the subject of the contract or agreement, a brief description Respondents' contributions or investments, and the nature and scope of exclusivity terms.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of a Respondent;

Decision and Order

- B. Any proposed acquisition, merger or consolidation of a Respondent; or
- C. Any other change in any Respondent, including but not limited to, assignment, the creation or dissolution of subsidiaries, or if such change may affect compliance obligations arising out of this Order.

VI.

IT IS FURTHER ORDERED that for the purpose of determining or securing compliance with this order, upon written request, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of any Respondent relating to any matters contained in this Order, which copying services shall be provided by Respondents at the request of the authorized representative(s) of the Commission and at the expense of Respondents; and
- B. Upon five (5) days' notice to a Respondent and without restraint or interference from Respondents, to interview officers, directors, or employees of any Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on July 13, 2036.

By the Commission.

Decision and Order

Exhibit A**EXHIBIT A**
[Internal Notice]

The Federal Trade Commission ("FTC") has been investigating various practices used by Victrex plc, Invibio, Inc., and Invibio Limited (hereinafter collectively referred to as "Invibio") in the marketing and sale of implant- and medical-grade polyetheretherketone ("PEEK"). The purpose of the FTC's investigation has been to determine if any of those practices violate United States antitrust laws.

Invibio does not believe that its past or present practices violate any state or federal laws. However, to end the investigation quickly, and without admitting to any violations of any law, Invibio has signed a consent agreement with the FTC agreeing that the FTC can issue and Invibio will be bound by a Decision and Order ("Order") issued by the FTC.

It is very important to Invibio that all of its executives, employees and contractors understand and comply with the Order. We are providing this notice as a first step to help you do that by telling you about the Order, describing a few of its most important terms, and telling you how you can learn more about the Order and get answers to any questions you may have about it.

Generally, the Order prohibits Invibio and its employees from, directly or indirectly, formally or informally, entering agreements or engaging in practices that require its customers to purchase PEEK exclusively from Invibio. The terms of the Order affect how Invibio can offer discounts, product development support, and regulatory support to its customers. The Order prohibits Invibio from using its pricing and marketing policies and programs to retaliate against or punish customers who refuse to purchase Invibio's PEEK exclusively.

Invibio management wants to help you better understand Invibio's rights and obligations under the Order. Therefore, as required by the Order, Invibio has appointed [name and title] to oversee a program to train Invibio's executives and sales staff on the Order and the antitrust laws. You will be contacted soon to schedule your training, which must be conducted by [insert date 30 days from the date the Order is issued]. In the meantime, if you have any questions at any time about the Order or your training, please contact [identify contact person] at [e-mail or telephone].

Decision and Order

Exhibit B**EXHIBIT B***[Letter to Customers with Exclusivity Terms]*

[Invibio letterhead]

[Name and address of customer]

Dear [name of customer]:

The Federal Trade Commission ("FTC") has been investigating various practices used by Victrex plc, Invibio, Inc., and Invibio Limited (hereinafter collectively referred to as "Invibio") in the marketing and sale of implant- and medical-grade polyetheretherketone ("PEEK"). The purpose of the FTC's investigation has been to determine if any of those practices violate United States antitrust laws.

Invibio does not believe that its past or present practices violate any state or federal laws. However, to end the investigation quickly, and without admitting to any violations of any law, Invibio has signed a consent agreement with the FTC agreeing that the FTC can issue and Invibio will be bound by a Decision and Order ("Order") issued by the FTC.

Generally, the Order prohibits Invibio, directly or indirectly, formally or informally, from requiring its customers to purchase PEEK exclusively from Invibio for any customer product or group of products, subject to certain narrow exceptions set forth in the Order. The Order also prohibits Invibio from retaliating against or penalizing customers who use an alternative source of PEEK.

Accordingly, notwithstanding any provision to the contrary in the supply agreement between you and Invibio, you may use an alternative source of PEEK as the sole source of PEEK for any product that you submit to the FDA for clearance after [date Order is issued]. In addition, *if you sign Attachment 1 to this letter and return it to Invibio at the name and address indicated on Attachment 1*, you may:

1. switch to an alternative PEEK supplier for any existing product that you currently source with Invibio PEEK; and
2. Dual Source PEEK for any of your products.

The term "Dual Source" is defined in the Order and in Attachment 1 to this letter.

A copy of the Order is enclosed. You also may read and download a copy of the Order from the FTC at its web site at [web link to case on FTC website]. Invibio's obligations under the Order are set out in Paragraph II of the Order, beginning on page 6. Capitalized terms used in the Order are defined in Paragraph I of the Order, which begins on page 2.

Decision and Order

If you have concerns in the future about whether Invibio is complying with its obligations under the Order, Invibio invites you to contact us, the FTC, or both. You may contact Invibio through the sales staff with whom you do business, or contact our corporate offices directly by phoning or e-mailing [name] at [phone number and e-mail address]. Alternatively or additionally, you may contact the FTC directly to express your concerns by phoning or e-mailing [name] at [phone number and e-mail address].

Thank you again for your continued support and the confidence you have shown for Invibio products.

Sincerely,

[name and title]

Encl.

Decision and Order

Exhibit C**EXHIBIT C**

[Attachment 1 to Letter to Customers with Exclusivity Terms]

_____ (“Customer”) hereby agrees to comply with the terms set forth below modifying all agreements, including supply agreements between Customer and Invibio. These terms shall remain in effect for so long as Customer has in its possession Invibio PEEK purchased under agreements between Customer and Invibio that has not been integrated into Customer’s products.

Whether or not Customer agrees to the terms below, Invibio has waived any term in the current supply agreement between Customer and Invibio that could otherwise be construed to prevent Customer from using a Competing PEEK as its sole source of PEEK for any Customer product that Customer submits to the FDA for clearance after [date Order is issued].

In exchange for Customer agreeing to the terms set forth below, when Customer delivers a signed copy of this Exhibit C, which shall become material terms to Customer’s existing contract, to Invibio at the address below, Invibio will waive any term in the supply agreement between Customer and Invibio that could otherwise be construed to prevent Customer from (a) for any existing Customer product, switching to a Competing PEEK; or (b) for any existing or new Customer product, Dual Sourcing PEEK.

1. Customer shall not Commingle PEEK.
2. Customer shall maintain or have maintained, for the expected life of the applicable Customer product, records sufficient to identify the source of PEEK used in each Batch of any Customer product (a) that is Dual Sourced; or (b) as to which Customer has switched from using Invibio PEEK to using a Competing PEEK.
3. As to any Customer product (a) that is Dual Sourced; or (b) as to which Customer has switched from Invibio PEEK to a Competing PEEK, Customer shall give prompt written notice after Customer becomes aware of any adverse facts or issues relating to the safety or efficacy of Invibio PEEK in a Customer product. Further, upon request by Invibio, Customer shall promptly inform Invibio whether a Customer product subject to a publicly disclosed recall contains Invibio PEEK.

“Batch” means a specific quantity of medical device, implant, medical instrument, or similar item intended for use inside of or in contact with a human body, which (i) is intended to have uniform character and quality, within specified limits; and (ii) is produced according to a single manufacturing order during the same cycle of manufacture.

“Commingle” or “Commingling” means the use or mixing of Invibio PEEK and Competing PEEK within a single unit of a Customer product. For the avoidance of doubt, Customer may satisfy the no-commingling requirement in Paragraph 1 above by

Decision and Order

using only one source of PEEK in a single Batch.

“Competing PEEK” means any PEEK manufactured or sold by any entity other than Invibio.

“Dual Source” or “Dual Sourcing” means selling, offering for sale, or distributing two or more units of a Customer product with the same product name and part number, some of which are manufactured from Invibio PEEK and some of which are manufactured from Competing PEEK.

“PEEK” means polyetheretherketone of any grade or form (including, but not limited to, granules, rods, near net shapes, and components) used or intended for continuous or discontinuous use in a medical device, implant, medical instrument, or similar item intended for use inside of or in contact with a human body for longer than 24 hours.

FOR INVIBIO:

Signature: _____

Printed Name: _____

Title: _____

Date: _____

FOR CUSTOMER:

Signature: _____

Printed Name: _____

Title: _____

Date: _____

AFTER SIGNING, DELIVER TO:

[NAME]

[TITLE]

[ADDRESS]

Decision and Order

Exhibit D**EXHIBIT D***[Letter to Customers with No Exclusivity Terms]***[Invibio letterhead]****[Name and address of customer]**Dear **[name of customer]**:

The Federal Trade Commission (“FTC”) has been investigating various practices used by Victrex plc, Invibio, Inc., and Invibio Limited (hereinafter collectively referred to as “Invibio”) in the marketing and sale of implant- and medical-grade polyetheretherketone (“PEEK”). The purpose of the FTC’s investigation has been to determine if any of those practices violate United States antitrust laws.

Invibio does not believe that its past or present practices violate any state or federal laws. However, to end the investigation quickly, and without admitting to any violations of any law, Invibio has signed a consent agreement with the FTC agreeing that the FTC can issue and Invibio will be bound by a Decision and Order (“Order”) issued by the FTC.

Generally, the Order prohibits Invibio, directly or indirectly, formally or informally, from requiring its customers to purchase PEEK exclusively from Invibio for any customer product or group of products, subject to certain narrow exceptions set forth in the Order. The Order also prohibits Invibio from retaliating against or penalizing customers who use an alternative source of PEEK.

A copy of the Order is enclosed. You also may read and download a copy of the Order from the FTC at its web site at **[web link to case on FTC website]**. Invibio’s obligations under the Order are set out in Paragraph II of the Order, beginning on page 6. Capitalized terms used in the Order are defined in Paragraph I of the Order, which begins on page 2.

If you have concerns in the future about whether Invibio is complying with its obligations under the Order, Invibio invites you to contact us, the FTC, or both. You may contact Invibio through the sales staff with whom you do business, or contact our corporate offices directly by phoning or e-mailing **[name]** at **[phone number and e-mail address]**. Alternatively or additionally, you may contact the FTC directly to express your concerns by phoning or e-mailing **[name]** at **[phone number and e-mail address]**.

Thank you again for your continued support and the confidence you have shown for Invibio products.

Sincerely,

[name and title]

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

I. Introduction

The Federal Trade Commission has accepted, subject to final approval, an Agreement Containing Consent Order with Victrex plc and its wholly owned subsidiaries Invibio Limited and Invibio, Inc. (collectively, “Invibio”). Invibio makes and sells implant-grade PEEK, a high-performance polymer contained in implantable devices used in spinal interbody fusion and other medical procedures. The proposed consent order seeks to address allegations that Invibio used exclusive supply contracts to maintain its monopoly power in the market for implant-grade PEEK, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

The proposed order contained in the consent agreement requires Invibio to cease and desist from enforcing most exclusivity terms in current supply contracts and generally prohibits Invibio from requiring exclusivity in future contracts. The order also prevents Invibio from adopting other mechanisms, such as market-share discounts or retroactive volume discounts, to maintain its monopoly power.

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the consent agreement and the comments received and will decide whether it should withdraw from the consent agreement and take appropriate action or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint, the consent agreement, or the proposed order, or to modify their terms in any way. The consent agreement is for settlement purposes only and does not constitute an admission by Invibio that the law has been violated as alleged in the complaint or that the facts alleged in the complaint, other than jurisdictional facts, are true.

Analysis to Aid Public Comment

II. The Complaint

The complaint makes the following allegations.

A. Industry Background

Implant-grade PEEK has properties, such as elasticity, machinability, and radiolucency, that are distinct from other materials used in implantable medical devices, such as titanium and bone. These properties make PEEK especially suitable for many types of implantable medical devices, particularly spinal interbody fusion devices. Invibio was the first company to develop and sell implant-grade PEEK. The United States Food and Drug Administration (“FDA”) first cleared a medical device containing Invibio PEEK in 1999. Upon introducing implant-grade PEEK, Invibio sold the product to its medical device maker customers under long-term supply contracts, many of which included exclusivity requirements.

For a number of years, Invibio was the only supplier of implant-grade PEEK. In the late 2000s, however, first Solvay Specialty Polymers LLC (“Solvay”) and then Evonik Corporation (“Evonik”) took steps to enter the market. The FDA cleared the first spinal implant device containing Solvay PEEK in 2010, and the first one containing Evonik PEEK in 2013.

B. Invibio’s Use of Exclusivity Terms to Impede Competitors

Invibio responded to Solvay’s and Evonik’s entry by tightening and expanding the scope of exclusivity provisions in its supply contracts with medical device makers. Invibio did this to impede Solvay and Evonik from developing into effective rivals. Invibio knew that if Solvay and Evonik could gain reputation and experience, in particular, by developing supply relationships with leading medical device makers, this would validate their status as PEEK suppliers with other potential PEEK buyers and ultimately lead to significant price competition—painful for Invibio but beneficial to medical device makers.

Analysis to Aid Public Comment

Invibio extracted exclusivity terms from customers both by threatening to withhold critical supply or support services and by offering minor inducements. For example, Invibio threatened to withhold access to new brands of its PEEK and to Invibio's FDA master file if a customer declined to purchase exclusively from Invibio. Where necessary, Invibio offered small price discounts in exchange for exclusivity.

Due to Invibio's efforts, nearly all medical device makers that purchase PEEK from Invibio do so under contracts that impose some form of exclusivity. Although precise exclusivity terms vary, they generally take one of three forms: (1) requiring the use of Invibio PEEK for all PEEK-containing devices; (2) requiring the use of Invibio PEEK for a broad category of PEEK-containing devices; or (3) requiring the use of Invibio PEEK for a list of identified PEEK-containing devices. Even where exclusivity terms apply at the device level, *i.e.*, to a list of specified devices, the foreclosure effect is substantial: the list often includes nearly every device in the customer's portfolio and the customer thus cannot source substantial volumes of PEEK from Invibio's competitors. Taken together, Invibio's exclusive contracts foreclose a substantial majority of PEEK sales from Invibio's rivals.

C. Invibio's Monopoly Power

Both direct and indirect evidence demonstrate that Invibio has monopoly power in the market for implant-grade PEEK. Invibio has priced its PEEK substantially higher than competing versions of PEEK, without ceding material market share, and has impeded competitors through its exclusive contracts. In addition, Invibio has consistently held an over-90% share of a relevant market with substantial entry barriers, which indirectly evidences its monopoly power. PEEK has distinctive properties from other materials used in spinal and other implants. Physician preferences typically drive the choice of materials used in an implant, and these preferences largely reflect material properties rather than price. Other materials are therefore not sufficiently close substitutes to prevent a monopolist PEEK supplier from profitably raising prices. The relevant product market is therefore no broader than implant-

Analysis to Aid Public Comment

grade PEEK, *i.e.*, PEEK that has been used in at least one device cleared by the FDA.

D. Competitive Impact of Invibio's Conduct

Through its exclusive contracting strategy, Invibio has maintained its monopoly power and harmed competition by marginalizing its competitors. In addition, Invibio's exclusive contracts have prevented its customers from exercising a meaningful choice between implant-grade PEEK suppliers and from enjoying the full benefits of competition, including price competition.

Invibio's exclusivity terms have prevented Solvay and Evonik from achieving a significant volume of implant-grade PEEK sales, notwithstanding their offering of significantly lower prices. Invibio has also excluded Solvay and Evonik from forming supply relationships with key medical device makers. As a result, Solvay and Evonik have been unable to achieve significant market share and have consistently missed sales targets. There is a significant risk that continued enforcement of Invibio's exclusive contracts would preclude Solvay and Evonik from achieving sufficient returns to justify future investments, including in innovative technologies. Without those investments, the firms would be even less effective competitors in the future.

Additionally, Invibio's exclusive contracts have deprived medical device makers of the opportunity to make a meaningful choice among competing suppliers and thereby enjoy the benefits of price, innovation, and quality competition. Even medical device makers that would not have switched to a competitor of Invibio would have benefited from a more competitive market. In addition, many medical device makers prefer to have more than one source of PEEK in order to mitigate risk and for other commercial benefits. Absent Invibio's exclusivity requirements, a significant number of device makers would contract with Solvay or Evonik to secure lower-priced PEEK and additional or alternate sources of supply. However, medical device makers locked into long-term exclusive contracts have been precluded from pursuing their preferred procurement strategy.

Analysis to Aid Public Comment

III. Legal Analysis

Monopolization is among the “unfair methods of competition” prohibited by Section 5 of the FTC Act.¹ A firm unlawfully maintains monopoly power when it “engage[s] in anti-competitive conduct that reasonably appears to be a significant contribution to maintaining monopoly power.”²

Exclusive dealing by a monopolist may be condemned when it “allows [the] monopolist to maintain its monopoly power by raising its rivals’ costs sufficiently to prevent them from growing into effective competitors.”³ Of particular relevance is whether an exclusive dealing policy has “foreclose[d] competition in such a substantial share of the relevant market so as to adversely affect competition.”⁴ To be unlawful, exclusive dealing need not have foreclosed all competition from the market.⁵

1 *See, e.g., McWane, Inc. v. FTC*, 783 F.3d 814, 827 n.10 (11th Cir. 2015), *cert. denied* 577 U.S. --- (Mar. 21, 2016).

2 *McWane*, 783 F.3d at 833 (internal quotation marks and citations omitted); *accord United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*) (citing 3 PHILIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 651c, at 78 (1996)).

3 *McWane*, 783 F.3d at 832 (citing XI PHILIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1804a, at 116–17 (2011)); *accord Dentsply*, 399 F.3d at 191; *Microsoft*, 253 F.3d at 69–71; *see also In re McWane, Inc.*, No. 9351, 2014 WL 556261 at *19, *28 (F.T.C. Jan. 30, 2014) (exclusive dealing by a monopolist may be unlawful where it “impair[s] the ability of rivals to grow into effective competitors that might erode the firm’s dominant position” or “denie[s] its customers the ability to make a meaningful choice”) (internal quotation marks and citations omitted), *aff’d, McWane, Inc. v. FTC*, 783 F.3d 814 (11th Cir. 2015).

4 *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 271 (3d Cir. 2012); *see also Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961) (“In practical application, even though a contract is found to be an exclusive-dealing arrangement, it does not violate the section unless the court believes it probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected.”).

5 *Dentsply*, 399 F.3d at 191.

Analysis to Aid Public Comment

The factual allegations in the complaint support a finding of monopolization. Invibio’s exclusivity strategy has not prevented entry entirely. But its exclusivity terms—whether full exclusivity terms or terms that apply at the product or product category level across a wide range of products—have foreclosed its rivals from a substantial portion of available sales opportunities in the relevant market and prevented those rivals from competing effectively. Among the foreclosed sales opportunities are key customers that would validate the reputations of Solvay and Evonik as legitimate rivals of Invibio, notwithstanding their more recent entry into the market. Invibio’s exclusionary conduct has also reduced incentives to innovate and prevented PEEK consumers from exercising a meaningful choice among suppliers.

A monopolist may rebut a showing of competitive harm by demonstrating that the challenged conduct is reasonably necessary to achieve a procompetitive benefit.⁶ Any proffered justification, if proven, must be balanced against the harm caused by the challenged conduct.⁷ Here, no procompetitive efficiencies justify the scope of Invibio’s exclusionary and anticompetitive conduct. Any procompetitive benefit could have been achieved through less restrictive means.

IV. The Proposed Order

The proposed order remedies Invibio’s anticompetitive conduct and imposes certain fencing-in requirements in order to prevent *de facto* exclusivity between Invibio and its customers.

Paragraph I of the proposed order defines the key terms used throughout the rest of the order.

Paragraph II addresses the core of Invibio’s anticompetitive conduct. Paragraph II.A prohibits Invibio from adopting or implementing any agreement or policy that results in “exclusivity” with customers. “Exclusivity” is defined to include any limit or prohibition by Invibio on its customers dealing with a competing implant-grade PEEK supplier or any requirement by

⁶ See, e.g., *Microsoft*, 253 F.3d at 59.

⁷ *Id.*

Analysis to Aid Public Comment

Invibio that a customer use only Invibio PEEK in (1) all of its devices, (2) in any group of devices, or (3) in any one device. The order thus applies to all forms of exclusivity that appear in Invibio's contracts.

Under Paragraph II.A, Invibio may not require exclusivity for any new contract, except in the limited circumstances set forth in Paragraph II.E (described below). Further, Invibio may not enforce exclusivity terms in an existing contract with any medical device maker that chooses to use an alternate implant-grade PEEK supplier instead of Invibio for any or all future devices. In addition, Paragraph II.A, in conjunction with Paragraph II.F (described below), prohibits Invibio from enforcing provisions in an existing contract that would prevent a medical device maker from using other suppliers of implant-grade PEEK for any device, or from switching suppliers for any current device, provided that the device maker agrees to the tracking requirements contained in Exhibit C of the order. The tracking requirements are designed to accommodate Invibio's concerns, related to potential product liability actions, about maintaining the ability to identify devices that use Invibio PEEK and are generally consistent with industry practice.

Paragraph II.B prohibits Invibio from retaliating against customers for using or preparing to use an alternate PEEK supplier. Prohibited retaliation includes cutting off PEEK sales or withholding access to regulatory support.

Paragraph II.C contains provisions designed to prevent *de facto* exclusivity in the future. For all new contracts, Invibio may not require minimum purchases, either as a condition of sale or as a condition for receiving important contract terms or services, other than as described in Paragraph II.D. Invibio may not offer volume discounts that are applied retroactively once a customer reaches a specified threshold. For example, Invibio may provide a discount on sales beyond 100 units but it may not lower the price of the first 99 units if and when the customer buys the 100th unit. Invibio may, however, provide certain discounts and non-price incentives designed to meet competition.

Analysis to Aid Public Comment

Paragraph II.D allows Invibio to condition its provision of certain types of extraordinary support to a customer for new devices on minimum purchase requirements for three years after the date of FDA clearance for such devices, so long as the minimum purchase amounts to less than 30 percent of the customer's implant-grade PEEK requirements for the device(s) that received the support. Extraordinary support excludes routine services such as maintaining and granting access to Invibio's FDA master file.

Paragraph II.E contains provisions designed to allow for procompetitive collaboration with a customer and preserve Invibio's incentives to innovate, including through investments that may be susceptible to free-riding by competitors. The paragraph allows Invibio to enter into a mutually exclusive contract with a customer when Invibio and the customer have engaged in the joint development of a new product that has required the contribution of significant capital, intellectual property rights, or labor by both Invibio and the customer, or when a customer asks that Invibio manufacture a custom component to the customer's specifications. Current PEEK sales subject to such contracts represent a small portion of the relevant market. Nonetheless, several limitations apply under this paragraph. The contracts must be: in writing, time-limited, applicable only to the jointly developed or custom product, and notified to the Commission. Invibio may not tie the availability of other forms, grades, or types of PEEK to a customer's willingness or agreement to enter into this type of contract. Further, sales resulting from these exclusive contracts may not account for more than 30 percent of Invibio's total annual sales.

Paragraph II.F allows Invibio to maintain limited exclusivity in existing contracts if customers do not agree to certain tracking requirements. Specifically, Invibio may enforce specified product-level exclusivity terms in existing contracts if the customer does not accept the terms set forth in Exhibit C to the proposed order, thereby agreeing: (1) not to mix (commingle) PEEK from different suppliers in a single unit of a device; (2) to maintain records that identify which supplier's PEEK is used in any batch of devices that are dual-sourced; and (3) to notify Invibio in the event of an adverse event related to Invibio's PEEK. These

Analysis to Aid Public Comment

tracking requirements are generally consistent with existing industry practice.

Paragraph III requires Invibio to implement an antitrust compliance program, which includes providing notice of the order to Invibio's customers. Paragraphs IV-VI impose reporting and other compliance requirements.

The proposed order would expire in 20 years.

Complaint

IN THE MATTER OF

AMERICAN AIR LIQUIDE HOLDINGS, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

Docket No. C-4574; File No. 161 0045
Complaint, May 12, 2016 – Decision, July 15, 2016

This consent order addresses the \$13.4 billion acquisition by American Air Liquide Holdings, Inc., of certain assets of Airgas, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in various geographic markets for bulk oxygen, bulk nitrogen, bulk argon, bulk nitrous oxide, bulk liquid carbon dioxide, dry ice, and retail packaged welding gases. The consent order requires Air Liquide to divest sixteen air separation units (“ASUs”), four vertically integrated dry ice and liquid carbon dioxide plants, two separate liquid carbon dioxide plants, two nitrous oxide plants, and three retail packaged welding gas and hardgoods stores.

Participants

For the *Commission*: Jeffrey Dahnke, Jonathan. Ripa, Christine Tasso, and Sarah Wohl.

For the *Respondent*: Bryan Byrne, Cleary Gottlieb Steen & Hamilton LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent American Air Liquide Holdings, Inc. (“Air Liquide”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Airgas, Inc. (“Airgas”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect

Complaint

thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent Air Liquide is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its corporate office and principal place of business located at 9811 Katy Freeway, Suite 100, Houston, Texas 77024. Air Liquide, is an indirect wholly owned subsidiary of L'Air Liquide, S.A., a French *société anonyme*.

2. The Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. ACQUIRED COMPANY

3. Airgas is a corporation organized, existing, and doing business under, and by virtue of the laws of Delaware, with its corporate office and principal place of business located at 259 N. Radnor-Chester Road, Suite 100, Radnor, Pennsylvania 19087.

4. Airgas is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

5. Pursuant to an Agreement and Plan of Merger dated November 17, 2015, a wholly owned subsidiary of Respondent will merge with and into Airgas in a transaction valued at approximately \$13.4 billion (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

Complaint

IV. THE RELEVANT MARKETS

6. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of:

- a. bulk oxygen;
- b. bulk nitrogen;
- c. bulk argon;
- d. bulk nitrous oxide;
- e. bulk liquid carbon dioxide;
- f. dry ice; and
- g. retail packaged welding gases.

7. For purposes of this Complaint, the relevant geographic areas in which to analyze the effects of the Acquisition on the bulk oxygen and bulk nitrogen markets are:

- a. the Northeast;
- b. the Mid-Atlantic;
- c. the Southeast;
- d. Atlanta and surrounding areas;
- e. Arkansas and surrounding areas;
- f. Oklahoma and surrounding areas;
- g. Western Kentucky and surrounding areas;
- h. Chicago, Milwaukee, and surrounding areas;
- i. Western Ohio and surrounding areas; and

Complaint

j. Pittsburgh, Cleveland, and surrounding areas.

8. For purposes of this Complaint, the relevant geographic area in which to analyze the effects of the Acquisition on the bulk argon market is the United States.

9. For purposes of this Complaint, the relevant geographic area in which to analyze the effects of the Acquisition on the bulk nitrous oxide market is the United States and Canada.

10. For purposes of this Complaint, the relevant geographic areas in which to analyze the effects of the Acquisition on the bulk liquid carbon dioxide market are:

- a. Indiana, Kentucky, and surrounding areas;
- b. Mississippi and surrounding areas; and
- c. the Texas Panhandle and surrounding areas.

11. For purposes of this Complaint, the relevant geographic areas in which to analyze the effects of the Acquisition on the dry ice market are:

- a. the San Francisco Bay Area;
- b. Iowa and surrounding areas; and
- c. the Texas Panhandle and surrounding areas.

12. For purposes of this Complaint, the relevant geographic areas in which to analyze the effects of the Acquisition on the retail packaged welding gases market are:

- a. Anchorage, Alaska;
- b. Fairbanks, Alaska; and
- c. Kenai, Alaska.

Complaint

V. THE STRUCTURE OF THE MARKETS

13. Respondent Air Liquide and Airgas are two of a limited number of significant participants in each of the relevant markets for bulk oxygen, bulk nitrogen, bulk argon, bulk liquid carbon dioxide, and dry ice, and each relevant market is concentrated, as measured by the Herfindahl-Hirschman Index. The Acquisition would further increase concentration levels, resulting in Air Liquide becoming one of the largest suppliers in each relevant area.

14. Respondent Air Liquide and Airgas are the only two participants in the relevant geographic markets for bulk nitrous oxide and retail packaged welding gases. The Acquisition would result in Respondent holding a monopoly in these relevant markets.

VI. ENTRY CONDITIONS

15. New entry into the relevant markets would not occur in a timely manner sufficient to deter or counteract the likely adverse competitive effects of the Acquisition.

16. Entry into the bulk oxygen, nitrogen, and argon markets is costly, difficult, and unlikely because of, among other things, the time and cost required to construct the air separation units that produce these products. Constructing an air separation unit at a scale sufficient to be viable in the market would cost at least \$30 to \$100 million, most of which are sunk costs. Moreover, it is not economically justifiable to build an air separation unit unless a significant amount of the plant's capacity has been pre-sold prior to construction, either to an on-site customer or to customers with commitments under contract. Such pre-sale opportunities occur infrequently and unpredictably and can take several years to secure.

17. Entry into the bulk nitrous oxide market is costly, difficult, and unlikely because of, among other things, the time and cost required to construct a plant capable of producing nitrous oxide. Constructing such a plant would cost at least \$5 to \$10 million, and the demand for nitrous oxide is generally insufficient to

Complaint

justify the high costs of building a nitrous oxide plant. In addition, there are regulatory barriers to overcome due to the hazardous nature of producing nitrous oxide.

18. Entry into the bulk liquid carbon dioxide and dry ice markets would also not be likely, timely, or sufficient to deter or counteract the likely adverse competitive effects of the Acquisition. Constructing a plant capable of producing bulk liquid carbon dioxide would cost at least \$10 to \$30 million. In addition, successful entry into the bulk liquid carbon dioxide market requires access to raw carbon dioxide supply sources, which are typically unavailable due to long-term contracts with incumbent liquid carbon dioxide suppliers. For dry ice production, there are similar entry barriers. Because liquid carbon dioxide is the primary input in dry ice production, the most significant barrier to entering the market for dry ice is obtaining a liquid carbon dioxide source. If the entrant does not have its own source, it would have to secure one or enter into a supply agreement with an existing liquid carbon dioxide manufacturer. The entrant would also have to build a dry ice facility, but sales opportunities would likely be too small to justify the sunk costs associated with the required investment.

19. Entry into the retail packaged welding gases market would also not be likely, timely, or sufficient to deter or counteract the likely adverse competitive effects of the Acquisition. Currently, Air Liquide is the only entity capable of filling packaged gases in the relevant geographic markets for retail packaged welding gas, all of which are in Alaska. A new entrant would be required either to purchase bulk gases and construct a fill plant to put the gases in packaged form or to establish a supply network to transport packaged gases from a fill plant outside of Alaska to the relevant geographic markets. Because of the obstacles that must be overcome, significant market impact is unlikely to occur and could not be achieved in a timely manner.

VII. EFFECTS OF THE ACQUISITION

20. The effects of the acquisition may be to substantially lessen competition or to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended,

Complaint

15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Respondent Air Liquide and Airgas;
- b. by increasing the likelihood that Respondent Air Liquide would unilaterally exercise market power in the bulk oxygen, bulk nitrogen, bulk argon, bulk nitrous oxide, bulk liquid carbon dioxide, dry ice, and retail packaged welding gases markets in the relevant geographic areas;
- c. by enhancing the likelihood of collusion or coordinated interaction between or among the remaining firms in the bulk oxygen, bulk nitrogen, bulk argon, bulk liquid carbon dioxide, and dry ice markets in the relevant geographic areas; and
- d. by increasing the likelihood that consumers would be forced to pay higher prices for bulk oxygen, bulk nitrogen, bulk argon, bulk nitrous oxide, bulk liquid carbon dioxide, dry ice, and retail packaged welding gases in the relevant geographic areas.

VIII. VIOLATIONS CHARGED

21. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twelfth day of May, 2016, issues its Complaint against said Respondent.

By the Commission.

Decision and Order

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed merger of a wholly owned subsidiary of Respondent American Air Liquide Holdings, Inc. (“Air Liquide,” a wholly owned subsidiary of L’Air Liquide, S.A.) with and into Airgas, Inc. (“Airgas”) and Respondent having been furnished thereafter with a copy of a draft of complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement (“Consent Agreement”) containing consent orders, an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the Consent Agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure described in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following Order to Maintain Assets:

1. Respondent American Air Liquide Holdings, Inc. is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its corporate office and principal place

Order to Maintain Assets

of business located at 9811 Katy Freeway, Suite 100, Houston, Texas 77024. American Air Liquide Holdings, Inc., is an indirect wholly owned subsidiary of L'Air Liquide, S.A., a French *société anonyme*.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent and the proceeding is in the public interest.

ORDER**I.**

IT IS HEREBY ORDERED that, as used in this Order to Maintain Assets, the following definitions shall apply (to the extent any capitalized term appearing in this Order to Maintain Assets is not defined below, the term shall be defined as that term is defined in the Decision and Order contained in the Consent Agreement):

- A. "Air Liquide" means (a) American Air Liquide Holdings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns and includes its parent L'Air Liquide, S.A.; and the subsidiaries, divisions, groups, and affiliates in each case controlled by American Air Liquide Holdings, Inc. (including Airgas, Inc., after the Acquisition) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Commission" means the Federal Trade Commission.
- C. "Acquirer" means any Person that acquires any of the Gases Assets pursuant to this Order.
- D. "Acquisition" means the proposed merger described in the Agreement and Plan of Merger by and among Airgas, Inc., L'Air Liquide, S.A. and AL Acquisition Corporation, dated as of November 17, 2015.

Decision and Order

- E. “Acquisition Date” means the date the Acquisition is consummated.
- F. “Airgas” means Airgas, Inc., a corporation organized, existing, and doing business under, and by virtue of the laws of Delaware, with its corporate office and principal place of business located at 259 N. Radnor-Chester Road, Suite 100, Radnor, Pennsylvania 19087.
- G. “CO₂ Business” means the business of producing, distributing, marketing, or selling liquid CO₂ and dry ice conducted by Air Liquide prior to the Acquisition at the CO₂ and CO₂/dry ice locations identified in Appendix A of this Order to Maintain Assets.
- H. “Confidential Information” means any and all of the following information:
1. all information that is a trade secret under applicable trade secret or other law;
 2. all information concerning product specifications, data, know-how, formulae, compositions, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, software and computer software and database technologies, systems, structures, and architectures;
 3. all information concerning the relevant business (which includes historical and current financial statements, financial projections and budgets, tax returns and accountants’ materials, historical, current and projected sales, capital spending budgets and plans, business plans, strategic plans, marketing and advertising plans, publications,

Order to Maintain Assets

client and customer lists and files, contracts, the names and backgrounds of key personnel, and personnel training techniques and materials); and

4. all notes, analyses, compilations, studies, summaries, and other material to the extent containing or based, in whole or in part, upon any of the information described above;

Provided, however, that Confidential Information shall not include information that (i) was, is, or becomes generally available to the public other than as a result of a breach of this Order to Maintain Assets; (ii) was or is developed independently of and without reference to any Confidential Information; or (iii) was available, or becomes available, on a non-confidential basis from a third party not bound by a confidentiality agreement or any legal, fiduciary, or other obligation restricting disclosure.

- I. “Decision and Order” means the:
 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance and service of a final Decision and Order by the Commission; and
 2. Final Decision and Order issued by the Commission in this matter following the issuance and service of a final Decision and Order by the Commission.
- J. “Divestiture Agreement” means any agreement between Respondent (or a Divestiture Trustee) and Acquirer that receives the prior approval of the Commission to divest the Gases Assets, including all related ancillary agreements, schedules, exhibits, and attachments thereto.
- K. “Divestiture Date” means the date on which Respondent (or the Divestiture Trustee) closes on the

Decision and Order

transaction to divest any of the Gases Assets to an Acquirer.

- L. “Gases Assets” means the assets identified in Paragraph I.O. of the Decision and Order.
- M. “Gases Business” means the I&M Gases Business, CO₂ Business, and the Retail Business.
- N. “Gases Employee” means any individual (i) employed on a full-time, part-time, or contract basis at any of the Gases Locations as of and after the date of the announcement of the Acquisition or (ii) identified by agreement between Respondent and an Acquirer and made part of a Divestiture Agreement.
- O. “Gases Locations” means the locations identified on Appendix A of this Order to Maintain Assets.
- P. “I&M Gases Business” means the business of producing, refining, distributing, marketing, or selling atmospheric gases (liquid oxygen, liquid nitrogen, and liquid argon) and nitrous oxide conducted by either Air Liquide or Airgas prior to the Acquisition at their respective atmospheric gases and nitrous oxide locations identified in Appendix A of this Order.
- Q. “Person” means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture or other entity or a governmental body.
- R. “Retail Business” means the business of selling hardgoods, welding products, and gases conducted by Airgas prior to the Acquisition at the retail locations identified in Appendix A of this Order to Maintain Assets.
- S. “Third Party Consent” means any consent, assignment, license, permit, or other authorization from any Person

Order to Maintain Assets

other than Respondent that is necessary to divest or operate the Gases Assets.

II.

IT IS FURTHER ORDERED that during the time period before the Divestiture Date, Respondent shall operate the Gases Business and Gases Assets in the ordinary course of business consistent with past practices as of the date that Respondent announced the Acquisition, including but not limited to, the following responsibilities:

- A. Respondent shall maintain (i) the Gases Business and Gases Assets in substantially the same condition (except for normal wear and tear) existing at the time Respondent signs the Consent Agreement, and (ii) relations and good will with suppliers, customers, landlords, creditors, agents, and other having business relationships with the Gases Business and Gases Assets;
- B. Respondent shall provide the Gases Business with sufficient financial and other resources to (i) operate the Gases Business and Gases Assets at least at the current rate of operation and staffing and to carry out, at their scheduled pace, all business plans, sales and promotional activities in place prior to the Acquisition; (ii) perform all maintenance to, and replacements or remodeling of, the assets of the Gases Business in the ordinary course of business and in accordance with past practice and current plans; (iii) carry on such capital projects, physical plant improvements, and business plans as are already underway or planned for which all necessary regulatory and legal approvals have been obtained, including but not limited to, existing or planned renovation, remodeling, or expansion projects; and (iv) maintain the viability, competitiveness, and marketability of the Gases Business and Gases Assets.

Decision and Order

- C. Respondent shall preserve the Gases Business and Gases Assets as an ongoing business and not take any affirmative action, or fail to take any action within Respondent's control, as a result of which the viability, competitiveness, and marketability of the Gases Business and Gases Assets would be diminished.

III.

IT IS FURTHER ORDERED that no later than the Divestiture Date, Respondent shall secure all Third Party Consents; *provided, however*, that if Respondent is unable to obtain any Third Party Consent, Respondent shall (i) provide such assistance as an Acquirer may reasonably request in its efforts to obtain a comparable consent or (ii) with the acceptance of an Acquirer and the prior approval of the Commission, substitute equivalent assets or arrangements.

IV.

IT IS FURTHER ORDERED that:

- A. Until the Divestiture Date, Respondent shall staff the Gases Business and Gases Assets with sufficient employees to maintain the viability and competitiveness of the Gases Business and Gases Assets, including but not limited to, providing each Gases Employee with reasonable financial incentives, if necessary, including continuation of all employee benefits and regularly scheduled raises and bonuses, to continue in his or her position pending divestiture of the Gases Assets.
- B. Respondent shall cooperate with and assist an Acquirer to evaluate and hire any Gases Employee necessary to operate the I&M Gases Business, CO₂ Business, or Retail Business in substantially the same manner as Air Liquide or Airgas prior to the Acquisition, including, but not limited to:

Order to Maintain Assets

1. Not later than twenty (20) days before the Divestiture Date, Respondent shall (i) identify the relevant Gases Employees, (ii) allow an Acquirer to inspect the personnel files and other documentation of the relevant Gases Employees, to the extent permissible under applicable laws, and (iii) allow an Acquirer an opportunity to interview the relevant Gases Employees;
2. Respondent shall (i) not offer any incentive to any Gases Employee to decline employment with an Acquirer, (ii) remove any contractual impediments that may deter any Gases Employee from accepting employment with an Acquirer, including, but not limited to, any non-compete or confidentiality provision of employment or other contracts with Respondent that would affect the ability of such employee to be employed by an Acquirer, and (iii) not otherwise interfere with the recruitment, hiring, or employment of any Gases Employee by an Acquirer;
3. Respondent shall (i) vest all current and accrued pension benefits as of the date of transition of employment with an Acquirer for any Gases Employee who accepts an offer of employment from Acquirer and (ii) provide each Gases Employee with a financial incentive as necessary to accept an offer of employment with an Acquirer; and
4. For a period of two (2) years after divestiture of any of the Gases Assets, Respondent shall not solicit the employment of any Gases Employee who becomes employed by an Acquirer at the time any of the Gases Assets are divested; *provided, however,* that a violation of this provision will not occur if: (i) the individual's employment has been terminated by an Acquirer, (ii) Respondent advertises for employees in newspapers, trade publications, or other media not targeted

Decision and Order

specifically at the employees, or (iii) Respondent hires employees who apply for employment with Respondent, so long as such employees were not solicited by Respondent in violation of this paragraph.

V.**IT IS FURTHER ORDERED** that:

- A. Respondent shall (i) keep confidential (including as to Respondent's employees) and (ii) not use for any reason or purpose, any Confidential Information received or maintained by Respondent relating to the Gases Assets or Gases Business; *provided, however*, that Respondent may disclose or use such Confidential Information in the course of:
1. Performing its obligations or as permitted under this Order to Maintain Assets, Decision and Order, or Divestiture Agreement; or
 2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the Gases Assets, Gases Business, or as required by law or rules or regulations of any stock exchange.
- B. If disclosure or use of any Confidential Information related to the Gases Assets or Gases Business is permitted to Respondent's employees or to any other Person under Paragraph V.A. of this Order to Maintain Assets, Respondent shall limit such disclosure or use (i) only to the extent such information is required; (ii) only to those employees or Persons who require such information for the purposes permitted under Paragraph V.A.; and (iii) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.

Order to Maintain Assets

- C. Respondent shall enforce the terms of this Paragraph V. as to its employees or any other Person, and take such action as is necessary to cause each of its employees and any other Person to comply with the terms of this Paragraph V., including implementation of access and data controls, training of its employees, and all other actions that Respondent would take to protect its own trade secrets and proprietary information.

VI.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement, the Commission may appoint a Person (“Monitor”) to monitor Respondent’s compliance with its obligations under this Order to Maintain Assets and the Decision and Order. The Monitor may be the same person appointed as Monitor under the Decision and Order.
- B. The Commission shall select the Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed in writing, including the reasons for opposing, the selection of any proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.
- C. Respondent shall, no later than five (5) days after the Commission appoints a Monitor, enter into an agreement with the Monitor, subject to the prior approval of the Commission, that (i) shall become effective no later than one (1) day after the date the Commission appoints the Monitor, and (ii) confers upon the Monitor all rights, powers, and authority necessary to permit the Monitor to perform his duties and responsibilities on the terms set forth in this Order

Decision and Order

to Maintain Assets and in consultation with the Commission:

1. The Monitor shall (i) monitor Respondent's compliance with the obligations set forth in this Order to Maintain Assets and the Decision and Order and (ii) act in a fiduciary capacity for the benefit of the Commission;
2. Respondent shall (i) ensure that the Monitor has full and complete access to all Respondent's personnel, books, records, documents, and facilities relating to compliance with this Order to Maintain Assets or the Decision and Order or to any other relevant information as the Monitor may reasonably request, and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his duties pursuant to this Order to Maintain Assets;
3. The Monitor (i) shall serve at the expense of Respondent, without bond or other security, on such reasonable and customary terms and conditions as the Commission may set, and (ii) may employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
4. Respondent shall indemnify the Monitor and hold him harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of his duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitor's gross negligence or willful misconduct; and

Order to Maintain Assets

5. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- D. The Monitor shall report in writing to the Commission concerning Respondent's compliance with this Order to Maintain Assets and the Decision and Order on a schedule as determined by Commission staff, including a final report after Respondent has completed all obligations required by Paragraph II. of the Decision and Order.
 - E. The Commission may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
 - F. The Monitor's power and duties shall terminate fifteen (15) days after the Monitor has completed his final report pursuant to Paragraph VI.D. of this Order to Maintain Assets, or at such other time as directed by the Commission.
 - G. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute Monitor in the manner described in this Paragraph VI.
 - H. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order to Maintain Assets.

Decision and Order

VII.**IT IS FURTHER ORDERED** that:

- A. Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to Maintain Assets and Decision and Order within thirty (30) days from the date Respondent signs the Consent Agreement (as set forth in the Consent Agreement) and every thirty (30) days thereafter until this Order to Maintain Assets terminates.
- B. With respect to any divestiture required by Paragraph II.A. of the Decision and Order, Respondent shall include in its compliance reports (i) the status of the divestiture and transfer of the Gases Assets; (ii) a description of all substantive contacts with a proposed acquirer (in the event that the Gases Assets are divested pursuant to Paragraph II.A.1. of the Decision and Order); and (iii) as applicable, a statement that the divestiture approved by the Commission has been accomplished, including a description of the manner in which Respondent completed such divestiture and the date the divestiture was accomplished.

VIII.

IT IS FURTHER ORDERED that the purpose of this Order to Maintain Assets is to (i) preserve the Gases Business and Gases Assets as a viable, competitive, and ongoing business until the divestiture required by the Decision and Order is achieved; (ii) prevent interim harm to competition pending the relevant divestiture and other relief; and (iii) help remedy any anticompetitive effects of the proposed Acquisition as alleged in the Commission's Complaint.

Order to Maintain Assets

IX.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent;
- B. Any proposed acquisition, merger, or consolidation of Respondent; or
- C. Any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

X.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order to Maintain Assets, which copying services shall be provided by the Respondent at its expense; and
- B. To interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

Decision and Order

XI.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. Three (3) business days after the date that Respondent completes the divestiture required by Paragraph II.A. of the Decision and Order; *provided, however*, that if at the time such divestiture has been completed, the Decision and Order in this matter is not yet final, then this Order to Maintain Assets shall terminate three (3) business days after the Decision and Order becomes final.

By the Commission.

Order to Maintain Assets

Appendix A**Appendix A****Gases Locations**

Pre-Acquisition	Products	Property Address
Air Liquide	Atmospheric Gases	815 McHenry Street Burlington, Wisconsin 53105
Air Liquide	Atmospheric Gases	4531 North Access Road Chattanooga, Tennessee 37415
Air Liquide	Atmospheric Gases	1297 Feura Bush Road Feura Bush, New York 12067
Air Liquide	Atmospheric Gases	1720 Trade Road Holland, OH 43528
Air Liquide	Atmospheric Gases	7700 West Wheeler Road Mapleton, Illinois 61547
Air Liquide	Atmospheric Gases	c/o AK Steel 1801 Crawford Street Door 360 Middletown, Ohio 45042
Air Liquide	Atmospheric Gases	1101 Holler Road Mount Vernon, Indiana 47620
Air Liquide	Atmospheric Gases	8000 North County Road 225 East Pittsboro, Indiana 46167
Air Liquide	Atmospheric Gases	203 West Creek Road St. Marys, Pennsylvania 15857
Air Liquide	Atmospheric Gases	125 Brooks Boulevard Spartanburg, South Carolina 29307
Air Liquide	Atmospheric Gases	1540 Dewberry Road Spartanburg, South Carolina 29307
Air Liquide	Atmospheric Gases	326 Forestville Road Wake Forest, North Carolina 27587
Air Liquide	Atmospheric Gases	300 Dupont Street West Point, Virginia 23181
Airgas	Atmospheric Gases	109 Tom Harris Road Carrollton, Kentucky 41008

Decision and Order

Pre-Acquisition	Products	Property Address
Airgas	Atmospheric Gases	180 Frontage Road Gaston, South Carolina 29053
Airgas	Atmospheric Gases	1302 SW 112 th Street Lawton, Oklahoma 73505
Airgas	Atmospheric Gases	500 Industrial Park Drive Mulberry, Arkansas 72947 305 East Mulberry Highway 64 Mulberry, Arkansas 72947
Air Liquide	Nitrous Oxide	1 Nitrous Lane Donora, Pennsylvania 15033
Air Liquide	Nitrous Oxide	1100 Hensley Street Richmond, California 94801
Air Liquide	Liquid CO ₂ / Dry Ice	2300 Fairlanes Boulevard Borger, Texas 79007
Air Liquide	CO ₂ Rail Depot	3301 Highway 630 West Fort Meade, Florida 33841
Air Liquide	Liquid CO ₂ / Dry Ice	1584 Market Avenue Galva, Iowa 51020
Air Liquide	Liquid CO ₂	218 Weisenberger Road Madison, Mississippi 39130
Air Liquide	Liquid CO ₂ / Dry Ice	651 Solano Way Martinez, California 94553
Air Liquide	Liquid CO ₂ / Dry Ice	1182 260 th Street Sergeant Bluff, Iowa 51054
Air Liquide	Liquid CO ₂	1285 South 300 West Washington, Indiana 47501
Airgas	Retail	6350 Arctic Boulevard Anchorage, Alaska 99518
Airgas	Retail	641 Hughes Avenue Fairbanks, Alaska 99701
Airgas	Retail	42400 Kenai Spur Highway Kenai, Alaska 99611

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed merger of a wholly owned subsidiary of Respondent American Air Liquide Holdings, Inc. (“Air Liquide,” a wholly owned subsidiary of L’Air Liquide, S.A.) with and into Airgas, Inc. (“Airgas”) and Respondent having been furnished thereafter with a copy of a draft of complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement (“Consent Agreement”) containing consent orders, an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a complaint should issue stating its charges in that respect, and having thereupon issued its complaint and its Order to Maintain Assets and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from an interested person, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and enters the following Decision and Order (“Order”):

Decision and Order

1. Respondent American Air Liquide Holdings, Inc. is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its corporate office and principal place of business located at 9811 Katy Freeway, Suite 100, Houston, Texas 77024. American Air Liquide Holdings, Inc., is an indirect wholly owned subsidiary of L'Air Liquide, S.A., a French *société anonyme*.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent and the proceeding is in the public interest.

ORDER**I.**

IT IS HEREBY ORDERED that, as used in this Order, the following definitions shall apply:

- A. "Air Liquide" means American Air Liquide Holdings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns and includes its parent L'Air Liquide, S.A.; and the subsidiaries, divisions, groups, and affiliates in each case controlled by American Air Liquide Holdings, Inc. (including Airgas, Inc., after the Acquisition) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. "Commission" means the Federal Trade Commission.
- C. "Acquirer" means any Person that acquires any of the Gases Assets pursuant to this Order.
- D. "Acquisition" means the proposed merger described in the Agreement and Plan of Merger by and among Airgas, Inc., L'Air Liquide, S.A. and AL Acquisition Corporation, dated as of November 17, 2015.

Decision and Order

- E. “Acquisition Date” means the date the Acquisition is consummated.
- F. “Airgas” means Airgas, Inc., a corporation organized, existing, and doing business under, and by virtue of the laws of Delaware, with its corporate office and principal place of business located at 259 N. Radnor-Chester Road, Suite 100, Radnor, Pennsylvania 19087.
- G. “CO₂ Business” means the business of producing, distributing, marketing, or selling liquid CO₂ and dry ice conducted by Air Liquide prior to the Acquisition at the CO₂ and CO₂/dry ice locations identified in Appendix A of this Order.
- H. “Confidential Information” means any and all of the following information:
1. all information that is a trade secret under applicable trade secret or other law;
 2. all information concerning product specifications, data, know-how, formulae, compositions, processes, designs, sketches, photographs, graphs, drawings, samples, inventions and ideas, past, current and planned research and development, current and planned manufacturing or distribution methods and processes, customer lists, current and anticipated customer requirements, price lists, market studies, business plans, software and computer software and database technologies, systems, structures, and architectures;
 3. all information concerning the relevant business (which includes historical and current financial statements, financial projections and budgets, tax returns and accountants’ materials, historical, current and projected sales, capital spending budgets and plans, business plans, strategic plans, marketing and advertising plans, publications,

Decision and Order

client and customer lists and files, contracts, the names and backgrounds of key personnel, and personnel training techniques and materials); and

4. all notes, analyses, compilations, studies, summaries, and other material to the extent containing or based, in whole or in part, upon any of the information described above;

Provided, however, that Confidential Information shall not include information that (i) was, is, or becomes generally available to the public other than as a result of a breach of this Order; (ii) was or is developed independently of and without reference to any Confidential Information; or (iii) was available, or becomes available, on a non-confidential basis from a third party not bound by a confidentiality agreement or any legal, fiduciary, or other obligation restricting disclosure.

- I. “Contract” means any agreement, contract, lease, license agreement, consensual obligation, promise, or undertaking (whether written or oral and whether express or implied).
- J. “Corporate Trade Names” means all trademarks, trade names, service marks, trade dress, logos, corporate names, domain names, emblems, signs or insignia, and other source identifiers whether registered or common law, including but not limited to all such items containing or comprising the brands and marks “Air Liquide,” “Airgas,” “EMIXAL,” “Penguin,” “Blue Ice,” “Red-D-Arc,” and “Radnor.”
- K. “Cost” means the actual cost of raw materials or parts, direct labor, utilities, administrative and third party expenses, and reasonably allocated operations, distribution, and factory expenses and shared corporate services overhead used to develop, manufacture, and supply the relevant good or service.

Decision and Order

- L. “Divestiture Agreement” means any agreement between Respondent (or a Divestiture Trustee) and Acquirer that receives the prior approval of the Commission to divest the Gases Assets, including all related ancillary agreements, schedules, exhibits, and attachments thereto.
- M. “Divestiture Date” means the date on which Respondent (or the Divestiture Trustee) closes on the transaction to divest any of the Gases Assets to an Acquirer.
- N. “Divestiture Trustee” means the Person appointed by the Commission pursuant to Paragraph V. of this Order.
- O. “Gases Assets” means all of Respondent’s right, title, and interest in and to all property and assets, real, personal, or mixed, tangible and intangible, of every kind and description, wherever located, relating to operation of the Gases Business, including, but not limited to:
1. all real property interests (including fee simple interests and real property leasehold interests), including all easements, and appurtenances, together with all buildings and other structures, facilities, and improvements located thereon, owned, leased, or otherwise held;
 2. all Tangible Personal Property, including any Tangible Personal Property removed (outside of the ordinary course of business) from any Gases Location since the date of the announcement of the Acquisition and not replaced;
 3. all inventories;
 4. all Contracts and all outstanding offers or solicitations to enter into any Contract, and all rights thereunder and related thereto;

Decision and Order

5. all consents, licenses, registrations, or permits issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement, and all pending applications therefor or renewals thereof, to the extent assignable;
6. all data and Records, including client and customer lists and Records, referral sources, research and development reports and Records, production reports and Records, service and warranty Records, equipment logs, operating guides and manuals, financial and accounting Records, creative materials, advertising materials, promotional materials, studies, reports, notices, orders, inquiries, correspondence, and other similar documents and Records, and copies of all personnel Records (to the extent permitted by law);
7. all intangible rights and property, including Intellectual Property owned or licensed (as licensor or licensee) by Respondent (to the extent transferable or licensable), going concern value, goodwill, and telephone and telecopy listings; and
8. all rights relating to deposits and prepaid expenses, claims for refunds and rights to offset in respect thereof;

Provided, however, that the Gases Assets need not include (i) the Retained Assets, (ii) the Retained Intellectual Property, or (iii) any part of the Gases Assets if not needed by Acquirer and the Commission approves the divestiture without such assets.

- P. “Gases Business” means the I&M Gases Business, CO₂ Business, and the Retail Business.
- Q. “Gases Employee” means any individual (i) employed on a full-time, part-time, or contract basis at any of the Gases Locations as of and after the date of the

Decision and Order

announcement of the Acquisition or (ii) identified by agreement between Respondent and an Acquirer and made a part of a Divestiture Agreement.

- R. “Gases Locations” means the locations identified on Appendix A of this Order.
- S. “I&M Gases Business” means the business of producing, refining, distributing, marketing, or selling atmospheric gases (liquid oxygen, liquid nitrogen, and liquid argon) and nitrous oxide conducted by either Air Liquide or Airgas prior to the Acquisition at their respective atmospheric gases and nitrous oxide locations identified in Appendix A of this Order.
- T. “Intellectual Property” means all intellectual property, including (i) commercial names, all assumed fictional business names, trade names, “doing business as” (d/b/a names), registered and unregistered trademarks, service marks and applications, and tradenames; (ii) all patents, patent applications and inventions and discoveries that may be patentable; (iii) all registered and unregistered copyrights in both published works and unpublished works; (iv) all rights in mask works; (v) all know-how, trade secrets, confidential or proprietary information, customer lists, software, technical information, data, process technology, plans, drawings, and blue prints; and (vi) all rights in internet web sites and internet domain names currently used.
- U. “License” means a royalty-free, fully paid-up, perpetual, irrevocable, non-exclusive, transferable, and sublicensable license and such tangible embodiments of the licensed rights (including, but not limited to, physical and electronic copies) as may be necessary or appropriate to enable Acquirer to use the rights.
- V. “Multi-Product Customer” means any customer who purchased from Respondent, as of the Acquisition Date, both (i) atmospheric gases (liquid oxygen, liquid

Decision and Order

nitrogen, and liquid argon) or nitrous oxide and (ii) any other products or services.

- W. “Multi-Location Customer” means any customer who purchased from Respondent atmospheric gases (liquid oxygen, liquid nitrogen, and liquid argon) or nitrous oxide, as of the Acquisition Date, both (i) from the Gases Locations and (ii) from other facilities of Respondent.
- X. “Person” means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture or other entity or a governmental body.
- Y. “Record” means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.
- Z. “Retail Business” means the business of selling hardgoods, welding products, and gases conducted by Airgas prior to the Acquisition at the retail locations identified in Appendix A of this Order.
- AA. “Retained Assets” means:
1. Corporate Trade Names and portions of website content, domain names, or e-mail addresses that contain Corporate Trade Names;
 2. Software that can readily be purchased or licensed from sources other than Respondent and which has not been materially modified (other than through user preference settings), or enterprise software that Respondent also uses to manage and account for businesses other than the Gases Business;
 3. Corporate headquarters of Air Liquide and Airgas;
 4. Assets located outside of the United States;

Decision and Order

5. Assets relating to the Gases Business that are shared with, or also pertain to, retained businesses of Respondent, including but not limited to, plants and facilities, computers, telecommunications equipment, and Tangible Personal Property, unless such assets primarily relate to the operation of any or all of the Gases Business;
 6. Data and Records that contain information (a) that relates to both the Gases Business and to retained businesses of Respondent, or (b) of which Respondent has a legal obligation to retain the original copies; *provided, however,* that Respondent shall provide copies of those portions of such data and Records that relate to the Gases Business;
 7. Insurance benefits, including rights and proceeds; and
 8. Any assets, rights, or interests relating to the production, refinement, distribution, marketing, or sale of packaged gases (including packaged atmospheric gases), such as dewars, cylinders, or cylinder fill plants, other than the Retail Business.
- BB. “Retained Intellectual Property” means any Intellectual Property, other than Retained Assets, that relates to the operation of the Gases Business and is shared with, or also pertains to, businesses operated by Respondent other than the Gases Business unless such Intellectual Property primarily relates to the operation of any or all of the Gases Business.
- CC. “Tangible Personal Property” means all machinery, equipment, spare parts, tools, furniture, office equipment, computer hardware, supplies, materials, vehicles, and other items of tangible personal property (other than inventories) of every kind owned or leased, together with any express or implied warranty by the manufacturers or sellers or lessors (to the extent

Decision and Order

transferable) of any item or component part thereof and all maintenance records and other documents relating thereto.

- DD. "Third Party Consent" means any consent, assignment, license, permit, or other authorization from any Person other than Respondent that is necessary to divest or operate the Gases Assets.
- EE. "Transitional Assistance" means logistical, administrative, and technical support, as required by Acquirer.

II.**IT IS FURTHER ORDERED** that:

- A. No later than 120 days after the Acquisition Date, Respondent shall divest the Gases Assets, absolutely and in good faith, at no minimum price, as on-going businesses, to a Person or Persons that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission (including execution of a Divestiture Agreement); *provided, however*, that Respondent shall divest the Gases Assets relating to operation of the I&M Gases Business to no more than one Person.
- B. No later than the Divestiture Date, Respondent shall secure all Third Party Consents; *provided, however*, that if Respondent is unable to obtain any Third Party Consent, Respondent shall (i) provide such assistance as an Acquirer may reasonably request in its efforts to obtain a comparable consent or (ii) with the acceptance of an Acquirer and the prior approval of the Commission, substitute equivalent assets or arrangements.
- C. Respondent shall cooperate with and assist an Acquirer to evaluate and hire any Gases Employee necessary to operate the I&M Gases Business, CO₂

Decision and Order

Business, or Retail Business in substantially the same manner as Air Liquide or Airgas prior to the Acquisition, including, but not limited to:

1. Not later than twenty (20) days before the Divestiture Date, Respondent shall (i) identify the relevant Gases Employees, (ii) allow an Acquirer to inspect the personnel files and other documentation of the relevant Gases Employees, to the extent permissible under applicable laws, and (iii) allow an Acquirer an opportunity to interview the relevant Gases Employees;
2. Respondent shall (i) not offer any incentive to any Gases Employee to decline employment with an Acquirer, (ii) remove any contractual impediments that may deter any Gases Employee from accepting employment with an Acquirer, including, but not limited to, any non-compete or confidentiality provision of employment or other contracts with Respondent that would affect the ability of such employee to be employed by an Acquirer, and (iii) not otherwise interfere with the recruitment, hiring, or employment of any Gases Employee by an Acquirer;
3. Respondent shall (i) vest all current and accrued pension benefits as of the date of transition of employment with an Acquirer for any Gases Employee who accepts an offer of employment from Acquirer and (ii) provide each Gases Employee with a financial incentive as necessary to accept an offer of employment with an Acquirer; and
4. For a period of two (2) years after divestiture of any of the Gases Assets, Respondent shall not solicit the employment of any Gases Employee who becomes employed by an Acquirer at the time any of the Gases Assets are divested; *provided, however,* that a violation of this provision will not

Decision and Order

occur if: (i) the individual's employment has been terminated by an Acquirer, (ii) Respondent advertises for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (iii) Respondent hires employees who apply for employment with Respondent, so long as such employees were not solicited by Respondent in violation of this paragraph.

- D. At the option of an Acquirer, Respondent shall:
1. For a period of twelve (12) months after the divestiture of any of the Gases Assets, provide Transitional Assistance to Acquirer at a price not to exceed Cost and in quality and quantity sufficient to enable Acquirer to operate the relevant Gases Business in substantially the same manner (including allowing for growth of the Gases Business) as Air Liquide or Airgas prior to the Acquisition;
 2. For a period of three (3) years after the divestiture of any of the Gases Assets, provide Acquirer a supply of products at a price not to exceed Cost and in quality and quantity sufficient to enable Acquirer to operate the relevant Gases Business in substantially the same manner (including allowing for growth of the Gases Business) as Air Liquide or Airgas prior to the Acquisition; and
 3. For a period of three (3) years after the divestiture of the Gases Assets relating to operation of the I&M Gases Business, purchase products from Acquirer as a customer in volumes equivalent to the historical internal transfers to Respondent's businesses other than the I&M Gases Business;

Provided, however, that the period of time for providing any assistance under this Paragraph II.D.

Decision and Order

shall be extended at the request of an Acquirer, subject to the prior approval of the Commission.

- E. With respect to Intellectual Property, Respondent:
1. Shall grant a License to an Acquirer under the Retained Intellectual Property sufficient for Acquirer to operate the relevant Gases Business in substantially the same manner as Air Liquide or Airgas prior to the Acquisition with the freedom to extend existing products and services and develop new products and services; and
 2. May enter into an agreement with an Acquirer for a License back under any Intellectual Property included in the Gases Assets that also relates to operation of a business other than the Gases Business for use in such other business.
- F. Respondent's obligations pursuant to Paragraphs II.D. and II.E. of this Order shall be set forth in one or more agreements incorporated into the Divestiture Agreement, subject to the prior approval of the Commission. Respondent shall not terminate its obligations pursuant to Paragraphs II.D. and II.E. because of a material breach by an Acquirer of any such agreement in the absence of a final order of a court of competent jurisdiction.
- G. For a period of two (2) years after divestiture of the Gases Assets relating to operation of the I&M Gases Business, Respondent shall not solicit any Multi-Product or Multi-Location Customer to discontinue or reduce such customer's purchases from the Gases Locations relating to the I&M Gases Business; *provided, however*, that a violation of this provision will not occur if: (1) a customer initiates communications with Respondent to purchase atmospheric gases or nitrous oxide or (2) Respondent advertises in newspapers, trade publications, or other

Decision and Order

media in a manner not targeted specifically at customers of an Acquirer.

- H. The purpose of the divestiture of the Gases Assets is to ensure the continued use of the assets in the same businesses in which such assets were engaged at the time of the announcement of the Acquisition by Respondent and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.**IT IS FURTHER ORDERED** that:

- A. Respondent shall (i) keep confidential (including as to Respondent's employees) and (ii) not use for any reason or purpose, any Confidential Information received or maintained by Respondent relating to the Gases Assets or Gases Business; *provided, however*, that Respondent may disclose or use such Confidential Information in the course of:
1. Performing its obligations or as permitted under this Order, the Order to Maintain Assets, or Divestiture Agreement; or
 2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the Gases Assets, Gases Business, or as required by law or rules or regulations of any stock exchange.
- B. If disclosure or use of any Confidential Information related to the Gases Assets or Gases Business is permitted to Respondent's employees or to any other Person under Paragraph III.A. of this Order, Respondent shall limit such disclosure or use (i) only to the extent such information is required; (ii) only to those employees or Persons who require such

Decision and Order

information for the purposes permitted under Paragraph III.A.; and (iii) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.

- C. Respondent shall enforce the terms of this Paragraph III. as to its employees or any other Person, and take such action as is necessary to cause each of its employees and any other Person to comply with the terms of this Paragraph III., including implementation of access and data controls, training of its employees, and all other actions that Respondent would take to protect its own trade secrets and proprietary information.

IV.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement, the Commission may appoint a Person (“Monitor”) to monitor Respondent’s compliance with its obligations under this Order. The Monitor may be the same person appointed as Monitor under the Order to Maintain Assets issued in this matter.
- B. The Commission shall select the Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed in writing, including the reasons for opposing, the selection of any proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.
- C. Respondent shall, no later than five (5) days after the Commission appoints a Monitor, enter into an agreement with the Monitor, subject to the prior approval of the Commission, that (i) shall become effective no later than one (1) day after the date the

Decision and Order

Commission appoints the Monitor, and (ii) confers upon the Monitor all rights, powers, and authority necessary to permit the Monitor to perform his duties and responsibilities on the terms set forth in this Order and in consultation with the Commission:

1. The Monitor shall (i) monitor Respondent's compliance with the obligations set forth in this Order and (ii) act in a fiduciary capacity for the benefit of the Commission;
2. Respondent shall (i) ensure that the Monitor has full and complete access to all Respondent's personnel, books, records, documents, and facilities relating to compliance with this Order or to any other relevant information as the Monitor may reasonably request, and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his duties pursuant to this Order;
3. The Monitor (i) shall serve at the expense of Respondent, without bond or other security, on such reasonable and customary terms and conditions as the Commission may set, and (ii) may employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
4. Respondent shall indemnify the Monitor and hold him harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of his duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or

Decision and Order

expenses result from the Monitor's gross negligence or willful misconduct; and

5. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- D. The Monitor shall report in writing to the Commission concerning Respondent's compliance with this Order on a schedule as determined by Commission staff, including a final report after Respondent has completed all obligations required by Paragraph II. of this Order (other than any obligations pursuant to any extensions of the agreements contemplated by Paragraph II.D. beyond the earlier of (i) their respective initial terms or (ii) three years after the divestiture of the relevant Gases Assets).
 - E. The Commission may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
 - F. The Monitor's power and duties shall terminate fifteen (15) days after the Monitor has completed his final report pursuant to Paragraph IV.D. of this Order, or at such other time as directed by the Commission.
 - G. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute Monitor in the manner described in this Paragraph IV.

Decision and Order

- H. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

V.**IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the divestiture and other obligations as required by Paragraph II. of this Order, the Commission may appoint a Divestiture Trustee to divest the Gases Assets and perform Respondent's other obligations in a manner that satisfies the requirements of this Order.
- B. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to Section 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondent to comply with this Order.
- C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of

Decision and Order

the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

- D. Within ten (10) days after appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture or other action required by the Order.
- E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the relevant assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and to take such other action as may be required to divest the Divestiture Assets.
 2. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or in the case of a court-appointed Divestiture Trustee, by the court.

Decision and Order

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph V. in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; *provided further* that Respondent shall select such entity within five (5) days of receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of

Decision and Order

Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph V.E.6., the term "Divestiture Trustee" shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph V.E.5. of this Order.

Decision and Order

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
 8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- F. The Commission may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- G. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph V.
- H. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures and other obligations or action required by this Order.
- I. The Divestiture Trustee may be the same person as the Monitor appointed under this Order.

Decision and Order

VI.**IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreement shall be incorporated by reference into this Order and made a part hereof, and Respondent shall comply with all terms of such agreement. The Divestiture Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order and nothing in this Order shall be construed to reduce any rights or benefits of Acquirer or to reduce any obligations of Respondent under such agreement.

- B. If any term of the Divestiture Agreement varies from Paragraphs I.-IX. of this Order (“Order Term”), then to the extent that Respondent cannot fully comply with both terms, the Order Term shall determine Respondent’s obligations under this Order. Respondent shall not modify, replace, or extend the terms of the Divestiture Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission’s Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5).

VII.**IT IS FURTHER ORDERED** that:

- A. Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order:
 - 1. Every thirty (30) days from the date this Order is issued until Respondent has fully complied with Paragraph II.D.1. of this Order;
 - 2. Every six (6) months thereafter until Respondent has fully complied with Paragraphs II.D.2. and II.D.3. of this Order (other than any obligations

Decision and Order

under any extension of the agreements contemplated by those Paragraphs beyond the earlier of (i) the respective initial terms of such agreements or (ii) three years after the divestiture of the Gases Assets); and

3. One (1) year from the date this Order is issued, annually thereafter for the next four (4) years on the anniversary of the date this Order is issued, and at such other times as the Commission staff may request.
- B. With respect to any divestiture required by Paragraph II.A. of this Order, Respondent shall include in its compliance reports (i) the status of the divestiture and transfer of the Gases Assets; (ii) a description of all substantive contacts with a proposed acquirer; and (iii) as applicable, a statement that the divestiture approved by the Commission has been accomplished, including a description of the manner in which Respondent completed such divestiture and the date the divestiture was accomplished.

VIII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent;
- B. Any proposed acquisition, merger, or consolidation of Respondent; or
- C. Any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

Decision and Order

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession, or under the control, of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at its expense; and
- B. To interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on July 15, 2026.

By the Commission.

Decision and Order

Appendix A**Appendix A****Gases Locations**

Pre-Acquisition	Products	Property Address
Air Liquide	Atmospheric Gases	815 McHenry Street Burlington, Wisconsin 53105
Air Liquide	Atmospheric Gases	4531 North Access Road Chattanooga, Tennessee 37415
Air Liquide	Atmospheric Gases	1297 Feura Bush Road Feura Bush, New York 12067
Air Liquide	Atmospheric Gases	1720 Trade Road Holland, OH 43528
Air Liquide	Atmospheric Gases	7700 West Wheeler Road Mapleton, Illinois 61547
Air Liquide	Atmospheric Gases	c/o AK Steel 1801 Crawford Street Door 360 Middletown, Ohio 45042
Air Liquide	Atmospheric Gases	1101 Holler Road Mount Vernon, Indiana 47620
Air Liquide	Atmospheric Gases	8000 North County Road 225 East Pittsboro, Indiana 46167
Air Liquide	Atmospheric Gases	203 West Creek Road St. Marys, Pennsylvania 15857
Air Liquide	Atmospheric Gases	125 Brooks Boulevard Spartanburg, South Carolina 29307
Air Liquide	Atmospheric Gases	1540 Dewberry Road Spartanburg, South Carolina 29307
Air Liquide	Atmospheric Gases	326 Forestville Road Wake Forest, North Carolina 27587
Air Liquide	Atmospheric Gases	300 Dupont Street West Point, Virginia 23181
Airgas	Atmospheric Gases	109 Tom Harris Road Carrollton, Kentucky 41008

Decision and Order

Pre-Acquisition	Products	Property Address
Airgas	Atmospheric Gases	180 Frontage Road Gaston, South Carolina 29053
Airgas	Atmospheric Gases	1302 SW 112 th Street Lawton, Oklahoma 73505
Airgas	Atmospheric Gases	500 Industrial Park Drive Mulberry, Arkansas 72947 305 East Mulberry Highway 64 Mulberry, Arkansas 72947
Air Liquide	Nitrous Oxide	1 Nitrous Lane Donora, Pennsylvania 15033
Air Liquide	Nitrous Oxide	1100 Hensley Street Richmond, California 94801
Air Liquide	Liquid CO ₂ / Dry Ice	2300 Fairlanes Boulevard Borger, Texas 79007
Air Liquide	CO ₂ Rail Depot	3301 Highway 630 West Fort Meade, Florida 33841
Air Liquide	Liquid CO ₂ / Dry Ice	1584 Market Avenue Galva, Iowa 51020
Air Liquide	Liquid CO ₂	218 Weisenberger Road Madison, Mississippi 39130
Air Liquide	Liquid CO ₂ / Dry Ice	651 Solano Way Martinez, California 94553
Air Liquide	Liquid CO ₂ / Dry Ice	1182 260 th Street Sergeant Bluff, Iowa 51054
Air Liquide	Liquid CO ₂	1285 South 300 West Washington, Indiana 47501
Airgas	Retail	6350 Arctic Boulevard Anchorage, Alaska 99518
Airgas	Retail	641 Hughes Avenue Fairbanks, Alaska 99701
Airgas	Retail	42400 Kenai Spur Highway Kenai, Alaska 99611

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT****I. INTRODUCTION**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) designed to remedy the anticompetitive effects resulting from the proposed acquisition of Airgas, Inc. (“Airgas”) by American Air Liquide Holdings, Inc. (“Air Liquide”). Pursuant to the Consent Agreement, Air Liquide will divest sixteen air separation units (“ASUs”), four vertically integrated dry ice and liquid carbon dioxide plants, two separate liquid carbon dioxide plants, two nitrous oxide plants, and three retail packaged welding gas and hardgoods stores. Air Liquide has agreed to divest the required facilities to one or more Commission-approved buyers within four months of consummating its transaction with Airgas. The divestiture of these facilities and related assets will preserve the competition between Air Liquide and Airgas that the proposed acquisition would otherwise eliminate.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the accompanying Decision and Order (“Order”).

II. THE TRANSACTION

Pursuant to an Agreement and Plan of Merger dated November 17, 2015, a wholly owned subsidiary of Air Liquide will merge with and into Airgas in a transaction valued at approximately \$13.4 billion. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in various

Analysis to Aid Public Comment

geographic markets for bulk oxygen, bulk nitrogen, bulk argon, bulk nitrous oxide, bulk liquid carbon dioxide, dry ice, and retail packaged welding gases.

III. THE PARTIES

Air Liquide is an international company specializing in industrial gases and related services. Air Liquide is the fourth-largest atmospheric gas producer in the United States, operating forty-nine liquid ASUs spread throughout the country. In the United States, Air Liquide also operates two nitrous oxide production facilities and eleven liquid carbon dioxide production facilities, six of which also produce dry ice. Air Liquide has largely exited its retail packaged gas and hardgoods business in the United States, but still operates five branch locations in Alaska. In 2015, Air Liquide's revenue totaled €16.4 billion, with €3.9 billion coming from the United States.

Airgas, headquartered in Radnor, Pennsylvania, is the leading U.S. distributor of packaged industrial, medical, and specialty gases and hardgoods, such as welding equipment and supplies. Airgas is the fifth-largest atmospheric gas producer in the United States, operating seventeen liquid ASUs, most of which are concentrated in the eastern half of the country. Airgas also operates a number of other industrial gas production plants, including three nitrous oxide production facilities, eleven liquid carbon dioxide production facilities, and fourteen dry ice production facilities. Airgas operates a network of approximately nine hundred retail branches where it sells hardgoods and packaged gas. For the fiscal year ending March 31, 2015, Airgas's consolidated net sales were approximately \$5.3 billion, with over 98% of those revenues coming from the United States.

IV. THE RELEVANT MARKETS FOR BULK OXYGEN, BULK NITROGEN, AND BULK ARGON

Atmospheric gases are gases that are present in the Earth's atmosphere. Industrial gas suppliers like Airgas and Air Liquide produce atmospheric gases for use in a wide range of applications, including oil and gas, steelmaking, health care, and food manufacturing. Liquid oxygen, nitrogen, and argon are three of

Analysis to Aid Public Comment

the most widely used atmospheric industrial gases, and each has specific properties that make it uniquely suited for the applications for which it is used. For most of these applications, there is no substitute for the use of oxygen, nitrogen, or argon.

Atmospheric gases are distributed to customers in different forms and methods depending on the volume of gas the customer requires. Customers who require large volumes are supplied either by on-site ASUs that are located at the customer's facility or by a pipeline connecting a plant to that customer. Bulk customers are those who have significant volume requirements, but are not large enough to justify on-site or pipeline gas delivery. Bulk customers typically are supplied with bulk oxygen, bulk nitrogen, or bulk argon in cryogenic trailers carrying the gas in liquid form. The liquid form is more condensed than the gaseous form and therefore easier to transport and store in large quantities. The bulk liquid gases are then stored in tanks located at the customer site. From there, customers can either use the product in its liquid form or convert it back to gas. Small-volume customers purchase nitrogen, oxygen, or argon in cylinders containing the product in gaseous form. These smaller customers are usually served by distributors, who receive their product from industrial gas suppliers in bulk liquid form. It is not feasible for bulk oxygen, bulk nitrogen, or bulk argon customers to switch distribution methods because their demand is too great for cylinder delivery and too small for on-site, or pipeline delivery.

For atmospheric gases, the ratio of the product's value to its transportation costs largely determines the relevant geographic market. Due to the relatively low sales price of bulk oxygen and nitrogen and the significant freight costs associated with transporting them, these gases can generally only be shipped economically a maximum distance of approximately 100 to 250 miles from the ASU that produces the gas. Therefore, it is appropriate to analyze the competitive effects of the proposed acquisition in regional geographic markets for bulk oxygen and bulk nitrogen. The relevant geographic markets in which to analyze the effects of the proposed acquisition are: (1) the Northeast; (2) the Mid-Atlantic; (3) the Southeast; (4) Atlanta and surrounding areas; (5) Arkansas and surrounding areas; (6) Oklahoma and surrounding areas; (7) Western Kentucky and

Analysis to Aid Public Comment

surrounding areas; (8) Chicago, Milwaukee, and surrounding areas; (9) Western Ohio and surrounding areas; and (10) Pittsburgh, Cleveland, and surrounding areas. Because bulk argon is a rarer and more expensive product than bulk oxygen and bulk nitrogen, it may be economically transported over greater distances. Therefore, the relevant geographic area in which to analyze the effects of the proposed acquisition on the bulk argon market is the United States.

The proposed acquisition would harm competition in the relevant markets for bulk oxygen and bulk nitrogen. Each market includes areas in which both Air Liquide and Airgas have plants that are particularly well situated to economically serve a large set of customers. The proposed acquisition would eliminate an important source of competition for those customers, would increase concentration in the relevant markets, and would cause prices to rise. For bulk argon, there are six significant suppliers in the United States, the largest of which is Air Liquide. The proposed acquisition would substantially increase concentration in bulk argon, creating a highly concentrated market.

V. THE RELEVANT MARKET FOR BULK NITROUS OXIDE

Nitrous oxide is a clear, odorless gas that is produced by heating and purifying ammonium nitrate. Commonly known as “laughing gas,” nitrous oxide is mainly used by dentists as an analgesic or a weak anesthetic. Other uses for nitrous oxide include augmenting combustion in automotive products, oxidizing rocket fuel, and manufacturing whipped cream and semiconductors. Customers who purchase nitrous oxide in bulk form are typically distributors who repackage the gas in smaller quantities. Most sales for end-use are made in cylinders to dental offices. Because of the unique properties of nitrous oxide, other gases are not considered substitutes. Consequently, customers would not switch to another gas or product even if the price of bulk nitrous oxide increased by five to ten percent.

Currently only five nitrous oxide production facilities service the entire United States and Canada. Bulk nitrous oxide is typically transported in tanker trucks. When purchasing bulk

Analysis to Aid Public Comment

nitrous oxide, customers are not concerned with finding the closest production facility when choosing a supplier. Therefore, the relevant geographic area in which to analyze the effects of the proposed acquisition on the bulk nitrous oxide market is the United States and Canada.

Air Liquide and Airgas are the only two producers of nitrous oxide in the United States and Canada. Airgas is the largest producer of nitrous oxide in North America and maintains three separate facilities located Cantonment, Florida, Yazoo City, Mississippi, and Maitland, Ontario. Air Liquide operates two North American nitrous oxide plants in Donora, Pennsylvania and Richmond, California. The proposed acquisition would produce a monopoly in the market for bulk nitrous oxide.

VI. THE RELEVANT MARKETS FOR BULK LIQUID CARBON DIOXIDE

Carbon dioxide is a “process gas,” meaning that it is captured as a by-product of other manufacturing processes, such as ethanol, ammonia, and hydrogen. It is also captured from natural sources such as natural gas wells. The carbon dioxide is then put in liquid form through a cryogenic process in plants typically located adjacent to carbon dioxide gas sources. The most common application for liquid carbon dioxide is food and beverage production, where it is used to carbonate beverages, chill and freeze food, and stun animals before they are slaughtered. For the vast majority of applications, there are no viable substitutes for liquid carbon dioxide.

Suppliers deliver liquid carbon dioxide to customers in bulk trailers or rail cars. Most customers store liquid carbon dioxide in tanks located at their manufacturing facilities until it is used. Customers would not switch to micro-bulk or cylinder delivery because bulk delivery is far cheaper and they would have to contend with managing significantly more deliveries to meet their needs. In addition, customers would not consider self-sourcing liquid carbon dioxide unless the cost increased significantly more than ten percent because extracting carbon dioxide requires expensive infrastructure and the supply of carbon dioxide is shrinking.

Analysis to Aid Public Comment

Significant freight costs associated with transporting liquid carbon dioxide relative to its sales price make it economical to ship liquid carbon dioxide no more than 250 miles by truck. In areas with few or no carbon dioxide sources, liquid carbon dioxide is shipped as much as 750 miles by rail. Therefore, it is appropriate to analyze the competitive effects of the proposed acquisition in regional geographic markets for bulk liquid carbon dioxide. For bulk liquid carbon dioxide, the relevant geographic markets in which to analyze the effects of the proposed acquisition are: (1) Indiana, Kentucky, and surrounding areas; (2) Mississippi and surrounding areas; and (3) the Texas Panhandle and surrounding areas.

Two of the three relevant markets for bulk liquid carbon dioxide are highly concentrated and the proposed acquisition would substantially increase concentration. While the Indiana, Kentucky and surrounding areas market is moderately concentrated, the proposed acquisition would produce a significant increase in concentration and would leave the combined entity as the leading supplier. In addition, for some customers in that region, the merging firms are the closest competitors.

VII. THE RELEVANT MARKETS FOR DRY ICE

In the United States, both parties produce and sell dry ice. Dry ice is the solid form of carbon dioxide, and a significant portion of the carbon dioxide market. It is produced when liquid carbon dioxide is injected into an atmospheric chamber, which causes some of the liquid carbon dioxide to vaporize into a gas, while reducing the temperature of the remaining liquid. The remaining liquid solidifies into a snow-like consistency. This snow is then collected and pressed into dry ice blocks or pellets, and distributed to customers in standard or bulk pellet bags, or in blocks, slices, or sticks. Dry ice has many applications, including shipping of frozen food and medical supplies, cooling of materials during production, and industrial blast cleaning. It is used in a variety of industries such as food processing, transportation, and biotechnology. Suppliers of dry ice either sell directly to end users, or wholesale to distributors or resellers. For the vast majority of applications, there are no viable substitutes for dry ice.

Analysis to Aid Public Comment

Dry ice begins to dissipate as soon as it is produced. As a result, dry ice is not typically transported more than 150 miles to a customer, although where local supply is insufficient, customers are willing to have dry ice shipped up to 350 miles. Therefore, it is appropriate to analyze the competitive effects of the proposed acquisition in regional geographic markets for dry ice. The relevant geographic markets in which to analyze the effects of the proposed acquisition are: (1) the San Francisco Bay Area; (2) Iowa and surrounding areas; and (3) the Texas Panhandle and surrounding areas.

Air Liquide and Airgas are the only two producers of dry ice in the San Francisco Bay Area. Consequently, the proposed acquisition, without remedy, would lead to Air Liquide holding a monopoly. In the two remaining dry ice markets, the proposed acquisition would substantially decrease competition in an already highly concentrated market, and would leave the combined entity as the leading supplier.

VIII. THE RELEVANT MARKETS FOR RETAIL PACKAGED WELDING GASES

Air Liquide and Airgas operate retail packaged gas stores in close proximity to each other in Anchorage, Fairbanks, and Kenai, Alaska. Packaged welding gas and hardgoods stores are outlets where customers can purchase cylinders of various gases and related hardgoods used for welding, such as safety gear and other physical goods. While customers may choose to purchase both their packaged welding gases and hardgoods at the same retail location, they are also willing to purchase packaged welding gas from one store and hardgoods from another. Customers cannot turn to alternatives for their packaged welding gases, such as bulk delivery from ASUs or filling their own cylinders because their purchasing volumes are too low to justify large quantity purchases. Additionally, for the vast majority of applications, there are no viable substitutes for packaged welding gases.

Generally, purchasers of packaged welding gases travel approximately twenty-five miles to make purchases at retail outlets. Even in Alaska, where there are fewer retail stores and customers may be willing to travel further, it is unlikely that

Analysis to Aid Public Comment

customers would travel over fifty miles to a retail location to purchase packaged welding gases. Therefore, it is appropriate to analyze the competitive effects of the proposed acquisition in local geographic markets for retail packaged welding gas. Accordingly, the relevant geographic markets at issue in this case are the local areas of: (1) Anchorage, Alaska; (2) Fairbanks, Alaska; and (3) Kenai, Alaska. The proposed acquisition would reduce the number of competitors from two to one in each of these markets.

VIII. EFFECTS OF THE ACQUISITION

The proposed acquisition would eliminate direct and substantial competition between Air Liquide and Airgas in each of the relevant markets, provide Air Liquide with a larger base of sales on which to enjoy the benefit of a unilateral price increase, and eliminate a competitor to which customers otherwise could have diverted their sales in markets where alternative sources of supply are limited. The proposed acquisition, therefore, likely would allow Air Liquide to exercise market power unilaterally, increasing the likelihood that purchasers of bulk oxygen, bulk nitrogen, bulk argon, bulk nitrous oxide, bulk liquid carbon dioxide, dry ice, or retail packaged welding gas would be forced to pay higher prices in the relevant areas.

The proposed acquisition would also enhance the likelihood of collusion or coordinated action between or among the remaining firms in the relevant markets for bulk oxygen, bulk nitrogen, bulk argon, bulk liquid carbon dioxide, and dry ice because a significant competitor would be eliminated, and only a small number of viable competitors would remain. In addition, certain conditions prevalent in these relevant markets, including the relative homogeneity of the firms and products involved and availability of detailed market information, are conducive to collusion or coordinated action.

X. ENTRY

New entry into the relevant markets would not occur in a timely manner sufficient to deter or counteract the likely adverse competitive effects of the proposed acquisition.

Analysis to Aid Public Comment

Entry into the bulk oxygen, nitrogen, and argon markets is costly, difficult, and unlikely because of, among other things, the time and cost required to construct the ASUs that produce these products. Constructing an ASU at a scale sufficient to be viable in the market would cost at least \$30 to \$100 million, most of which are sunk costs. Moreover, it is not economically justifiable to build an ASU unless a significant amount of the plant's capacity has been pre-sold prior to construction, either to an on-site customer or to customers with commitments under contract. Such pre-sale opportunities occur infrequently and unpredictably and can take several years to secure.

Entry into the bulk nitrous oxide market is costly, difficult, and unlikely because of, among other things, the time and cost required to construct a plant capable of producing nitrous oxide. Constructing such a plant would cost at least \$5 to \$10 million, and the demand for nitrous oxide is generally insufficient to justify the investment in building a nitrous oxide plant. In addition, there are regulatory barriers to overcome due to the hazardous nature of producing nitrous oxide.

Entry into the bulk liquid carbon dioxide and dry ice markets would also not be timely, likely, or sufficient to deter or counteract the adverse competitive effects of the proposed acquisition. Constructing a plant capable of producing bulk liquid carbon dioxide would cost at least \$10 to \$30 million. In addition, successful entry into the bulk liquid carbon dioxide market requires access to raw carbon dioxide supply sources, which are typically unavailable due to long-term contracts with incumbent liquid carbon dioxide suppliers. For dry ice production, there are similar entry barriers. Because liquid carbon dioxide is the primary input in dry ice production, the most significant barrier to entering the market for dry ice is obtaining a liquid carbon dioxide source. The entrant would also have to build a dry ice facility, but sales opportunities would likely be too small to justify the sunk costs associated with the required investment.

Entry into the retail packaged welding gases market would also not be timely, likely or sufficient to deter or counteract the likely adverse competitive effects of the proposed acquisition.

Analysis to Aid Public Comment

Currently, Air Liquide is the only entity capable of filling packaged gases in the relevant geographic markets for retail packaged welding gas, all of which are in Alaska. A new entrant would be required either to purchase bulk gases and construct a fill plant to put the gases in packaged form or to establish a supply network to transport packaged gases from a fill plant outside of Alaska to the relevant geographic markets. Because of these obstacles, new entry into the relevant markets is unlikely to occur.

XI. THE CONSENT AGREEMENT

The proposed Consent Agreement is designed to eliminate the competitive concerns raised by Air Liquide's proposed acquisition of Airgas in each relevant market. Under the terms of the proposed Consent Agreement, Air Liquide is required to divest sixteen ASUs, twelve of which are currently owned and operated by Air Liquide and four of which are currently owned and operated by Airgas. The Air Liquide-operated ASUs are located in: (1) Burlington, Wisconsin; (2) Chattanooga, Tennessee; (3) Feura Bush, New York; (4) Holland, Ohio; (5) Mapleton, Illinois; (6) Middletown, Ohio; (7) Mount Vernon, Indiana; (8) Pittsboro, Indiana; (9) St. Marys, Pennsylvania; (10) Spartanburg, South Carolina; (11) Wake Forest, North Carolina; and (12) West Point, Virginia. The Airgas-operated ASUs are located in: (1) Carrollton, Kentucky; (2) Gaston, South Carolina; (3) Lawton, Oklahoma; and (4) Mulberry, Arkansas. Air Liquide is also required to divest both of its nitrous oxide plants, one located in Denora, Pennsylvania and the other in Richmond, California. Air Liquide must also divest four co-located liquid carbon dioxide and dry ice facilities, which comprise its entire dry ice business, located in: (1) Borger, Texas; (2) Galva, Iowa; (3) Sioux City, Iowa; (4) and Martinez, California.

Additionally, Air Liquide will divest two liquid carbon dioxide-only facilities in Madison, Mississippi and Washington, Indiana along with the associated rail depot located in Fort Meade, Florida. Lastly, Air Liquide will divest Airgas's retail packaged welding gas and hardgoods stores located in Anchorage, Fairbanks, and Kenai, Alaska. Additionally, with regard to the ASU assets, although the anticompetitive effects of Air Liquide's acquisition of Airgas are related to the bulk liquid oxygen,

Analysis to Aid Public Comment

nitrogen, and argon markets, the pipeline oxygen and nitrogen businesses and contracts located at the ASUs are also being divested because they are critical to the viability, efficiency, and competitiveness of each plant. Air Liquide has agreed to divest the required facilities, together with all related equipment, customer and supply contracts, technology, and goodwill, to one or more Commission-approved buyers within four months of consummating its transaction with Airgas.

Any acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems. There are a number of parties interested in purchasing the assets to be divested that have the expertise, experience, and financial viability to successfully purchase and manage these assets and retain the current level of competition in the relevant markets. The Commission is therefore satisfied that sufficient potential buyers for the divested assets in each relevant market currently exist.

The proposed Consent Agreement incorporates a proposed Order to Maintain Assets to ensure the continued operations of the divestiture assets while a sale is conducted, and for a brief transition period once the Commission approves a buyer for the assets. The proposed Order to Maintain Assets also allows the Commission to appoint an interim monitor to oversee compliance with all the obligations and responsibilities under the proposed Order and requires Air Liquide to execute an agreement conferring upon the interim monitor all of the rights, powers, and authorities necessary to permit the monitor to ensure the continued health and competitiveness of the divested businesses.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

Complaint

IN THE MATTER OF

ASUSTEK COMPUTER, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4587; File No. 142 3156
Complaint, July 18, 2016 – Decision, July 18, 2016*

This consent order addresses ASUSTeK Computer, Inc.'s marketing of its routers, and related software and services, intended for consumer use. The complaint alleges that despite respondent's representations, ASUS engaged in a number of practices that, taken together, failed to provide reasonable security in the design and maintenance of the software developed for its routers and related "cloud" features. The consent order requires ASUS to establish and implement, and thereafter maintain, a comprehensive security program that is reasonably designed to (1) address security risks related to the development and management of new and existing covered devices; and (2) protect the privacy, security, confidentiality, and integrity of covered information.

Participants

For the *Commission*: Jarad Brown, and Nithan Sannappa.

For the *Respondent*: Law Offices of David A. Balto.

COMPLAINT

The Federal Trade Commission, having reason to believe that ASUSTeK Computer, Inc. ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent ASUSTeK Computer, Inc. is a Taiwanese corporation with its principal office or place of business at 15, Li-Te Rd., Peitou, Taipei 11259, Taiwan.
2. The acts and practices of respondent as alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Complaint

RESPONDENT'S BUSINESS PRACTICES

3. Respondent ASUSTeK Computer, Inc. (“ASUS”) is a hardware manufacturer that, among other things, sells routers, and related software and services, intended for consumer use. ASUS designs the software for its routers, controls U.S. marketing and advertising for its routers, including on websites targeting U.S. consumers, and is responsible for developing and distributing software updates to remediate security vulnerabilities and other flaws in routers sold to U.S. consumers. ASUS sells its routers in the United States through a wholly owned U.S. subsidiary, which distributes the routers for sale through third-party retailers, in stores and online, throughout the United States.

RESPONDENT'S ROUTERS AND “CLOUD” FEATURES

4. Routers forward data packets along a network. In addition to routing network traffic, consumer routers typically function as a hardware firewall for the local network, and act as the first line of defense in protecting consumer devices on the local network, such as computers, smartphones, internet-protocol (“IP”) cameras, and other connected appliances, against malicious incoming traffic from the internet. Respondent marketed its routers as including security features such as “SPI intrusion detection” and “DoS protection,” advertised that its routers could “protect computers from any unauthorized access, hacking, and virus attacks” (*see* Exh. A, p. 1 of 2), and instructed consumers to “enable the [router’s] firewall to protect your local network against attacks from hackers” (*see* Exh. A, p. 2 of 2).

5. Consumers set up and control the router’s configuration settings, including its security-related settings, through a web-based graphical user interface (the “admin console”). In order to configure these settings, consumers must log in to the admin console with a username and password, which ASUS preset on all of its routers to the default username “admin” and password “admin” (*see* Exh. B). The admin console also provides a tool that ostensibly allows consumers to check whether the router is using the latest available firmware – the software that operates the router.

Complaint

6. Many of respondent's routers include software features called AiCloud and AiDisk that allow consumers to wirelessly access and share files through their router. Depending on the model, respondent's routers that include these "cloud" features have a list price in the range of \$69.99 to \$219.99. As of March 2014, respondent had sold over 918,000 of these routers to U.S. consumers.

AICLOUD

7. In August 2012, ASUS introduced and began marketing a feature known as AiCloud on its routers. Respondent publicized AiCloud as a "private personal cloud for selective file sharing" that featured "indefinite storage and increased privacy" (*see* Exh. C, p. 1 of 6). In the following months, ASUS provided software updates for certain older router models to add the AiCloud feature, which respondent touted as "the most complete, accessible, and secure cloud platform" (*see* Exh. C, p. 2 of 6).

8. Described as "your secure space," AiCloud allows consumers to plug a USB storage device, such as an external hard drive, into the router, and then use web and mobile applications to access files on the storage device (*see* Exh. C, p. 3 of 6). For example, a consumer could save documents to the storage device using a desktop computer, and then later access those documents using a laptop, smartphone, or tablet. AiCloud also allows consumers to share specific files with others through a "secure URL," manage shared files, and revoke file access (*see* Exh. C, pp. 3-6 of 6).

Multiple Vulnerabilities

9. The AiCloud web and mobile applications require consumers to log in with the router's username and password (*see* Exh. D). However, the AiCloud web application included multiple vulnerabilities that would allow attackers to gain unauthorized access to consumers' files and router login credentials. In order to exploit these vulnerabilities, an attacker would only need to know the router's IP address – information that, as described in Paragraph 32, is easily discoverable.

Complaint

10. First, attackers could exploit an authentication bypass vulnerability to access the consumer's AiCloud account without the consumer's login credentials. By sending a specific command, or simply entering a specific URL in a web browser, an attacker could bypass the AiCloud web application's authentication screen and gain unauthorized access to a consumer's files, even if the consumer had not designated any of these files for sharing.

11. Second, attackers could exploit a password disclosure vulnerability in the AiCloud web application to retrieve the consumer's router login credentials in clear, readable text. In addition to providing the attacker with access to the consumer's AiCloud account, attackers could also use these login credentials to gain unauthorized access to the router's configuration settings. For example, if a consumer had enabled the admin console's remote management feature, an attacker could use the login credentials to simply log into the consumer's admin account and modify any of the router's settings, including its firewall and other security settings. Even if this remote management feature was disabled, an attacker could use the credentials in conjunction with other well-known vulnerabilities that affected respondent's routers, such as the cross-site request forgery vulnerabilities described in Paragraphs 24-26, to force unauthorized changes to the router's security settings, placing the consumer's local network at risk.

Failure to Provide Timely Notice

12. Several individuals notified respondent about the AiCloud vulnerabilities in June 2013. Furthermore, in September 2013, a consumer complained to ASUS that his "entire life [was] hacked" due to the AiCloud vulnerabilities, and that he needed to obtain identity theft protection services as a result. Despite knowing about these serious vulnerabilities and their impact on respondent's customers, respondent failed to notify consumers about the vulnerabilities or advise them to take simple steps, such as disabling the AiCloud features, that would have mitigated the vulnerabilities.

Complaint

13. Between July 2013 and September 2013, ASUS updated the firmware for affected routers in order to correct the AiCloud vulnerabilities. However, it was not until February 2014, eight months after respondent first learned of the vulnerabilities and after the events described in Paragraph 32, that respondent emailed registered customers notifying them that firmware updates addressing these and other security risks were available.

AIDISK

14. ASUS has offered another “cloud” feature on many of its routers called “AiDisk” since as early as 2009. Like AiCloud, AiDisk enables consumers to remotely access files on a USB storage device attached to the router, but does so through a file transfer protocol (“FTP”) server. Despite the fact that FTP does not support transit encryption, since at least 2012 respondent has promoted AiDisk as a way to “safely secure and access your treasured data through your router” (*see* Exh. E). In addition to transferring files unencrypted, the AiDisk software included a number of other design flaws that placed consumers’ sensitive personal information at risk.

Insecure Design

15. Consumers could set up an AiDisk FTP server in two ways. The first was through a set of menus called the “AiDisk wizard.” During setup, the AiDisk wizard asks the consumer to “Decide how to share your folders,” and presents three options: “limitless access rights,” “limited access rights,” and “admin rights.” Prior to January 2014, the AiDisk wizard did not provide consumers with sufficient information to evaluate these options, and pre-selected the “limitless access rights” option for the consumer (*see* Exh. F, p. 1 of 2). If the consumer completed setup with this default option in place, the AiDisk wizard created an FTP server that would provide anyone on the internet who had the router’s IP address with unauthenticated access to the consumer’s USB storage device.

16. The second way consumers could set up an AiDisk FTP server was through a submenu in the admin console called “USB Application – FTP Share.” The submenu did not provide

Complaint

consumers with any information regarding the default settings or the alternative settings that were available. If a consumer clicked on the option to “Enable FTP” (*see* Exh. G, p. 1 of 2), the software created an AiDisk FTP server that, by default, provided anyone on the internet who had the router’s IP address with unauthenticated access to the consumer’s USB storage device.

17. Neither set-up option provided any explanation that the default settings would provide anyone on the internet with unauthenticated access to all of the files saved on the consumer’s USB storage device. And in both cases, search engines could index any of the files exposed by these unauthenticated FTP servers, making them easily searchable online.

18. If a consumer wanted to prevent unauthenticated access through the AiDisk wizard, the consumer needed to deviate from the default settings and select “limited access rights.” The consumer would then be presented with the option to create login credentials for the FTP server. However, the AiDisk wizard recommended that the consumer choose weak login credentials, such as the preset username “Family” and password “Family” (*see* Exh. F, p. 2 of 2). In the alternative, the consumer could select “admin rights,” which would apply the same login credentials for the FTP server that the consumer used to log in to the router’s admin console. As described in Paragraphs 11 and 24, however, due to multiple password disclosure vulnerabilities, attackers could access these router login credentials in clear, readable text, undermining the protection provided by these credentials.

19. If a consumer wanted to prevent unauthenticated access through the “USB Application – FTP Share” submenu, the software provided no explanation or guidance as to how the consumer could change the default settings. The consumer would need to know to click on the “Share with account” option (*see* Exh. G, p. 1 of 2), which would allow the consumer to set up login credentials for the AiDisk FTP server. Confusingly, however, the software presented the consumer with a warning that implied that this option would expand, rather than restrict, access to the FTP server: “Enabling share with account enables multiple computers, with different access rights, to access the file

Complaint

resources. Are you sure you want to enable it?" (*see* Exh. G, p. 2 of 2). Through this misleading warning, respondent discouraged consumers from taking steps that could have prevented unauthenticated access to their sensitive personal information.

Notice of Design Flaws and Failure to Mitigate

20. In June 2013, a security researcher publicly disclosed that, based on his research, more than 15,000 ASUS routers allowed for unauthenticated access to AiDisk FTP servers over the internet. In his public disclosure, the security researcher claimed that he had previously contacted respondent about this and other security issues. In November 2013, the security researcher again contacted respondent, warning that, based on his research, 25,000 ASUS routers now allowed for unauthenticated access to AiDisk FTP servers. The researcher suggested that respondent warn consumers about this risk during the AiDisk set up process. However, ASUS took no action at the time.

21. Two months later, in January 2014, several European media outlets published stories covering the security risks caused by the AiDisk default settings. At that time, a large European retailer requested that respondent update the AiDisk default settings. Although respondent had known about the security risks for months, it was only after this retailer's request that respondent took some steps to protect its customers. In response, ASUS began releasing updated firmware that changed the AiDisk wizard's default setting – for new set-ups – from "limitless access rights" to "limited access rights," and displayed a warning message if consumers selected "limitless access rights" that "any user can access your FTP service without authentication!" However, respondent did not notify consumers about the availability of this firmware update.

22. Moreover, the January 2014 firmware update did not change the insecure default settings for consumers who had already set up AiDisk. Respondent did not notify those consumers that they would need to complete the AiDisk wizard process again in order for the new defaults to apply, or would need to manually change the settings.

Complaint

23. It was not until February 2014 – following the events described in Paragraph 32 – that respondent sent an email to registered customers notifying them that firmware updates addressing these security risks and other security vulnerabilities were available. Furthermore, it was not until February 21, 2014 that ASUS released a firmware update that would provide some protection to consumers who had previously set up AiDisk. This firmware update forced consumers’ routers to turn off unauthenticated access to the AiDisk FTP server.

OTHER VULNERABILITIES

24. ASUS’s router firmware and admin console have also been susceptible to a number of other well-known and reasonably foreseeable vulnerabilities – including multiple password disclosure, cross-site scripting, cross-site request forgery, and buffer overflow vulnerabilities – that attackers could exploit to gain unauthorized administrative control over consumers’ routers.

25. For example, the admin console has been susceptible to pervasive cross-site request forgery (“CSRF”) vulnerabilities that would allow an attacker to force malicious changes to any of the router’s security settings (*e.g.*, disabling the firewall, enabling remote management, allowing unauthenticated access to an AiDisk server, or configuring the router to redirect the consumer to malicious websites) without the consumer’s knowledge. Despite the serious consequences of these vulnerabilities, respondent did not perform pre-release testing for this class of vulnerabilities. Nor did respondent implement well-known, low-cost measures to protect against them, such as anti-CSRF tokens – unique values added to requests sent between a web application and a server that only the server can verify, allowing the server to reject forged requests sent by attackers.

26. Beginning in March 2013, respondent received multiple reports from security researchers regarding the CSRF vulnerabilities affecting respondent’s routers. Despite these reports, respondent took no action to fix the vulnerabilities for at least a year, placing consumers’ routers at risk of exploit. Indeed, in April 2015, a malware researcher discovered a large-scale, active CSRF exploit campaign that reconfigured vulnerable

Complaint

routers so that the attackers could control and redirect consumers' web traffic. This exploit campaign specifically targeted numerous ASUS router models.

FIRMWARE UPGRADE TOOL

27. The admin console includes a tool that ostensibly allows consumers to check whether their router is using the most current firmware ("firmware upgrade tool"). When consumers click on the "Check" button, the tool indicates that the "router is checking the ASUS server for the firmware update" (*see* Exh. H).

28. In order for the firmware upgrade tool to recognize the latest available firmware, ASUS must update a list of available firmware on its server. On several occasions, ASUS has failed to update this list. In July 2013, respondent received reports that the firmware upgrade tool was not recognizing the latest available firmware from both a product review journalist and by individuals calling into respondent's customer-support call center. Likewise, in February 2014, a security researcher notified respondent that the firmware upgrade tool did not recognize the latest available firmware, and detailed the reasons for the failure. In an internal email from that time, respondent acknowledged that, "if this list is not up to date when you use the check for update button in the [admin console,] the router doesn't find an update and states it is already up to date." Again, in October 2014 and January 2015, additional consumers reported to ASUS that the firmware upgrade tool still did not recognize the latest available firmware.

29. As a result, in many cases, respondent's firmware upgrade tool inaccurately notifies consumers that the "router's current firmware is the latest version" when, in fact, newer firmware with critical security updates is available.

**RESPONDENT'S FAILURE TO REASONABLY SECURE
ITS ROUTERS AND RELATED "CLOUD" FEATURES**

30. Respondent has engaged in a number of practices that, taken together, failed to provide reasonable security in the design and maintenance of the software developed for its routers and

Complaint

related “cloud” features. Among other things, respondent failed to:

- a. perform security architecture and design reviews to ensure that the software is designed securely, including failing to:
 - i. use readily-available secure protocols when designing features intended to provide consumers with access to their sensitive personal information. For example, respondent designed the AiDisk feature to use FTP rather than a protocol that supports transit encryption;
 - ii. implement secure default settings or, at the least, provide sufficient information that would ensure that consumers did not unintentionally expose sensitive personal information;
 - iii. prevent consumers from using weak default login credentials to protect critical security functions or sensitive personal information. For example, respondent allowed consumers to retain the weak default login credentials username “admin” and password “admin” for the admin console, and username “Family” and password “Family” for the AiDisk FTP server;
- b. perform reasonable and appropriate code review and testing of the software to verify that access to data is restricted consistent with a user’s privacy and security settings;
- c. perform vulnerability and penetration testing of the software, including for well-known and reasonably foreseeable vulnerabilities that could be exploited to gain unauthorized access to consumers’ sensitive personal information and local networks, such as authentication bypass, clear-text password disclosure, cross-site scripting, cross-site request forgery, and buffer overflow vulnerabilities;

Complaint

- d. implement readily-available, low-cost protections against well-known and reasonably foreseeable vulnerabilities, as described in (c), such as input validation, anti-CSRF tokens, and session time-outs;
- e. maintain an adequate process for receiving and addressing security vulnerability reports from third parties such as security researchers and academics;
- f. perform sufficient analysis of reported vulnerabilities in order to correct or mitigate all reasonably detectable instances of a reported vulnerability, such as those elsewhere in the software or in future releases; and
- g. provide adequate notice to consumers regarding (i) known vulnerabilities or security risks, (ii) steps that consumers could take to mitigate such vulnerabilities or risks, and (iii) the availability of software updates that would correct or mitigate the vulnerabilities or risks.

THOUSANDS OF ROUTERS COMPROMISED

31. Due to the failures described in Paragraphs 7-30, respondent has subjected its customers to a significant risk that their sensitive personal information and local networks will be subject to unauthorized access.

32. For example, on or before February 1, 2014, a group of hackers used readily available tools to locate the IP addresses of thousands of vulnerable ASUS routers. Exploiting the AiCloud vulnerabilities and AiDisk design flaws, the hackers gained unauthorized access to the attached USB storage devices of thousands of consumers and saved a text file on the storage devices warning these consumers that their routers were compromised: “This is an automated message being sent out to everyone effected [sic]. Your Asus router (and your documents) can be accessed by anyone in the world with an internet connection.” The hackers then posted online a list of IP addresses for 12,937 vulnerable ASUS routers as well as the login

Complaint

credentials for 3,131 AiCloud accounts, further exposing these consumers to potential harm.

33. Numerous consumers reported having their routers compromised, based on their discovery of the text-file warning the hackers had saved to their attached USB storage devices. Some complained that a major search engine had indexed the files that the vulnerable routers had exposed, making them easily searchable online. Others claimed to be the victims of related identity theft. For example, one consumer claimed that identity thieves had gained unauthorized access to his USB storage device, which contained his family's sensitive personal information, including login credentials, social security numbers, dates of birth, and tax returns. According to the consumer, in March 2014, identity thieves used this information to make thousands of dollars of fraudulent charges to his financial accounts, requiring him to cancel accounts and place a fraud alert on his credit report. Moreover, the consumer claimed that he had attempted to upgrade his router's firmware on several occasions after he bought the device in December 2013, but that the firmware upgrade tool had erroneously indicated that his router was using the latest available firmware. Given the sensitivity of the stolen personal information, he and his family are at a continued risk of identity theft.

34. Even consumers who did not enable the AiCloud and AiDisk features have been at risk of harm due to numerous vulnerabilities in respondent's router firmware and admin console. As described in Paragraphs 24-26, attackers could exploit these vulnerabilities to gain unauthorized control over a consumer's router and modify its security settings without the consumer's knowledge.

THE IMPACT OF RESPONDENT'S FAILURES ON CONSUMERS

35. As demonstrated by the thousands of compromised ASUS routers, respondent's failure to employ reasonable security practices has subjected consumers to substantial injury. Unauthorized access to sensitive personal information stored on attached USB storage devices, such as financial information,

Complaint

medical information, and private photos and videos, could lead to identity theft, extortion, fraud, or other harm. Unauthorized access and control over the router could also lead to the compromise of other devices on the local network, such as computers, smartphones, IP cameras, or other connected appliances. Finally, such unauthorized access and control could allow an attacker to redirect a consumer seeking, for example, a legitimate financial site to a fraudulent site, where the consumer would unwittingly provide the attacker with sensitive financial information. Consumers had little, if any, reason to know that their sensitive personal information and local networks were at risk.

36. Respondent could have prevented or mitigated these risks through simple, low-cost measures. In several instances, respondent could have prevented consumer harm by simply informing consumers about security risks, and advising them to disable or update vulnerable software. In other cases, respondent could have protected against vulnerabilities by implementing well-known and low-cost protections, such as input validation, anti-CSRF tokens, and session time-outs, during the software design process. Finally, simply preventing consumers from using weak default login credentials would have greatly increased the security of consumers' routers.

ROUTER SECURITY MISREPRESENTATIONS

(Count 1)

37. As described in Paragraph 4, respondent has represented, expressly or by implication, directly or indirectly, that it took reasonable steps to ensure that its routers could protect consumers' local networks from attack.

38. In fact, as described in Paragraphs 11, 24-26, and 30, respondent did not take reasonable steps to ensure that its routers could protect consumers' local networks from attack. Therefore, the representation set forth in Paragraph 37 is false or misleading.

Complaint

**AICLOUD SECURITY MISREPRESENTATIONS
(Count 2)**

39. As described in Paragraphs 7-8, respondent has represented, expressly or by implication, directly or indirectly, that it took reasonable steps to ensure that its AiCloud feature is a secure means for a consumer to access sensitive personal information.

40. In fact, as described in Paragraphs 9-13 and 30, respondent did not take reasonable steps to ensure that its AiCloud feature is a secure means for a consumer to access sensitive personal information. Therefore, the representation set forth in Paragraph 39 is false or misleading.

**AIDISK SECURITY MISREPRESENTATIONS
(Count 3)**

41. As described in Paragraph 14, respondent has represented, expressly or by implication, directly or indirectly, that it took reasonable steps to ensure that its AiDisk feature is a secure means for a consumer to access sensitive personal information.

42. In fact, as described in Paragraphs 14-23 and 30, respondent did not take reasonable steps to ensure that its AiDisk feature is a secure means for a consumer to access sensitive personal information. Therefore, the representation set forth in Paragraph 41 is false or misleading.

**FIRMWARE UPGRADE TOOL MISREPRESENTATIONS
(Count 4)**

43. As described in Paragraph 27, respondent has represented, expressly or by implication, that consumers can rely upon the firmware upgrade tool to indicate accurately whether their router is using the most current firmware.

44. In fact, as described in Paragraphs 28-29, consumers cannot rely upon the firmware upgrade tool to indicate accurately whether their router is using the most current firmware.

Complaint

Therefore, the representation set forth in Paragraph 43 is false or misleading.

UNFAIR SECURITY PRACTICES
(Count 5)

45. As set forth in Paragraphs 4-36, respondent has failed to take reasonable steps to secure the software for its routers, which respondent offered to consumers for the purpose of protecting their local networks and accessing sensitive personal information. Respondent's actions caused or are likely to cause substantial injury to consumers in the United States that is not outweighed by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers themselves. This practice is an unfair act or practice.

46. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

THEREFORE, the Federal Trade Commission this eighteenth day of July, 2016, has issued this complaint against respondent.

By the Commission.

Complaint

Exhibit A

Separate and Secure Wi-Fi Network via Guest Network Access
The RT-N66U supports up to three wireless networks over the 2.4 GHz band and three over the 5 GHz band, so it can protect computers from any unauthorized access, hacking and virus attacks. The parental control allows you to set up your kids' computer access times.

VPN Server Enabled
Easily set up a VPN server to surf the Web and access data—no matter where you are. Featuring MPPE encryption, your data transmission will be secure and confidential.

Staff Administrator Guest 1 Guest 2
User-Friendly Guest Network Settings

Encryption	64-bit WEP, 128-bit WEP, WPA2-PSK, WPA-PSK, WPA-Enterprise, WPA2-Enterprise, WPS support
Firewall & Access Control	Firewall: SPI intrusion detection, DoS protection Access control: Parental control, Network service filter, URL filter, Port filter

Exh. A, p. 1 of 2, Examples of Security Features Respondent Marketed in Router Product Descriptions

ASUS RT-AC86U | Logout | Reboot | English

Operation Mode: **wireless router** | Firmware Version: 3.0.0.4.372_b7

SSID: ASUS ASUS_5G

General | URL Filter | Keyword Filter | Network Services Filter

Firewall - General

Enable the firewall to protect your local area network against attacks from hackers. The firewall filters the incoming and outgoing packets based on the filter rules.

Enable Firewall	<input type="radio"/> Yes <input checked="" type="radio"/> No
Enable DoS protection	<input checked="" type="radio"/> Yes <input type="radio"/> No
Logged packets type	none
Respond Ping Request from WAN	<input checked="" type="radio"/> Yes <input type="radio"/> No

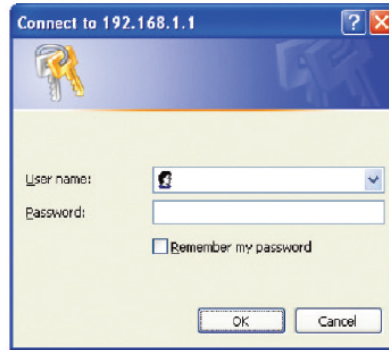
Apply

Exh. A, p. 2 of 2, Respondent's Router Security Representation

Complaint

Exhibit B

1. On your web browser such as Internet Explorer, Firefox, Safari, or Google Chrome, manually key in the wireless router's default IP address: **192.168.1.1**
2. On the login page, key in the default user name (**admin**) and password (**admin**).



Exh. B, Respondent's Login Instructions

Complaint

Exhibit C

ASUS Introduces AiCloud and a Range of New Innovations at IFA

Enriching users' digital lives with the latest technologies

2012/08/29

ASUS, a global leader in the new digital era, today announces a number of new products that are designed to work together to enrich users' digital lives with the latest technologies. ASUS AiCloud combines a cutting-edge 802.11ac Wi-Fi router with easy-to-use services that allow anyone to create their own personal cloud storage, while two new Design MX monitors deliver incredible visuals in a stunningly slim and elegant design.

Gamers have not been overlooked either with the introduction of the powerful ASUS ROG TYTAN CG890 gaming desktop; while business users can deliver crystal-clear presentations with the compact B1 Portable LED Projector designed to maximize ease-of-use and mobility. In addition, the Zen-inspired ASUS SDRW-080SS-U External DVD Writer makes a perfect companion for the ZENBOOK™.

ASUS AiCloud – make an incredible connection

ASUS AiCloud brings the convenience of cloud-based storage to everyone with a combination of easy-to-use technology and services, as well as indefinite storage and increased privacy. Smart Access lets users keep all their data on their home network or online storage facility easily accessible from anything from a smartphone to a PC, as long as they have an internet connection. It allows any networked computer to be incorporated into a private personal cloud for selective file sharing over the internet, using any compatible Windows, Mac and Linux device. Files can be easily shared through a simple web link.

Cloud Disk gives users access to an always-on data and media library by connecting a USB storage drive to an ASUS router like the RT-AC66U to act as a cloud services hub. This gives users their own media server on everything from Android or iOS-based smartphones or tablets to notebooks and no longer need to store space-hungry music and movie collections locally.

ASUS Smart Sync makes it easy to synchronise data on local storage devices with an ASUS WebStorage account. Synchronisation is automatic and takes place in real time to ensure that files are always up to date.

Exh. C, p. 1 of 6, Respondent's AiCloud Press Release

FAST Networking Solutions
FAST · EASY · STABLE Networks & Wireless Products E-News, Apr-May, 2013

RP-N53 RT-N14U **Product Updates**

RT-N56U/DSL-N55U supports ASUSWRT & AiCloud

AiCloud: Sync, share, and stream everywhere

ASUS AiCloud works with ASUS routers to offer the most complete, accessible, and secure cloud platform. It's a free app for iOS and Android devices, and allows you to easily sync, share, stream, and access all your content from any location. It creates your own private cloud server at home, and connects it seamlessly with the public cloud. Sharing is easier than ever with confidential links, which can be sent via email, SMS, and more. For the most intuitive and flexible cloud access from almost any device and location, ASUS AiCloud is your launch point.

ASUSWRT: Intuitive network setup and control

ASUSWRT makes network setup and settings easy and accessible for a better experience. Optimize your connection with one-click QoS bandwidth prioritization, network mapping, printer sharing, and parental controls – all through one graphical interface.

Stream media using AiCloud Share files using AiCloud

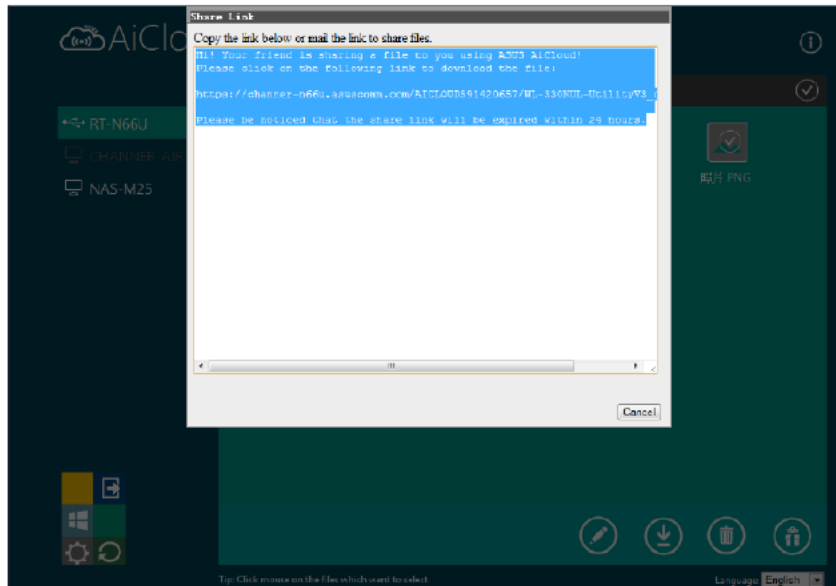
(The graphic also includes a screenshot of the ASUSWRT web interface and two images of hands using a smartphone to interact with the AiCloud app.)

Exh. C, p. 2 of 6, Respondent's AiCloud Product Update News Release

Complaint



Exh. C, p. 3 of 6, Respondent's AiCloud Website: "Your secure space"



Exh. C, p. 4 of 6, AiCloud Web Application Share Link

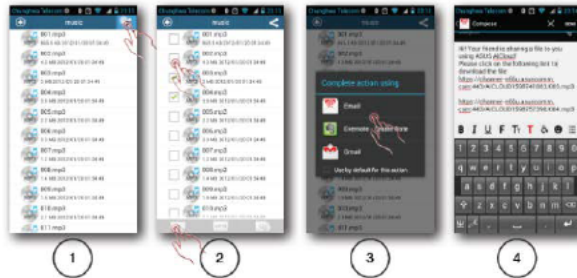
Complaint

Name	Create Time	Expire Time	Left Time	Delete
IMG_8678.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘
IMG_8677.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘
IMG_8676.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘
IMG_8675.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘
IMG_8674.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘
IMG_8673.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘
IMG_8672.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘
IMG_8671.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘
IMG_8670.JPG	2012/08/15 00:03:44	2012/08/16 00:03:44	23 hours 59 mins	✘

Exh. C, p. 5 of 6, AiCloud Web Application Share Link Manager

Sharing the file to friend with secure URL by App

Cloud Disk offers you an easy way to share files with friends. Simply open AiCloud, then choose the specific files you want to share. Cloud Disk creates short HTTPS links for those files. You can then select a way to share (via email, SMS, or copying links to other popular communication applications) these links with other people instantly.

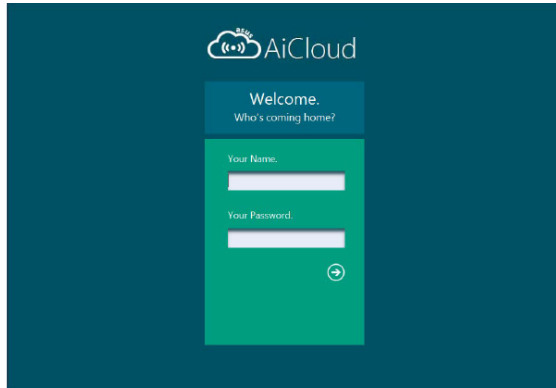
**Steps:**

- (1) Tap the function icon at the upper right corner.
- (2) Tap the check box in front of the file you want to share, then click the button corresponding to the way you want to share the file's URL.
- (3) Click email: you can send URLs by Bluetooth, Evernote, and normal email apps such as Gmail.
- (4) The HTTPS file's URL is automatically added in the mail body, but you can edit mail contents before sending.

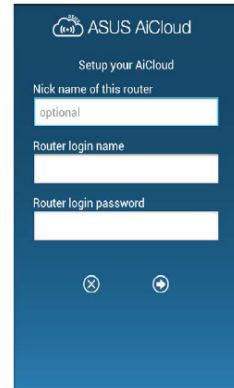
Exh. C, p. 6 of 6, AiCloud User Manual Explaining Mobile Sharing Options

Complaint

Exhibit D



Web Application



Mobile Application

Exh. D, AiCloud Web Application and Mobile Application Login Screens

Complaint

Exhibit E**The Ultra Versatile Download Master**

The RT-N56U router sets itself apart from ordinary routers by offering BitTorrent and FTP server functionality.

BitTorrent

Share your movies, music, games, and other files. The included Download Master application utilizes the BitTorrent P2P protocol to download and seed Torrents to and from the connected USB storage device. What's more, you can shut off your PC after setting up a torrent file to continue the download, PC-free. Download Master also lets you customize how you choose to share with custom bandwidth allocation when seeding.

FTP

Create your own personal FTP Server with ASUS AiDisk located within the EZ UI, and upload or download files from the connected USB storage device to any Internet-accessible PCs. Perfect when you forget documents at home or when sharing large files, FTP access grants you the ability to safely secure and access your treasured

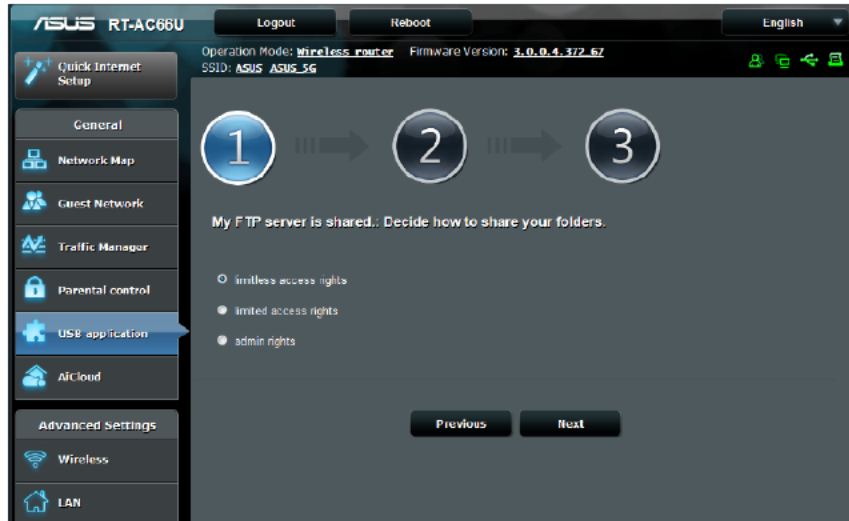
data through your router. This feature can also work without having to leave your PC on.

[View larger](#)

Exh. E, Respondent's Description of AiDisk on Retailer Website

Complaint

Exhibit F



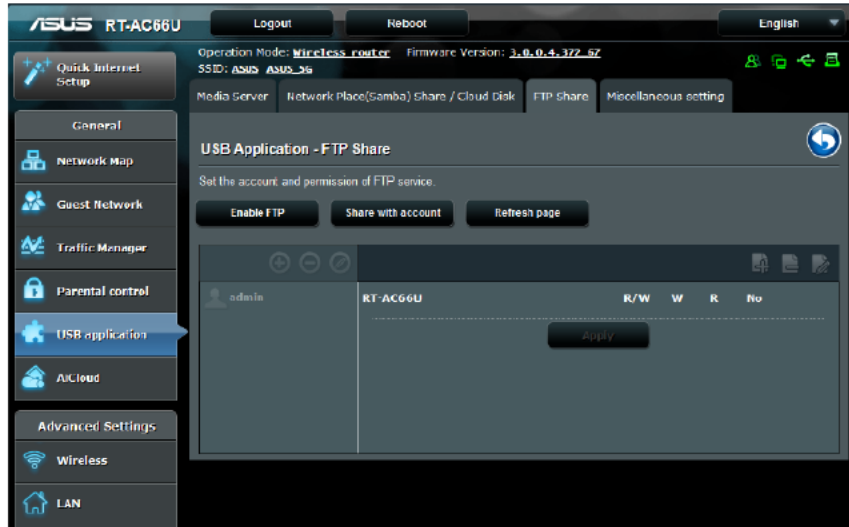
Exh. F, p. 1 of 2, AiDisk Wizard “limitless access rights” Default Setting



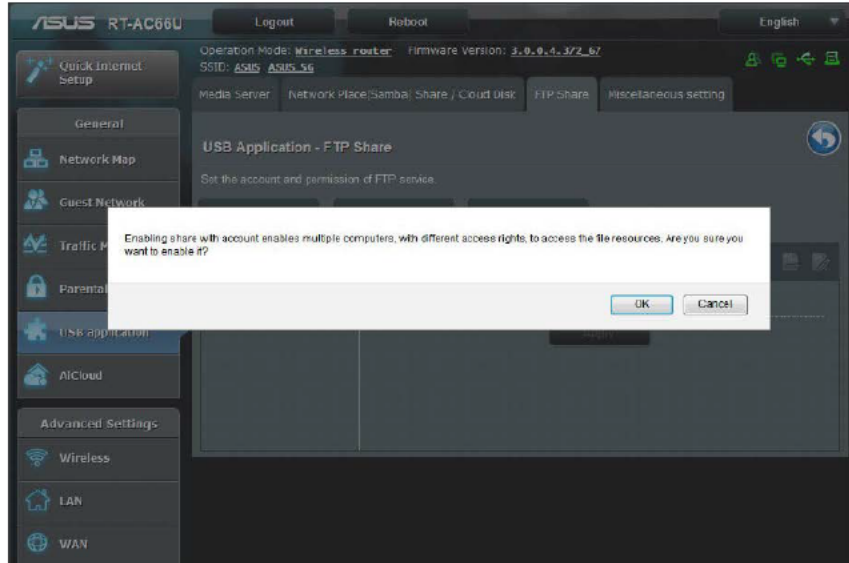
Exh. F, p. 2 of 2, Weak Recommended Login Credentials

Complaint

Exhibit G

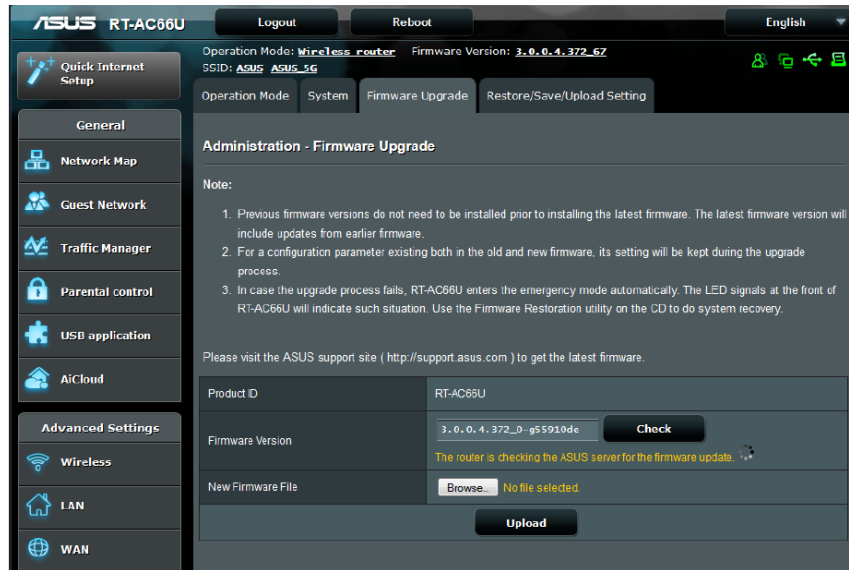


Exh. G, p. 1 of 2, “Enable FTP” and “Share with account” Options



Exh. G, p. 2 of 2, “Share with account” Warning

Decision and Order

Exhibit H

Exh. H, Firmware Upgrade Tool

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of certain acts and practices of the Respondent named above in the caption. The Commission’s Bureau of Consumer Protection (“BCP”) prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violation of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statements by Respondent that it neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for

Decision and Order

purposes of this action, it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days, and duly considered the comments filed thereafter by interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

1. Respondent ASUSTeK Computer, Inc., is a Taiwanese corporation with its principal office or place of business at 15, Li-Te Rd., Peitou, Taipei 11259, Taiwan.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For purposes of this Order, the following definitions shall apply:

- A. Unless otherwise specified, "respondent" shall mean ASUSTeK Computer, Inc., corporation, and its subsidiaries and divisions in the United States, and successors and assigns.
- B. "Clear(ly) and conspicuous(ly)" means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

Decision and Order

1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication, even if the representation requiring the disclosure is made in only one means.
 2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
 3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
 4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
 5. The disclosure must use diction and syntax understandable to ordinary consumers.
 6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
 7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
- C. “Commerce” shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or

Decision and Order

between any such Territory and another, or between any such Territory and any State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation, as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

- D. “Covered Device” shall mean (a) any router, or device for which the primary purpose is connecting other client devices to a network, developed by respondent, directly or indirectly, that is marketed to consumers in the United States and (b) the software used to access, operate, manage, or configure such router or other device subject to part (a) of this definition, including, but not limited to, the firmware, web or mobile applications, and any related online services, that are advertised, developed, branded, or provided by respondent, directly or indirectly, for use with, or as compatible with, the router or other device.
- E. “Covered Information” shall mean any individually-identifiable information from or about an individual consumer collected by respondent through a Covered Device or input into, stored on, captured with, accessed, or transmitted through a Covered Device, including but not limited to (a) a first and last name; (b) a home or other physical address; (c) an email address or other online contact information; (d) a telephone number; (e) a Social Security number; (f) financial information; (g) an authentication credential, such as a username or password; (h) photo, video, or audio files; (i) the contents of any communication, the names of any websites sought, or the information entered into any website.
- F. “Default Settings” shall mean any configuration option on a Covered Device that respondent preselects, presets, or prefills for the consumer.
- G. “Software Update” shall mean any update designed to address a Security Flaw.

Decision and Order

- H. “Security Flaw” is a software vulnerability or design flaw in a Covered Device that creates a material risk of (a) unauthorized access to or modification of any Covered Device, (b) the unintentional exposure by a consumer of Covered Information, or (c) the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of Covered Information.

I.

IT IS ORDERED that respondent and its officers, agents, representatives, and employees, directly or indirectly, in or affecting commerce, must not misrepresent in any manner, expressly or by implication:

- A. The extent to which respondent or its products or services maintain and protect:
1. The security of any Covered Device;
 2. The security, privacy, confidentiality, or integrity of any Covered Information;
- B. The extent to which a consumer can use a Covered Device to secure a network; and
- C. The extent to which a Covered Device is using up-to-date software.

II.

IT IS FURTHER ORDERED that respondent must, no later than the date of service of this order, establish and implement, and thereafter maintain, a comprehensive security program that is reasonably designed to (1) address security risks related to the development and management of new and existing Covered Devices, and (2) protect the privacy, security, confidentiality, and integrity of Covered Information. Such program, the content and implementation of which must be fully documented in writing, must contain administrative, technical, and physical safeguards

Decision and Order

appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the Covered Device's function or the Covered Information, including:

- A. The designation of an employee or employees to coordinate and be accountable for the security program;
- B. The identification of material internal and external risks to the security of Covered Devices that could result in unauthorized access to or unauthorized modification of a Covered Device, and assessment of the sufficiency of any safeguards in place to control these risks;
- C. The identification of material internal and external risks to the privacy, security, confidentiality, and integrity of Covered Information that could result in the unintentional exposure of such information by consumers or the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks;
- D. At a minimum, the risk assessments required by Subparts B and C must include consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management, including in secure engineering and defensive programming; (2) product design, development, and research; (3) secure software design, development, and testing, including for Default Settings; (4) review, assessment, and response to third-party security vulnerability reports, and (5) prevention, detection, and response to attacks, intrusions, or systems failures;
- E. The design and implementation of reasonable safeguards to control the risks identified through risk assessment, including through reasonable and appropriate software security testing techniques, such as (1) vulnerability and penetration testing; (2) security

Decision and Order

architecture reviews; (3) code reviews; and (4) other reasonable and appropriate assessments, audits, reviews, or other tests to identify potential security failures and verify that access to Covered Devices and Covered Information is restricted consistent with a user's security settings;

- F. Regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures;
- G. The development and use of reasonable steps to select and retain service providers capable of maintaining security practices consistent with this order, and requiring service providers by contract to implement and maintain appropriate safeguards consistent with this order; and
- H. The evaluation and adjustment of respondent's security program in light of the results of the testing and monitoring required by Subpart F, any material changes to respondent's operations or business arrangements, or any other circumstances that respondent knows or has reason to know may have a material impact on the effectiveness of the security program.

III.

IT IS FURTHER ORDERED that, in connection with its compliance with Part II of this order, respondent must obtain initial and biennial assessments and reports ("Assessments") from a qualified, objective, independent third-party professional, who uses procedures and standards generally accepted in the profession. Professionals qualified to prepare such Assessments must be: a person qualified as a Certified Secure Software Lifecycle Professional (CSSLP) with experience programming secure Internet-accessible consumer-grade devices; or as a Certified Information System Security Professional (CISSP) with professional experience in the Software Development Security domain and in programming secure Internet-accessible consumer-grade devices; or a similarly qualified person or organization

Decision and Order

approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580. The reporting period for the Assessments must cover: (1) the first one hundred eighty (180) days after service of the order for the initial Assessment; and (2) each two (2) year period thereafter for twenty (20) years after service of the order for the biennial Assessments. Each Assessment must:

- A. Set forth the specific controls and procedures that respondent has implemented and maintained during the reporting period;
- B. Explain how such safeguards are appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the Covered Device's function or the Covered Information;
- C. Explain how the safeguards that have been implemented meet or exceed the protections required by Part II of this order; and
- D. Certify that respondent's security program is operating with sufficient effectiveness to provide reasonable assurance that the security of Covered Devices and the privacy, security, confidentiality, and integrity of Covered Information is protected and has so operated throughout the reporting period.

Each Assessment must be prepared and completed within sixty (60) days after the end of the reporting period to which the Assessment applies. Respondent must provide the initial Assessment to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, within ten (10) days after the Assessment has been prepared. All subsequent biennial Assessments must be retained by respondent until the order is terminated and provided to the Associate Director of Enforcement within ten (10) days of request. Unless otherwise directed by a representative of the Commission, the initial Assessment, and any subsequent

Decision and Order

Assessments requested, must be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580. The subject line must begin: *In re ASUSTek Computer Inc.*, FTC File No. 142 3156.

IV.

IT IS FURTHER ORDERED that respondent must:

- A. Notify consumers, Clearly and Conspicuously, when a Software Update is available, or when respondent is aware of reasonable steps that a consumer could take to mitigate a Security Flaw. The notice must explain how to install the Software Update, or otherwise mitigate the Security Flaw, and the risks to the consumer's Covered Device or Covered Information if the consumer chooses not to install the available Software Update or take the recommended steps to mitigate the Security Flaw. Notice must be provided through at least each of the following means:
1. Posting of a Clear and Conspicuous notice on at least the primary, consumer-facing website of respondent and, to the extent feasible, on the user interface of any Covered Device that is affected;
 2. Directly informing consumers who register, or who have registered, a Covered Device with respondent, by email, text message, push notification, or another similar method of providing notifications directly to consumers; and
 3. Informing consumers who contact respondent to complain or inquire about any aspect of the Covered Device they have purchased.
- B. Provide consumers with an opportunity to register an email address, phone number, device, or other information during the initial setup or configuration of

Decision and Order

a Covered Device, in order to receive the security notifications required by this Part. The consumer's registration of such information must not be dependent upon or defaulted to an agreement to receive non-security related notifications or any other communications, such as advertising. Notwithstanding this requirement, respondent may provide an option for consumers to opt-out of receiving such security-related notifications.

V.

IT IS FURTHER ORDERED that respondent must maintain and upon request make available to the Federal Trade Commission for inspection and copying, a print or electronic copy of:

- A. For a period of three (3) years after the date of preparation of each Assessment required under Part III of this order, all materials relied upon to prepare the Assessment, whether prepared by or on behalf of the respondent, including but not limited to all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, and any other materials relating to respondent's compliance with Part III of this order, for the compliance period covered by such Assessment;
- B. Unless covered by V.A, for a period of five (5) years from the date of preparation or dissemination, whichever is later, all other documents relating to compliance with this order, including but not limited to:
 1. All advertisements, promotional materials, installation and user guides, and packaging containing any representations covered by this order, as well as all materials used or relied upon in making or disseminating the representation;

Decision and Order

2. All notifications required by Part IV of this order; and
3. Any documents, whether prepared by or on behalf of respondent, that contradict, qualify, or call into question respondent's compliance with this order.

VI.

IT IS FURTHER ORDERED that respondent must deliver a copy of this order to all current and future subsidiaries, current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having supervisory responsibilities relating to the subject matter of this order. Respondent must deliver this order to such current subsidiaries and personnel within thirty (30) days after service of this order, and to such future subsidiaries and personnel within thirty (30) days after the person assumes such position or responsibilities. For any business entity resulting from any change in structure set forth in Part VII, delivery must be at least ten (10) days prior to the change in structure.

VII.

IT IS FURTHER ORDERED that respondent must notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including, but not limited to: a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation(s) about which respondent learns fewer than thirty (30) days prior to the date such action is to take place, respondent must notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part must be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director of

Decision and Order

Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580. The subject line must begin: *In re ASUSTek Computer Inc.*, FTC File No. 142 3156.

VIII.

IT IS FURTHER ORDERED that respondent, within sixty (60) days after the date of service of this order, must file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it must submit additional true and accurate written reports.

IX.

This order will terminate on July 18, 2036, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in fewer than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order as to such respondent will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing

Analysis to Aid Public Comment

such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, a consent order applicable to ASUSTeK Computer, Inc. (“ASUS”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

ASUS is a hardware manufacturer that, among other things, sells routers, and related software and services, intended for consumer use. Routers forward data packets along a network. In addition to routing network traffic, consumer routers typically function as a hardware firewall for the local network, and act as the first line of defense in protecting consumer devices on the local network, such as computers, smartphones, internet-protocol (“IP”) cameras, and other connected appliances, against malicious incoming traffic from the internet. ASUS marketed its routers as including security features such as “intrusion detection,” and instructed consumers to “enable the [router’s] firewall to protect your local network against attacks from hackers.”

Many of ASUS’s routers also include “cloud” software features called AiCloud and AiDisk that allow consumers to attach a USB storage device to their router and then wirelessly

Analysis to Aid Public Comment

access and share files. ASUS publicized AiCloud as a “private personal cloud for selective file sharing” that featured “indefinite storage and increased privacy” and described the feature as “the most complete, accessible, and secure cloud platform.” Similarly, ASUS promoted AiDisk as a way to “safely secure and access your treasured data through your router.”

The Commission’s complaint alleges that, despite these representations, ASUS engaged in a number of practices that, taken together, failed to provide reasonable security in the design and maintenance of the software developed for its routers and related “cloud” features. The complaint challenges these failures as both deceptive and unfair. Among other things, the complaint alleges that ASUS failed to:

- a. perform security architecture and design reviews to ensure that the software is designed securely, including failing to:
 - i. use readily-available secure protocols when designing features intended to provide consumers with access to their sensitive personal information. For example, ASUS designed the AiDisk feature to use FTP rather than a protocol that supports transit encryption;
 - ii. implement secure default settings or, at the least, provide sufficient information that would ensure that consumers did not unintentionally expose sensitive personal information;
 - iii. prevent consumers from using weak default login credentials. For example, respondent allowed consumers to retain weak default login credentials to protect critical functions, such as username “admin” and password “admin” for the admin console, and username “Family” and password “Family” for the AiDisk FTP server;
- b. perform reasonable and appropriate code review and testing of the software to verify that access to data is

Analysis to Aid Public Comment

restricted consistent with a user's privacy and security settings;

- c. perform vulnerability and penetration testing of the software, including for well-known and reasonably foreseeable vulnerabilities that could be exploited to gain unauthorized access to consumers' sensitive personal information and local networks, such as authentication bypass, clear-text password disclosure, cross-site scripting, cross-site request forgery, and buffer overflow vulnerabilities;
- d. implement readily-available, low-cost protections against well-known and reasonably foreseeable vulnerabilities, as described in (c), such as input validation, anti-CSRF tokens, and session time-outs;
- e. maintain an adequate process for receiving and addressing security vulnerability reports from third parties such as security researchers and academics;
- f. perform sufficient analysis of reported vulnerabilities in order to correct or mitigate all reasonably detectable instances of a reported vulnerability, such as those elsewhere in the software or in future releases; and
- g. provide adequate notice to consumers regarding (i) known vulnerabilities or security risks, (ii) steps that consumers could take to mitigate such vulnerabilities or risks, and (iii) the availability of software updates that would correct or mitigate the vulnerabilities or risks.

The Complaint further alleges that, due to these failures, ASUS has subjected its customers to a significant risk that their sensitive personal information and local networks will be subject to unauthorized access. For example, on or before February 1, 2014, a group of hackers exploited vulnerabilities and design flaws in ASUS's routers to gain unauthorized access to thousands of consumers' USB storage devices. Numerous consumers reported having their routers compromised, and some complained

Analysis to Aid Public Comment

that a major search engine had indexed the files that the vulnerable routers had exposed, making them easily searchable online. Others claimed to be the victims of related identity theft, including a consumer who claimed identity thieves had gained unauthorized access to his USB storage device, which contained his family's sensitive personal information, such as login credentials, social security numbers, dates of birth, and tax returns. According to the consumer, the identity thieves used this information to make thousands of dollars of fraudulent charges to his financial accounts, requiring him to cancel accounts and place a fraud alert on his credit report. In addition, in April 2015, a malware researcher discovered a large-scale, active exploit campaign that reconfigured vulnerable routers so that the attackers could control and redirect consumers' web traffic. This exploit campaign specifically targeted numerous ASUS router models.

The proposed consent order contains provisions designed to prevent ASUS from engaging in the future in practices similar to those alleged in the complaint. Part I of the proposed consent order prohibits ASUS from misrepresenting: (1) the extent to which it maintains and protects the security of any covered device (including routers), or the security, privacy, confidentiality, or integrity of any covered information; (2) the extent to which a consumer can use a covered device to secure a network; and (3) the extent to which a covered device is using up-to-date software.

Part II of the proposed consent order requires ASUS to establish and implement, and thereafter maintain, a comprehensive security program that is reasonably designed to (1) address security risks related to the development and management of new and existing covered devices; and (2) protect the privacy, security, confidentiality, and integrity of covered information. The security program must contain administrative, technical, and physical safeguards appropriate to ASUS's size and complexity, nature and scope of its activities, and the sensitivity of the covered device's function or the sensitivity of the covered information. Specifically, the proposed order requires ASUS to:

- a. designate an employee or employees to coordinate and be accountable for the information security program;

Analysis to Aid Public Comment

- b. identify material internal and external risks to the security of covered devices that could result in unauthorized access to or unauthorized modification of a covered device, and assess the sufficiency of any safeguards in place to control these risks;
- c. identify material internal and external risks to the privacy, security, confidentiality, and integrity of covered information that could result in the unintentional exposure of such information by consumers or the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks;
- d. consider risks in each area of relevant operation, including, but not limited to: (1) employee training and management, including in secure engineering and defensive programming; (2) product design, development, and research; (3) secure software design, development, and testing, including for default settings; (4) review, assessment, and response to third-party security vulnerability reports, and (5) prevention, detection, and response to attacks, intrusions, or systems failures;
- e. design and implement reasonable safeguards to control the risks identified through risk assessment, including through reasonable and appropriate software security testing techniques, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures;
- f. develop and use reasonable steps to select and retain service providers capable of maintaining security practices consistent with the order, and require service providers by contract to implement and maintain appropriate safeguards; and
- g. evaluate and adjust its information security program in light of the results of testing and monitoring, any

Analysis to Aid Public Comment

material changes to ASUS's operations or business arrangement, or any other circumstances that it knows or has reason to know may have a material impact on its security program.

Part III of the proposed consent order requires ASUS to obtain, within the first one hundred eighty (180) days after service of the order and on a biennial basis thereafter for a period of twenty (20) years, an assessment and report from a qualified, objective, independent third-party professional, certifying, among other things, that: (1) it has in place a security program that provides protections that meet or exceed the protections required by Part II of the proposed consent order; and (2) its security program is operating with sufficient effectiveness to provide reasonable assurance that the security of covered devices and the privacy, security, confidentiality, and integrity of covered information is protected.

Part IV of the proposed consent order requires ASUS to provide clear and conspicuous notice to consumers when a software update for a covered device that addresses a security flaw is available or when ASUS is aware of reasonable steps that a consumer could take to mitigate a security flaw in a covered device. In addition to posting notice on its website and informing consumers that contact the company, ASUS must provide security-related notifications directly to consumers. For this purpose, ASUS must provide consumers with an opportunity to register an email address, phone number, device, or other information during the initial setup or configuration of a covered device.

Parts V through IX of the proposed consent order are reporting and compliance provisions. Part V requires ASUS to retain documents relating to its compliance with the order. The order requires that materials relied upon to prepare the assessments required by Part III be retained for a three-year period, and that all other documents related to compliance with the order be retained for a five-year period. Part VI requires dissemination of the order now and in the future to all current and future subsidiaries, current and future principals, officers, directors, and managers, and to all current and future employees,

Analysis to Aid Public Comment

agents, and representatives having supervisory responsibilities relating to the subject matter of the order. Part VII ensures notification to the FTC of changes in corporate status. Part VIII mandates that ASUS submit a compliance report to the FTC within 60 days, and periodically thereafter as requested. Part IX is a provision “sunsetting” the order after (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed consent order. It is not intended to constitute an official interpretation of the proposed complaint or consent order or to modify the consent order’s terms in any way.

Complaint

IN THE MATTER OF

LABMD, INC.COMPLAINT, OPINION OF THE COMMISSION AND FINAL ORDER IN
REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE
FEDERAL TRADE COMMISSION ACT*Docket No. 9357; File No. 102 3099*
Complaint, August 28, 2013 – Order, July 28, 2016

This case addresses LabMD, Inc.'s alleged failure to protect the sensitive personal information, including medical information, of consumers whose physicians had entrusted that information to the company. The complaint alleges that LabMD failed to implement reasonable security measures to protect the sensitive consumer information on its computer network and therefore that its data security practices were unfair under Section 5 of the Federal Trade Commission Act. In his Initial Decision, 160 F.T.C. 1190 (2015), the Administrative Law Judge dismissed the Complaint following an administrative trial, holding that Complaint Counsel had not shown that LabMD's data security practices either caused or were likely to cause substantial injury. The Commission reversed the ALJ's decision and ordered LabMD to notify affected consumers, establish a comprehensive information security program reasonably designed to protect the security and confidentiality of the personal consumer information in its possession, and obtain independent assessments regarding its implementation of the program.

Participants

For the *Commission*: Megan Cox, Maggie Lassack, Ryan Mehm, Laura Riposo VanDruff, Alain Sheer, and Ruth Yodaiken.

For the *Respondent*: Stephen Fusco, Fusco & Associates, LLC; Charles C. Murphy, Jr., Vaughan & Murphy; and Amber Abassi. *Cause of Action*.

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that LabMD, Inc. ("LabMD" or "respondent"), a corporation, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

Complaint

RESPONDENT'S BUSINESS

1. Respondent LabMD is a Georgia corporation with its principal office or place of business at 2030 Powers Ferry Road, Building 500, Suite 520, Atlanta, Georgia 30339.

2. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

3. Since at least 2001, respondent has been in the business of conducting clinical laboratory tests on specimen samples from consumers and reporting test results to consumers' health care providers.

4. Respondent files insurance claims for charges related to the clinical laboratory tests with health insurance companies. Insured consumers typically pay the part of respondent's charges not covered by insurance; uninsured consumers are responsible for the full amount of the charges. Consumers in many instances pay respondent's charges with credit cards or personal checks.

5. Respondent tests samples from consumers located throughout the United States.

6. In performing tests, respondent routinely obtains information about consumers, including, but not limited to: names; addresses; dates of birth; gender; telephone numbers; Social Security numbers ("SSN"); medical record numbers; bank account or credit card information; health care provider names, addresses, and telephone numbers; laboratory tests, test codes and results, and diagnoses; clinical histories; and health insurance company names and policy numbers (collectively, "personal information").

7. Respondent has accumulated and maintains personal information for nearly one million consumers.

8. Respondent operates computer networks in conducting its business. The computer networks include computers, servers, and other devices in respondent's corporate offices and laboratory,

Complaint

computers used by its personnel in different parts of the country, and computers that respondent provides to some health care providers.

9. Among other things, respondent uses the computer networks to: receive orders for tests from health care providers; report test results to health care providers; file insurance claims with health insurance companies; prepare bills and other correspondence to consumers; obtain approvals for payments made by consumers with credit cards; and prepare medical records. For example, respondent's billing department uses the computer networks to generate or access documents related to processing claims and payments, such as:

- a. monthly spreadsheets of insurance claims and payments ("insurance aging reports"), which may include personal information such as consumer names, dates of birth, SSNs, the American Medical Association current procedural terminology ("CPT") codes for the laboratory test conducted, and health insurance company names, addresses, and policy numbers;
- b. spreadsheets of payments received from consumers ("Day Sheets"), which may include personal information such as consumer names, SSNs, and methods, amounts, and dates of payments; and
- c. copies of consumer checks, which may include personal information such as names, addresses, telephone numbers, payment amounts, bank names and routing numbers, and bank account numbers ("copied checks").

RESPONDENT'S SECURITY PRACTICES

10. At all relevant times, respondent engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for personal information on its computer networks. Among other things, respondent:

Complaint

- a. did not develop, implement, or maintain a comprehensive information security program to protect consumers' personal information. Thus, for example, employees were allowed to send emails with such information to their personal email accounts without using readily available measures to protect the information from unauthorized disclosure;
- b. did not use readily available measures to identify commonly known or reasonably foreseeable security risks and vulnerabilities on its networks. By not using measures such as penetration tests, for example, respondent could not adequately assess the extent of the risks and vulnerabilities of its networks;
- c. did not use adequate measures to prevent employees from accessing personal information not needed to perform their jobs;
- d. did not adequately train employees to safeguard personal information;
- e. did not require employees, or other users with remote access to the networks, to use common authentication-related security measures, such as periodically changing passwords, prohibiting the use of the same password across applications and programs, or using two-factor authentication;
- f. did not maintain and update operating systems of computers and other devices on its networks. For example, on some computers respondent used operating systems that were unsupported by the vendor, making it unlikely that the systems would be updated to address newly discovered vulnerabilities; and
- g. did not employ readily available measures to prevent or detect unauthorized access to personal information on its computer networks. For example, respondent did not use appropriate measures to prevent employees

Complaint

from installing on computers applications or materials that were not needed to perform their jobs or adequately maintain or review records of activity on its networks. As a result, respondent did not detect the installation or use of an unauthorized file sharing application on its networks.

11. Respondent could have corrected its security failures at relatively low cost using readily available security measures.

12. Consumers have no way of independently knowing about respondent's security failures and could not reasonably avoid possible harms from such failures, including identity theft, medical identity theft, and other harms, such as disclosure of sensitive, private medical information.

PEER-TO-PEER FILE SHARING APPLICATIONS

13. Peer-to-peer ("P2P") file sharing applications are often used to share music, videos, pictures, and other materials between persons and entities using computers with the same or a compatible P2P application ("P2P network").

14. P2P applications allow a user to both designate files on the user's computer that are available to others on a P2P network and search for and access designated files on other computers on the P2P network.

15. After a designated file is shared with another computer, it can be passed along among other P2P network users without being downloaded again from the original source. Generally, once shared, a file cannot with certainty be removed permanently from a P2P network.

16. Since at least 2005, security professionals and others (including the Commission) have warned that P2P applications present a risk that users will inadvertently share files on P2P networks.

Complaint

SECURITY INCIDENTS

17. In May 2008, a third party informed respondent that its June 2007 insurance aging report (the "P2P insurance aging file") was available on a P2P network through Limewire, a P2P file sharing application.

18. After receiving the May 2008 notice that the P2P insurance aging file was available through Limewire, respondent determined that:

- a. Limewire had been downloaded and installed on a computer used by respondent's billing department manager (the "billing computer");
- b. at that point in time, the P2P insurance aging file was one of hundreds of files that were designated for sharing from the billing computer using Limewire; and
- c. Limewire had been installed on the billing computer no later than 2006.

19. The P2P insurance aging file contains personal information about approximately 9,300 consumers, including names, dates of birth, SSNs, CPT codes, and, in many instances, health insurance company names, addresses, and policy numbers.

20. Respondent had no business need for Limewire and removed it from the billing computer in May 2008, after receiving notice.

21. In October 2012, the Sacramento, California Police Department found more than 35 Day Sheets and a small number of copied checks in the possession of individuals who pleaded no contest to state charges of identity theft. These Day Sheets include personal information, such as names and SSNs, of several hundred consumers in different states. Many of these consumers were not included in the P2P insurance aging file, and some of the information post-dates the P2P insurance aging file. A number of the SSNs in the Day Sheets are being, or have been, used by

Complaint

people with different names, which may indicate that the SSNs have been used by identity thieves.

VIOLATION OF THE FTC ACT

22.As set forth in Paragraphs 6 through 21, respondent's failure to employ reasonable and appropriate measures to prevent unauthorized access to personal information, including dates of birth, SSNs, medical test codes, and health information, caused, or is likely to cause, substantial injury to consumers that is not offset by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers. This practice was, and is, an unfair act or practice.

23.The acts and practices of respondent as alleged in this complaint constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a).

NOTICE

Notice is hereby given to the respondent that the twenty-eighth day of April, 2014, at 10:00 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532-H, Washington, D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

You are notified that the opportunity is afforded you to file with the Federal Trade Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the

Complaint

complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings of fact and conclusions of law under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint, and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the answer is filed by the respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532-H, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, but in any event no later than five (5) days after the answer is filed by the respondent. Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving respondent's answer, to make certain disclosures without awaiting a formal discovery request.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions

Complaint

might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- B. Unless otherwise specified, “respondent” shall mean LabMD, Inc., and its successors and assigns.
- C. “Affected Individual” shall mean any consumer whose personal information LabMD has reason to believe was, or could have been, accessible to unauthorized persons before the date of service of this order, including, but not limited to, consumers listed in the Insurance File and the Sacramento Documents.
- D. “Insurance File” shall mean the file containing personal information about approximately 9,300 consumers, including names, dates of birth, Social Security numbers, health insurance company names and policy numbers, and medical test codes, that was

Complaint

available to a peer-to-peer file sharing network through a peer-to-peer file sharing application installed on a computer on respondent's computer network.

- E. "Personal information" shall mean individually identifiable information from or about an individual consumer including, but not limited to: (a) first and last name; (b) telephone number; (c) a home or other physical address, including street name and name of city or town; (d) date of birth; (e) Social Security number; (f) medical record number; (g) bank routing, account, and check numbers; (h) credit or debit card information, such as account number; (i) laboratory test result, medical test code, or diagnosis, or clinical history; (j) health insurance company name and policy number; or (k) a persistent identifier, such as a customer number held in a "cookie" or processor serial number.
- F. "Sacramento Documents" shall mean the documents identified in Appendix A.

I.

IT IS ORDERED that the respondent shall, no later than the date of service of this order, establish and implement, and thereafter maintain, a comprehensive information security program that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers by respondent or by any corporation, subsidiary, division, website, or other device or affiliate owned or controlled by respondent. Such program, the content and implementation of which must be fully documented in writing, shall contain administrative, technical, and physical safeguards appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the personal information collected from or about consumers, including:

- A. the designation of an employee or employees to coordinate and be accountable for the information security program;

Complaint

- B. the identification of material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management; (2) information systems, including network and software design, information processing, storage, transmission, and disposal; and (3) prevention, detection, and response to attacks, intrusions, or other systems failures;
- C. the design and implementation of reasonable safeguards to control the risks identified through risk assessment, and regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures;
- D. the development and use of reasonable steps to select and retain service providers capable of appropriately safeguarding personal information they receive from respondent, and requiring service providers by contract to implement and maintain appropriate safeguards; and
- E. the evaluation and adjustment of respondent's information security program in light of the results of the testing and monitoring required by Subpart C, any material changes to respondent's operations or business arrangements, or any other circumstances that respondent knows or has reason to know may have a material impact on the effectiveness of its information security program.

II.

IT IS FURTHER ORDERED that, in connection with its compliance with Part I of this order, respondent shall obtain initial

Complaint

and biennial assessments and reports (“Assessments”) from a qualified, objective, independent third-party professional, who uses procedures and standards generally accepted in the profession. Professionals qualified to prepare such assessments shall be: a person qualified as a Certified Information System Security Professional (CISSP) or as a Certified Information Systems Auditor (CISA); a person holding Global Information Assurance Certification (GIAC) from the SysAdmin, Audit, Network, Security (SANS) Institute; or a similarly qualified person or organization approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580. The reporting period for the Assessments shall cover: (1) the first one hundred and eighty (180) days after service of the order for the initial Assessment, and (2) each two (2) year period thereafter for twenty (20) years after service of the order for the biennial Assessments. Each Assessment shall:

- A. set forth the specific administrative, technical, and physical safeguards that respondent has implemented and maintained during the reporting period;
- B. explain how such safeguards are appropriate to respondent’s size and complexity, the nature and scope of respondent’s activities, and the sensitivity of the personal information collected from or about consumers;
- C. explain how the safeguards that have been implemented meet or exceed the protections required by the Part I of this order; and
- D. certify that respondent’s security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of personal information is protected and has so operated throughout the reporting period.

Each Assessment shall be prepared and completed within sixty (60) days after the end of the reporting period to which the Assessment applies. Respondent shall provide the initial

Complaint

Assessment to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, within ten (10) days after the Assessment has been prepared. All subsequent biennial Assessments shall be retained by respondent until the order is terminated and provided to the Associate Director for Enforcement within ten (10) days of request. Unless otherwise directed by a representative of the Commission, the initial Assessment, and any subsequent Assessments requested, shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580, with the subject line *In the Matter of LabMD, Inc.*, FTC File No.1023099. *Provided, however*, that in lieu of overnight courier, assessments may be sent by first-class mail, but only if an electronic version of any such assessment is contemporaneously sent to the Commission at Debrief@ftc.gov.

III.

IT IS FURTHER ORDERED that respondent shall provide notice to Affected Individuals and their health insurance companies within 60 days of service of this order unless an appropriate notice has already been provided, as follows:

- A. Respondent shall send the notice to each Affected Individual by first class mail, only after obtaining acknowledgment from the Commission or its staff that the form and substance of the notice satisfies the provisions of the order. The notice must be easy to understand and must include:
 1. a brief description of why the notice is being sent, including the approximate time period of the unauthorized disclosure, the types of personal information that were or may have been disclosed without authorization (*e.g.*, insurance information, Social Security numbers, etc.), and the steps respondent has taken to investigate the unauthorized disclosure and protect against future unauthorized disclosures;

Complaint

2. advice on how Affected Individuals can protect themselves from identity theft or related harms. Respondent may refer Affected Individuals to the Commission's identity theft website (www.ftc.gov/idtheft), advise them to contact their health care providers or insurance companies if bills don't arrive on time or contain irregularities, or to obtain a free copy of their credit report from www.annualcreditreport.com and monitor it and their accounts for suspicious activity, or take such other steps as respondent deems appropriate; and
 3. methods by which Affected Individuals can contact respondent for more information, including a toll-free number for 90 days after notice to Affected Individuals, an email address, a website, and mailing address.
- B. Respondent shall send a copy of the notice to each Affected Individual's health insurance company by first class mail.
- C. If respondent does not have an Affected Individual's mailing address in its possession, it shall make reasonable efforts to find such mailing address, such as by reviewing online directories, and once found, shall provide the notice described in Subpart A, above.

IV.

IT IS FURTHER ORDERED that respondent shall maintain and, upon request, make available to the Federal Trade Commission for inspection and copying:

- A. for a period of five (5) years, a print or electronic copy of each document relating to compliance, including, but not limited to, notice letters required by Part III of this order and documents, prepared by or on behalf of respondent, that contradict, qualify, or call into question respondent's compliance with this order; and

Complaint

- B. for a period of three (3) years after the date of preparation of each Assessment required under Part II of this order, all materials relied upon to prepare the Assessment, whether prepared by or on behalf of respondent, including, but not limited to, all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, and any other materials relating to respondent's compliance with Parts I and II of this order, for the compliance period covered by such Assessment.

V.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this order to: (1) all current and future principals, officers, directors, and managers; (2) all current and future employees, agents, and representatives having responsibilities relating to the subject matter of this order; and (3) any business entity resulting from any change in structure set forth in Part VI. Respondent shall deliver this order to such current personnel within thirty (30) days after service of this order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities. For any business entity resulting from any change in structure set forth in Part VI, delivery shall be at least ten (10) days prior to the change in structure.

VI.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any change in respondent that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor company; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in either corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such

Complaint

knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580, with the subject line *In the Matter of LabMD, Inc.*, FTC File No. 1023099. *Provided, however*, that in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of any such notice is contemporaneously sent to the Commission at Debrief@ftc.gov.

VII.

IT IS FURTHER ORDERED that respondent, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580, with the subject line *In the Matter of LabMD, Inc.*, FTC File No. 1023099.

VIII.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. any Part in this order that terminates in less than twenty (20) years;

Complaint

- B. this order's application to any respondent that is not named as a defendant in such complaint; and
- C. this order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that each respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C. this twenty-eighth day of August, 2013.

By the Commission.

Complaint

Appendix A

Day Sheet - Transaction Detail
 LABMD, INCORPORATED
 LABMD
 Friday, June 01, 2007, 09:22 AM

Page 1

Chart	Name	Diagnosis	ICD9	ICD10	Diagnosis	ICD9	ICD10	Diagnosis	ICD9	ICD10
[REDACTED]	[REDACTED]	[REDACTED]	05/31/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/31/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	05/30/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Report Summary

Charges	Patient	[REDACTED]
	Inventory	[REDACTED]
	Sales Tax	[REDACTED]
	Managed Care	[REDACTED]
	Charges Subtotal	[REDACTED]
Credits	Insurance	[REDACTED]
	Patient	[REDACTED]
	Sales Tax	[REDACTED]
	Prepayment Received	[REDACTED]
	Prepayment Offset	[REDACTED]
	Credits Subtotal	[REDACTED]
Adjustments	Debit	[REDACTED]
	Credit	[REDACTED]
	Refunds	[REDACTED]
	Charge Backs	[REDACTED]
	Adjustments Subtotal	[REDACTED]
All Locations Total		[REDACTED]

Report Balance [REDACTED]

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Friday, June 01, 2007, 09:44 AM

Page 1

Chart	Name	Bulk	Date	Time	Provider	POS	Location	TX Code	Amount
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	06/01/2007	13					[REDACTED]

Report Summary

Charges	Patient Inventory Sales Tax Managed Care Charges Subtotal
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal
Adjustments	Debit Credit Refunds Charge Backs Adjustments Subtotal
Report Balance	All Locations Total

Complaint

Day Sheet - Transaction Detail

Page 2

LABMD, INCORPORATED
LABMD
Friday, June 01, 2007, 12:17 PM

Chart	Name	Billid	Date	To Provider	Pos	Diagnosis	TX Code	Amount
			06/01/2007	13				
			06/01/2007	13				
			06/01/2007	13				
			06/01/2007	13				
			06/01/2007	13				

Report Summary

Charges	Patient Inventory Sales Tax Managed Care Charge Subtotal		
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal		
Adjustments	Debit Credit Refunds Charge Backs Adjustments Subtotal		
	All Locations Total		
Report Balance			

Complaint

Day Sheet - Transaction Detail

LABMD, INCORPORATED
LABMD
Friday, June 08, 2007, 11:19 AM

Chart	Name	Room	Date	Provider	Pos	Diagnosis	TX Code	Amount
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				
			06/08/2007	13				

Report Summary

Charges	Patient	
	Inventory	
	Sales Tax	
	Managed Care	
	Charges Subtotal	
Credits	Insurance	
	Patient	
	Sales Tax	
	Prepayment Received	
	Prepayment Offset	
	Managed Care	
	Credits Subtotal	
Adjustments	Debit	
	Credit	
	Refunds	
	Charge Backs	
	Adjustments Subtotal	
	All Locations Total	
Report Balance		

Complaint

Day Sheet - Transaction Detail
 LABMD, INCORPORATED
 LABMD
 Monday, August 04, 2008, 10:12 AM

Page 1

Chart	Name	Billing	Date	Provider	Pos	Diagnosis	TX Code	Amount
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				
[REDACTED]	[REDACTED]	[REDACTED]	08/04/2008	13				

Report Summary

Charges	Patient Inventory Sales Tax Managed Care Charges Subtotal	[REDACTED]
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal	[REDACTED]
Adjustments	Debit Credit Refunds Charge Backs Adjustments Subtotal	[REDACTED]
	All Locations Total	[REDACTED]
Report Balance		[REDACTED]

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Friday, August 08, 2008, 02:19 PM

Page 1

Cher	Name	Billg	TX Date	PRG	POL	Prgrs	TX Code	Amount
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				
			08/08/2008	13				

Report Summary

Charges	Patient Inventory Sales Tax Managed Care		
	Charges Subtotal		
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care		
	Credits Subtotal		
Adjustments	Debit Credit Refunds Charge Backs		
	Adjustments Subtotal		
	All Locations Total		
Report Balance			

Complaint

Day Sheet - Transaction Detail
 LABMD, INCORPORATED
 LABMD
 Monday, August 11, 2008, 10:14 AM

Page 1

Chart	Name	Billing	Date	Provider	POS	Diagnosis	TX Code	Charge	Amount
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					
[REDACTED]	[REDACTED]	[REDACTED]	08/11/2008	13					

Report Summary

Charges	Patient Inventory Sales Tax Managed Care Charges Subtotal	[REDACTED]
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal	[REDACTED]
Adjustments	Debit Credit Refunds Charge Backs Adjustments Subtotal	[REDACTED]
All Locations Total		[REDACTED]
Report Balance		[REDACTED]

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Monday, August 11, 2008, 11:18 AM

Page 1

Charge	Description	Quantity	Unit Price	Amount	Account	Location
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Report Summary

Charges		Patient	[REDACTED]
		Inventory	[REDACTED]
		Sales Tax	[REDACTED]
		Managed Care	[REDACTED]
		Charge Subtotal	[REDACTED]
Credits		Insurance	[REDACTED]
		Patient	[REDACTED]
		Sales Tax	[REDACTED]
		Prepayment Received	[REDACTED]
		Prepayment Offset	[REDACTED]
		Managed Care	[REDACTED]
		Credits Subtotal	[REDACTED]
Adjustments		Debit	[REDACTED]
		Credit	[REDACTED]
		Refunds	[REDACTED]
		Charge Backs	[REDACTED]
		Adjustments Subtotal	[REDACTED]
		All Locations Total	[REDACTED]
Report Balance			[REDACTED]

Complaint

Day Sheet - Transaction Detail

Page 4

LABMD, INCORPORATED
LABMD

Tuesday, August 12, 2008, 10:39 AM

Chart	Name	DOB	Age	Sex	Race	Admission	Code	Amount
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	08/12/2008	13

Report Summary

Charges	Patient	[REDACTED]
	Inventory	[REDACTED]
	Sales Tax	[REDACTED]
	Managed Care	[REDACTED]
	Charges Subtotal	[REDACTED]
Credits	Insurance	[REDACTED]
	Patient	[REDACTED]
	Sales Tax	[REDACTED]
	Prepayment Received	[REDACTED]
	Prepayment Offset	[REDACTED]
	Managed Care	[REDACTED]
	Credits Subtotal	[REDACTED]
Adjustments	Debit	[REDACTED]
	Credit	[REDACTED]
	Refunds	[REDACTED]
	Charge Backs	[REDACTED]
	Adjustments Subtotal	[REDACTED]
	All Locations Total	[REDACTED]
Report Balance		[REDACTED]

Complaint

Day Sheet - Transaction Detail

Page 1

LABMD, INCORPORATED

LABMD

Thursday, August 21, 2008, 04:57 PM

Chrg	Nbr	Desc	QTY	Rate	Total	TX Code	Amnt
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Report Summary

Charges	Patient	[Redacted]
	Inventory	[Redacted]
	Sales Tax	[Redacted]
	Managed Care	[Redacted]
	Charges Subtotal	[Redacted]
Credits	Insurance	[Redacted]
	Patient	[Redacted]
	Sales Tax	[Redacted]
	Prepayment Received	[Redacted]
	Prepayment Offset	[Redacted]
	Managed Care	[Redacted]
	Credits Subtotal	[Redacted]
Adjustments	Debit	[Redacted]
	Credit	[Redacted]
	Refunds	[Redacted]
	Charge Backs	[Redacted]
	Adjustments Subtotal	[Redacted]
	All Locations Total	[Redacted]
Report Balance		[Redacted]

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Wednesday, August 27, 2008, 10:27 AM

Page 1

Chart	Name	Blind	Date	Prov	Pos	Diagnosis	TX Code	Amount
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				
			08/27/2008	13				

Report Summary

Charges	<ul style="list-style-type: none"> Patient Inventory Sales Tax Managed Care Charges Subtotal 		
Credits	<ul style="list-style-type: none"> Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal 		
Adjustments	<ul style="list-style-type: none"> Debit Credit Refunds Charge Backs Adjustments Subtotal All Locations Total 		
Report Balance			

FEDERAL TRADE COMMISSION DECISIONS
VOLUME 162

Complaint

Day Sheet - Transaction Detail

Page 1

LABMD, INCORPORATED
LABMD
Wednesday, August 27, 2008, 11:35 AM

Chart	Pos	Name	Bill	Date	Prov	Pos	Code	TX Code	Amount
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				
				08/27/2008	13				

Report Summary

Charges	Patient	[REDACTED]
	Inventory	
	Sales Tax	
	Managed Care	
Charges Subtotal		
Credits	Insurance	[REDACTED]
	Patient	
	Sales Tax	
	Prepayment Received	
	Prepayment Offset	
Managed Care		
Credits Subtotal		
Adjustments	Debit	[REDACTED]
	Credit	
	Refunds	
	Charge Backs	
	Adjustments Subtotal	
All Locations Total		
Report Balance		[REDACTED]

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD

Page 1

Wednesday, August 27, 2008, 12:06 PM

DATE	TIME	AMOUNT	DESCRIPTION	TX CODE	AMOUNT
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				
08/27/2008	13				

Report Summary

Charges	Patient Inventory Sales Tax Managed Care Charges Subtotal
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal
Adjustments	Debit Credit Refunds Charge Backs Adjustments Subtotal
All Locations Total	

Report Balance		

Complaint

Day Sheet - Transaction Detail

Page 1

LABMD, INCORPORATED

LABMD

Friday, August 26, 2008, 09:21 AM

Name	Bill to	Day	Time	Location	POS	Diagnosis	Code	Amount
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]
[REDACTED]	[REDACTED]	08/23/2008					13	[REDACTED]

Report Summary

Charges	Patient	[REDACTED]
	Inventory	[REDACTED]
	Sales Tax	[REDACTED]
	Managed Care	[REDACTED]
	Charges Subtotal	[REDACTED]
Credits	Insurance	[REDACTED]
	Patient	[REDACTED]
	Sales Tax	[REDACTED]
	Prepayment Received	[REDACTED]
	Prepayment Offset	[REDACTED]
Managed Care	[REDACTED]	
Credits Subtotal	[REDACTED]	
Adjustments	Debit	[REDACTED]
	Credit	[REDACTED]
	Refunds	[REDACTED]
	Charge Backs	[REDACTED]
	Adjustments Subtotal	[REDACTED]
All Locations Total	[REDACTED]	
Report Balance	[REDACTED]	

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Wednesday, September 10, 2008, 04:22 PM

Page 1

Chart	Name	Room	Unit	Ref	Date	Time	Provider	Procedure	Diagnosis	ICD9	ICD10	Code	Rate	Amount	Unit	Rate	Amount
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/10/2008	13											

Report Summary

Charges	Patient	Inventory	Sales Tax	Managed Care	Charges Subtotal		
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		
Credits	Insurance	Patient	Sales Tax	Prepayment Received	Prepayment Offset	Managed Care	Credits Subtotal
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Adjustments	Debit	Credit	Refunds	Charge Backs	Adjustments Subtotal		
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		
All Locations Total	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		
Report Balance	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]		

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Wednesday, September 10, 2008, 04:59 PM

Page 1

Char	Name	Bill	Date	Prov	RS	Diagn	TX Code	Amount
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/10/2008	13				[Redacted]

Report Summary

Charges
Patient
Inventory
Sales Tax
Managed Care
Charges Subtotal

Credits
Insurance
Patient
Sales Tax
Prepayment Received
Prepayment Offset
Managed Care
Credits Subtotal

Adjustments
Debit
Credit
Refunds
Charge Backs
Adjustments Subtotal

All Locations Total

Report Balance

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Thursday, September 11, 2008, 09:46 AM

Page 1

Charge	Name	Bill	Invoice	Product	TX Code	Amount
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	09/11/2008	13	[REDACTED]

Report Summary

Charges	Patient	[REDACTED]
	Inventory	
	Sales Tax	
	Managed Care	
	Charges Subtotal	
Credits	Insurance	[REDACTED]
	Patient	
	Sales Tax	
	Prepayment Received	
	Prepayment Offset	
	Credits Subtotal	
Adjustments	Debit	[REDACTED]
	Credit	
	Refunds	
	Charge Backs	
	Adjustments Subtotal	
	All Locations Total	
Report Balance		[REDACTED]

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD.
Thursday, September 11, 2008, 10:02 AM

Page 1

CHARGE	TRANSACT NAME	DATE	TIME	PROVIDER	POS	DIAGNOSIS	CODE	AMOUNT
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						
		09/11/2008						

Report Summary

Charges	Patient Inventory Sales Tax Managed Care Charges Subtotal	
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal	
Adjustments	Debit Credit Refunds Charge Backs Adjustments Subtotal	
	All Locations Total	
Report Balance		

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Friday, September 19, 2006, 12:39 PM

Page 1

Chart	SN	Unit	Billable	Lab Data	Profile	Prior	Charge	PO	TS	Code	Amount
				09/19/2008	13						
				09/18/2008	13						
				09/18/2008	13						
				09/19/2008	13						
				09/19/2008	13						
				09/19/2008	13						
				09/18/2008	13						
				09/19/2008	13						
				09/19/2008	13						
				09/18/2008	13						
				09/19/2008	13						
				09/19/2008	13						
				09/18/2008	13						
				09/19/2008	13						

Report Summary

Charges	Patient	
	Inventory	
	Sales Tax	
	Managed Care	
	Charges Subtotal	
Credits	Insurance	
	Patient	
	Sales Tax	
	Prepayment Received	
	Prepayment Offset	
	Managed Care	
Credits Subtotal		
Adjustments	Debit	
	Credit	
	Refunds	
	Charge Backs	
	Adjustments Subtotal	
All Locations Total		
Report Balance		

Complaint

Day Sheet - Transaction Detail

Page 1

LABMD, INCORPORATED
LABMD

Friday, September 19, 2008, 01:51 PM

Charge Name	Amount	Date	Time	Code	Description	Diagnosis	TX Code	Amount
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]
[REDACTED]	[REDACTED]	09/19/2008	13					[REDACTED]

Report Summary

Charges Patient Inventory Sales Tax Managed Care Charges Subtotal	Credits Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal	Adjustments Debit Credit Refunds Charge Backs Adjustments Subtotal	All Locations Total	[REDACTED]
---	---	--	----------------------------	------------

Report Balance [REDACTED]

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Monday, September 22, 2008, 02:31 PM

Charge	Name	Quantity	Date	Time	Procedure	Room	Disposal	TX Code	Time
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					
			09/22/2008	13					

Report Summary

Charges	Patient Inventory Sales Tax Managed Care Charges Subtotal	
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal	
Adjustments	Debit Credit Refunds Charge Backs Adjustments Subtotal	
	All Locations Total	
Report Balance		

Complaint

Day Sheet - Transaction Detail
 LABMD, INCORPORATED
 LABMD
 Tuesday, November 25, 2008, 10:54 AM

Page 1

Chart	Name	Bill	Date	Provider	BoS	Diagnosis	TX Code	Amount
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					
			09/22/2008					

Report Summary

Charges	Patient	
	Inventory	
	Sales Tax	
	Managed Care	
	Charges Subtotal	
Credits	Insurance	
	Patient	
	Sales Tax	
	Prepayment Received	
	Prepayment Offset	
	Managed Care	
	Credits Subtotal	
Adjustments	Debit	
	Credit	
	Refunds	
	Charge Backs	
	Adjustments Subtotal	
	All Locations Total	
Report Balance		

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Tuesday, November 26, 2008, 11:18 AM

Page 1

Chart	Name	Blind	Date	Prvider	Pos	Diagnosis	TX Code	Amount
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]
[Redacted]	[Redacted]	[Redacted]	09/22/2008	13				[Redacted]

Report Summary

Category	Item	Amount
Charges	Patient	[Redacted]
	Inventory	[Redacted]
	Sales Tax	[Redacted]
	Managed Care	[Redacted]
	Charges Subtotal	[Redacted]
Credits	Insurance	[Redacted]
	Patient	[Redacted]
	Sales Tax	[Redacted]
	Prepayment Received	[Redacted]
	Prepayment Offset	[Redacted]
	Managed Care	[Redacted]
	Credits Subtotal	[Redacted]
Adjustments	Debit	[Redacted]
	Credit	[Redacted]
	Refunds	[Redacted]
	Charge Backs	[Redacted]
	Adjustments Subtotal	[Redacted]
All Locations Total		[Redacted]
Report Balance		[Redacted]

FEDERAL TRADE COMMISSION DECISIONS
VOLUME 162

Complaint

Day Sheet - Transaction Detail

Page 1

LABMD, INCORPORATED

LABMD

Monday, December 01, 2008, 11:19 AM

Chart	Name	Elig	08/01/2008	13	Procedure	Diagnosis	TX Code	Amount
			08/02/2008	13				
			08/03/2008	13				
			08/04/2008	13				
			08/05/2008	13				
			08/06/2008	13				
			08/07/2008	13				
			08/08/2008	13				
			08/09/2008	13				
			08/10/2008	13				
			08/11/2008	13				
			08/12/2008	13				
			08/13/2008	13				
			08/14/2008	13				
			08/15/2008	13				
			08/16/2008	13				
			08/17/2008	13				
			08/18/2008	13				
			08/19/2008	13				
			08/20/2008	13				
			08/21/2008	13				
			08/22/2008	13				
			08/23/2008	13				
			08/24/2008	13				
			08/25/2008	13				
			08/26/2008	13				
			08/27/2008	13				
			08/28/2008	13				
			08/29/2008	13				
			08/30/2008	13				
			08/31/2008	13				
			09/01/2008	13				
			09/02/2008	13				
			09/03/2008	13				
			09/04/2008	13				
			09/05/2008	13				
			09/06/2008	13				
			09/07/2008	13				
			09/08/2008	13				
			09/09/2008	13				
			09/10/2008	13				
			09/11/2008	13				
			09/12/2008	13				
			09/13/2008	13				
			09/14/2008	13				
			09/15/2008	13				
			09/16/2008	13				
			09/17/2008	13				
			09/18/2008	13				
			09/19/2008	13				
			09/20/2008	13				
			09/21/2008	13				
			09/22/2008	13				
			09/23/2008	13				
			09/24/2008	13				
			09/25/2008	13				
			09/26/2008	13				
			09/27/2008	13				
			09/28/2008	13				
			09/29/2008	13				
			09/30/2008	13				

Report Summary

Charges
Patient
Inventory
Sales Tax
Managed Care
Charges Subtotal

Credits
Insurance
Patient
Sales Tax
Prepayment Received
Prepayment Offset
Managed Care
Credits Subtotal

Adjustments
Debit
Credit
Refunds
Charge Backs
Adjustments Subtotal

All Locations Total

Report Balance

Complaint

Day Sheet - Transaction Detail

LABMD, INCORPORATED
LABMD
Tuesday, March 10, 2009, 12:31 PM

Clmt	Name	Blng	Date	Prvd	BoS	Diagnos	TY	Code	Amount
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█
█	█	█	03/10/2009	13					█

Report Summary

Charges	Patient	█
	Inventory	█
	Sales Tax	█
	Managed Care	█
	Charges Subtotal	█
Credits	Insurance	█
	Patient	█
	Sales Tax	█
	Prepayment Received	█
	Prepayment Offset	█
	Managed Care	█
	Credits Subtotal	█
Adjustments	Debit	█
	Credit	█
	Rebills	█
	Charge Backs	█
	Adjustments Subtotal	█
	All Locations Total	█
Report Balance		█

Complaint

Day Sheet - Transaction Detail
LABMD, INCORPORATED
LABMD
Tuesday, March 24, 2009, 03:30 PM

Page 1

Chart	Name	Billing	Date	Provider	POS	Diagnosis	TX Code	Amount
[REDACTED]	[REDACTED]	[REDACTED]	03/24/2009	13				[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	03/24/2009	13				[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	03/24/2009	13				[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	03/24/2009	13				[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	03/24/2009	13				[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	03/24/2009	13				[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	03/24/2009	13				[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	03/24/2009	13				[REDACTED]

Report Summary

Charges	Patient Inventory Sales Tax Managed Care Charges Subtotal	[REDACTED]
Credits	Insurance Patient Sales Tax Prepayment Received Prepayment Offset Managed Care Credits Subtotal	[REDACTED]
Adjustments	Debit Credit Refunds Charge Backs Adjustments Subtotal	[REDACTED]
	All Locations Total	[REDACTED]
Report Balance		[REDACTED]

Complaint

Name Redacted Redacted Redacted Handwritten Notes Redacted
 Address Redacted DATE 5-27-07
 PAY TO LABMD Amount Redacted
 Amount Redacted
 MEMO Redacted
 Banking Information Redacted

Name Redacted Redacted
 Address Redacted March 2 2008
 PAY TO THE ORDER OF LabMD Amount Redacted
 Amount Redacted
 FOR Redacted
 Banking Information Redacted

Name Redacted Redacted
 Address Redacted DATE Sept 25 2008
 PAY TO THE ORDER OF LABMD Amount Redacted
 Amount Redacted
 Memo Redacted
 Banking Information Redacted

Complaint

Name Redacted
Address Redacted
Date: 8/19/08
Amount Redacted
Pay to the order of: LABMD
Amount Redacted
Handwritten Notes Redacted
Family Notes Redacted
For: [Redacted]
Banking Information Redacted

Name Redacted
Address Redacted
Date: 25 Sept 08
Amount Redacted
Pay to the order of: LABMD
Amount Redacted
For: [Redacted]
Banking Information Redacted

Name Redacted
Address Redacted
Date: 9/24/08
Amount Redacted
Pay to the order of: LABMD, INC.
Amount Redacted
For: [Redacted]
Banking Information Redacted
Handwritten Note Redacted

Complaint

Name Redacted
Address Redacted

3/27/07

Redacted

Handwritten Notes Redacted

Pay to the Order of LABMD

Amount Redacted

Redacted

Redacted

For

Redacted

Name Redacted
Address Redacted

5/30 20 07

Redacted

Handwritten Notes Redacted

Pay To The Order Of LABMD

Amount Redacted

Amount Redacted

Redacted

Memo

Redacted

Name Redacted
Address Redacted

3/26/07

Redacted

Handwritten Notes Redacted

Pay to the Order of Labmd

Amount Redacted

Redacted

Redacted

FOR

Redacted

Complaint



Opinion of the Commission

OPINION OF THE COMMISSION

By Chairwoman Edith Ramirez, for the Commission:

This case concerns the alleged failure by Respondent LabMD, Inc. to protect the sensitive personal information, including medical information, of consumers whose physicians had entrusted that information to the company. Specifically, Complaint Counsel alleges that LabMD failed to implement reasonable security measures to protect the sensitive consumer information on its computer network and therefore that its data security practices were unfair under Section 5 of the Federal Trade Commission Act. The Administrative Law Judge dismissed the Complaint following an administrative trial, holding that Complaint Counsel had not shown that LabMD's data security practices either caused or were likely to cause substantial injury.

As we explain below, we conclude that the ALJ applied the wrong legal standard for unfairness. We also find that LabMD's security practices were unreasonable, lacking even basic precautions to protect the sensitive consumer information maintained on its computer system. Among other things, it failed to use an intrusion detection system or file integrity monitoring; neglected to monitor traffic coming across its firewalls; provided essentially no data security training to its employees; and never deleted any of the consumer data it had collected. These failures resulted in the installation of file-sharing software that exposed the medical and other sensitive personal information of 9,300 consumers on a peer-to-peer network accessible by millions of users. LabMD then left it there, freely available, for 11 months, leading to the unauthorized disclosure of the information.

We therefore reverse the ALJ's decision and conclude that LabMD's data security practices constitute an unfair act or practice within the meaning of Section 5 of the FTC Act. We enter an order requiring that LabMD notify affected consumers, establish a comprehensive information security program reasonably designed to protect the security and confidentiality of the personal consumer information in its possession, and obtain

Opinion of the Commission

independent assessments regarding its implementation of the program.

FACTUAL BACKGROUND

From 2001 until early 2014, LabMD operated as a clinical laboratory conducting tests on patient specimen samples and reporting the test results to its physician customers.¹ Once patients' personal information had been downloaded to LabMD's network, physician-clients could order tests and access test results using LabMD's online portal. IDF 46, 50. Over the course of its operations, LabMD collected sensitive personal information, including medical information, for over 750,000 patients. IDF 42-43. This information included names, addresses, dates of birth, Social Security numbers, insurance information, diagnosis codes, and physician orders for tests and services. IDF 44. In many instances, LabMD retrieved the personal information of all of the patients in its physician-clients' databases, regardless of whether LabMD performed tests for those patients. IDF 43.

As discussed in more detail below, from at least 2005 until 2010, LabMD did not have basic data security practices in place for its network. For instance, it had no file integrity monitoring or intrusion detection system in place and did not adequately monitor traffic coming across its firewalls. It failed to provide data security training to its information technology personnel or other employees, in violation of its own internal compliance program. LabMD also lacked a policy requiring strong passwords. For example, at least six employees used "labmd" as

¹ IDF 24-26. This opinion uses the following abbreviations for citations to the record:

Comp.: Complaint

ID: Initial Decision of the Administrative Law Judge

IDF: Numbered Findings of Fact in the ALJ's Initial Decision

Tr.: Transcript of Trial before the ALJ

CX: Complaint Counsel's Exhibit

RX: Respondent's Exhibit

RAB: Respondent LabMD Inc.'s Corrected Answering Brief

Motion to Dismiss: Respondent LabMD Inc.'s Motion to Dismiss Complaint with Prejudice and to Stay Administrative Proceedings (Nov. 12, 2013)

Opinion of the Commission

their login password.² It also failed to take steps to update its software and protect against known vulnerabilities that could be exploited to gain unauthorized access to consumers' personal information.³

Additionally, until at least the fall of 2009, management employees were given administrative rights over their workstations and sales employees had administrative rights over their laptop computers. This gave them the ability to change security settings and to download software applications and files of all types from the Internet, many of which – like peer-to-peer (“P2P”) file-sharing applications and music files – were unrelated to LabMD’s business.

In or about 2005, the P2P file-sharing program LimeWire was downloaded and installed on a computer used by LabMD’s billing manager.⁴ It was widely known in the billing department that the billing manager and others in the department regularly used LimeWire while at work, primarily for downloading and listening to music.⁵

Often used to share music, videos, and photographs, P2P file-sharing applications allow one computer user to search for and download all files that have been made available for sharing on a “host” computer that is also using the same file-sharing application. IDF 63. LimeWire was one of a number of common P2P applications that used the “Gnutella” P2P protocol.⁶ A user shares files on the Gnutella network by designating a directory on

2 CX0167; CX0705-A (Bradley dep.) at 125-26.

3 *See, e.g.*, CX0740 (Hill Expert Report) ¶¶ 70-71, 98-99; CX0731 (Truett dep.) at 81-84.

4 *See, e.g.*, CX0755 at 4, Response to Interrog. 3; CX0766 at 8-9, Admiss. 40-41; CX0447 at 6-7; CX0150 (Screenshot: C:\) at 1; CX0730 (Simmons dep.) at 10, 24-25.

5 CX0681 at 7; CX0733 (Boyle IH) at 27; CX0730 (Simmons dep.) at 140; CX0716 (Harris dep.) at 86-89, 149; CX0714-A ([Fmr. LabMD Empl.] dep.) at 29-33, 128-31.

6 IDF 69-71; Shields, Tr. 851.

Opinion of the Commission

his or her computer as a shared directory, making all of the files within the directory freely available for downloading and viewing by other users of the network.⁷ Once a file is downloaded by a user from the Gnutella network, the file can be shared further without downloading it again from the original computer. Because of the ease of sharing, it can be extremely difficult or impossible to remove a file from the network once it has been downloaded.⁸ Between 2005 and 2010, the Gnutella network had between two and five million users online at any given time.⁹

In February 2008, Richard Wallace, a forensic analyst employed by Tiversa Holding Company, a data security company, discovered and downloaded a copy of one of LabMD's insurance aging reports.¹⁰ Mr. Wallace testified that he used a P2P network and standard P2P application like LimeWire to download the file from a LabMD IP address in Atlanta, Georgia. IDF 121-22. This file, dated June 7, 2007 and referred to as the "1718 file," contained 1,718 pages of sensitive personal information for approximately 9,300 consumers, including their names, dates of birth, social security numbers, "CPT" codes designating specific medical tests and procedures for lab tests conducted by LabMD, and, in some instances, health insurance company names, addresses, and policy numbers. IDF 78, 82. Using the "browse host" function on LimeWire, which enabled him to view all of the shared, downloadable files on LabMD's computer, Mr. Wallace downloaded other documents from the same IP address. IDF 127. Three of these documents also contained sensitive personal information from three consumers, including health insurance data, date of birth, and social security number.¹¹

⁷ See, e.g., Shields, Tr. 852; CX0738 (Shields Rebuttal Report) ¶ 17; RX533 (Fisk Expert Report) at 10.

⁸ See, e.g., Shields, Tr. 852-54; CX0738 (Shields Rebuttal Report) ¶ 21; CX0740 (Hill Report) ¶ 44.

⁹ See Fisk, Tr. 1181; RX533 (Fisk Expert Report) at 15; Shields, Tr. 833.

¹⁰ IDF 121-24. Used to track accounts receivable, LabMD's insurance aging reports are spreadsheets documenting insurance claims and payments, and include patients' medical information supporting insurance claims. IDF 52-53.

¹¹ *Id.*; RX0645 at 39, 42, 43 (*in camera*). We have concentrated our analysis on the much larger 1718 file, but the exposure of sensitive personal information

Opinion of the Commission

In May 2008, Tiversa, with the aim of obtaining LabMD's business, informed LabMD that the 1718 file had been exposed through LimeWire. IDF 128. Tiversa repeatedly solicited LabMD, offering to sell its breach detection services, and later falsely claimed it had evidence that the 1718 file had spread further across P2P networks.¹²

After being contacted by Tiversa, LabMD conducted an internal investigation to determine how the 1718 file had been exposed. IDF 80, 84. It turned out that, during the time that LimeWire had been on the billing manager's computer, the entire contents of her "My Documents" folder had been designated for sharing. IDF 85, 89. Although most of the 950 files in the shared folder were music or videos, the 1718 file and other documents were shared as well. IDF 85-87. Despite clear onscreen warnings from LimeWire that the documents were being shared, neither the billing manager nor anyone else who knew about the P2P file-sharing program did anything to protect the patient information that was being exposed until Tiversa notified LabMD of the disclosure.¹³ Once informed of the disclosure, LabMD never notified any of the consumers listed in the 1718 file that their personal information had been disclosed.¹⁴

Later, in 2010, LabMD hired an independent security firm, ProviDyn, to perform penetration tests on its system and catalogue the vulnerabilities it found. CX0070. ProviDyn identified a number of urgent and critical vulnerabilities on four of the seven servers it tested and rated the overall security of each

in these additional documents raises concerns similar to those raised by the exposure of comparable information in the 1718 file.

12 IDF 128-29. In 2009, in response to a request for information from the Commission, a Tiversa affiliate provided the 1718 file to the FTC. IDF 138.

13 See CX0152 (Screenshot: LimeWire: My Shared Files) at 1; CX0154 (Screenshot: LimeWire Get Started) at 1 (screenshots showing warning that the billing computer was sharing numerous files and sub-folders, which could create a security risk); CX0730 (Simmons dep.) at 27-29, 93 (LabMD IT specialist who investigated the 1718 file incident, noting that the billing manager "had no idea what she was doing" when it came to P2P file sharing).

14 CX0710-A (Daugherty Designee dep.) at 48; Daugherty, Tr. 1087.

Opinion of the Commission

server as poor. CX0067-CX0071. Among the four servers was the “Mapper” server that LabMD used to receive sensitive information of hundreds of thousands of consumers from physician clients.¹⁵

Then, in 2012, the Sacramento California Police Department found 40 LabMD “day sheets” containing the names and social security numbers of 600 people, copied checks revealing the names, addresses, and bank numbers of nine individuals, and one money order payable to LabMD (collectively, the “Sacramento documents”) while searching the home of individuals suspected of utility billing theft. IDF 182-86, 189-92. The Sacramento Police Department collected the documents as evidence and arrested the two individuals who had possession of the documents; the arrested individuals later pled *nolo contendere* to identity theft. IDF 194-96.

In January 2014, LabMD stopped conducting lab tests and began winding down its business. IDF 36. It continues to preserve tissue samples and provide past test results to healthcare providers. IDF 37, 39. LabMD has not destroyed or deleted any of the patient data it collected. As a result, it continues to maintain the personal data of hundreds of thousands of people on its computer system. IDF 40-42.

PROCEDURAL BACKGROUND

A. The Allegations

On August 28, 2013, the Commission unanimously voted to issue a Complaint against LabMD, alleging that, from 2005 onward, LabMD failed to provide reasonable and appropriate security for personal information stored on its computer network and that its failure caused or was likely to cause substantial consumer injury, including identity theft, medical identity theft, and other harms, such as the disclosure of sensitive, private medical information. Comp. ¶¶ 10, 12, 22. The Complaint alleges further that LabMD “could have corrected its security failures at relatively low cost using readily available security

¹⁵ CX0725-A (Martin dep.) at 82-83; CX0704-A (Boyle dep.) at 24.

Opinion of the Commission

measures”; that “consumers have no way of independently knowing about respondent’s security failures and could not reasonably avoid [these] possible harms”; and that these harms are not offset by countervailing benefits to consumers or competition. *Id.* ¶¶ 11, 12, 22. The Complaint also alleges that LabMD experienced two security breach incidents exposing the 1718 file and possibly other documents containing personal information and the Sacramento documents. *Id.* ¶¶ 17-20. Accordingly, the Complaint alleges that LabMD’s security failures constitute an unfair act or practice in violation of Section 5 of the FTC Act, and seeks, among other things, relief requiring LabMD to implement a comprehensive program to protect the security, confidentiality, and integrity of the personal information in its possession. *Id.* ¶¶ 22-23; Comp., Notice Order § I at 7.

LabMD filed its Answer on September 17, 2013. It admitted that LimeWire had been downloaded and installed on a computer used by its billing manager, that it was installed “no later than 2006,” and that the 1718 file contains “personal information about approximately 9,300 referring physicians’ patients, including names, dates of birth, SSNs, CPT codes, and health insurance company names, addresses, and policy numbers.” Ans. ¶¶ 18-19. LabMD denied, or pled insufficient knowledge to admit or deny, most of the other allegations concerning the LimeWire and Sacramento security breach incidents. *Id.* ¶¶ 17-20. LabMD also denied that its security practices were unreasonable or inappropriate and that they violated the FTC Act. Ans. ¶¶ 10, 23.

In addition, LabMD asserted a number of affirmative defenses, including contentions that the Commission lacks statutory authority to regulate the acts or practices alleged in the Complaint; the practices alleged did not cause and are unlikely to cause substantial injury to consumers; and the Commission’s alleged failure to provide notice or meaningful standards on data security violates the Fifth Amendment’s due process guarantee and the Administrative Procedure Act. *Id.* at 6-7.

Opinion of the Commission

B. LabMD's Motions to Dismiss and for Summary Decision

On November 12, 2013, LabMD filed the first of several motions to dismiss the Complaint, arguing that the Commission lacks statutory authority to regulate or bring enforcement actions with respect to data security practices and that the Complaint failed to state a valid claim for relief. The Commission rejected LabMD's jurisdictional arguments and denied the motion on January 16, 2014.¹⁶

On April 21, 2014, LabMD filed a motion for summary decision in which it again raised many of the same jurisdictional challenges and due process arguments it had raised in previous filings. The Commission denied LabMD's motion by order dated May 19, 2014.

C. LabMD's Collateral Attempts to Enjoin the FTC's Enforcement Action

On November 14, 2013, LabMD filed a complaint in the U.S. District Court for the District of Columbia, seeking to enjoin the FTC's enforcement action based on many of the same arguments it had made in its motions to dismiss. A month later, LabMD filed a petition for review in the Eleventh Circuit and moved for a stay of the FTC's administrative proceedings. On February 18, 2014, the Eleventh Circuit dismissed LabMD's petition for lack of jurisdiction. *LabMD, Inc. v. FTC*, Case 13-15267 (11th Cir., Feb. 18, 2014) (*per curiam*). LabMD subsequently withdrew its pending complaint before the D.C. District Court.

¹⁶ On April 24, 2015, LabMD filed another motion to dismiss, arguing that Complaint Counsel had engaged in "misconduct and indiscretions" in the investigation and prosecution of the case, including its reliance on the evidence provided by Tiversa. The ALJ denied that motion on May 26, 2015. On July 14, 2015, LabMD moved to amend its Answer to add another affirmative defense claiming that the ALJ was not properly appointed under the Appointments Clause of the U.S. Constitution, and then filed another motion to dismiss contending that the FTC's enforcement action was therefore constitutionally defective. The ALJ granted LabMD leave to amend its Answer on July 27, 2015, and we denied the motion to dismiss on September 14, 2015.

Opinion of the Commission

In March 2014, LabMD sued for declaratory and injunctive relief in the U.S. District Court for the Northern District of Georgia seeking to enjoin the proceeding before the ALJ and to prohibit the FTC from bringing any further action against it. The district court denied LabMD's motion and granted the FTC's motion to dismiss for lack of subject matter jurisdiction on May 12, 2014. *LabMD, Inc. v. FTC*, 2014 WL 1908716 (N.D. Ga., May 12, 2014). The Eleventh Circuit affirmed on January 20, 2015, concluding that LabMD's arguments are reviewable only after the administrative proceedings are final. *LabMD, Inc. v. FTC*, 776 F.3d 1275, 1277 (11th Cir. 2015).

D. The Evidentiary Hearing

The evidentiary hearing before Chief Administrative Law Judge D. Michael Chappell began on May 20, 2014 and was completed on July 15, 2015.¹⁷

Complaint Counsel called four expert witnesses. Dr. Raquel Hill, a tenured professor of computer science at Indiana University, was called to assess whether LabMD provided reasonable security for the personal information on its computer networks. Rick Kam, a certified information privacy professional, was asked to assess the risk of injury to consumers resulting from the unauthorized disclosure of sensitive personal information and to describe the types of consumer injuries that occur when firms fail to take reasonable precautions to protect private financial and medical data. James Van Dyke, the founder and President of Javelin Strategy & Research, which conducts survey research on identity theft, assessed the risk of injury to consumers whose personally identifiable information has been disclosed or not adequately protected from unauthorized disclosure. Finally, Dr. Clay Shields, a tenured computer science professor at Georgetown University with special expertise in P2P networks, testified as a rebuttal expert on various issues relating to the functionality of P2P networks and LabMD's exposure of the 1718 file.

¹⁷ Completion of the trial was delayed while Mr. Wallace, the Tiversa forensic analyst who had discovered LabMD's 1718 file, sought to obtain prosecutorial immunity. ID 5.

Opinion of the Commission

LabMD called four fact witnesses: Michael J. Daugherty, LabMD's founder and President; Mr. Wallace of Tiversa; Professor Eric Johnson of Dartmouth University, with whom Tiversa shared the 1718 file as part of a research project; and Daniel Kaufman, a deputy director of the FTC's Bureau of Consumer Protection. LabMD also called one expert witness: Adam Fisk, a former lead engineer at LimeWire, who was asked to opine on whether LabMD provided adequate security for the medical information on its computer network.

E. The ALJ's Initial Decision

Judge Chappell issued his Initial Decision on November 13, 2015. He focused on only the first of the unfairness standard's three elements, holding that Complaint Counsel had failed to prove that LabMD's computer data security practices "caused" or were "likely to cause" "substantial consumer injury," as required by Section 5(n) of the FTC Act. On that basis, he dismissed the Complaint.

In so holding, the ALJ defined the phrase "likely to cause" to mean "having a high probability of occurring or being true." ID 54. Applying this standard, the ALJ rejected Complaint Counsel's argument that identity and medical identity theft-related harms were "likely" for consumers whose personal information was maintained on LabMD's computer network. He concluded that, "[a]t best, Complaint Counsel has proven the 'possibility' of harm, but not any 'probability' or likelihood of harm." ID 14.

According to the ALJ, neither the exposure of the 1718 file nor the Sacramento documents incident demonstrated that LabMD's security practices either caused or were likely to cause consumer injury. As to the 1718 file, he rejected Complaint Counsel's argument that the very disclosure of sensitive personal medical information, including lab tests for conditions such as HIV, prostate cancer, and herpes, itself represented substantial consumer injury. He concluded that "[e]ven if there were proof of such harm, this would constitute only subjective or emotional harm that, under the facts of this case, where there is no proof of

Opinion of the Commission

other tangible injury, is not a ‘substantial injury’ within the meaning of Section 5(n).” ID 13.

The ALJ also found there was little likelihood of future harm. He explained that Complaint Counsel had not shown that the 1718 file was downloaded by anyone other than Tiversa, and that Tiversa had shared the information only with an academic researcher and the FTC. *See* ID 59-60; IDF 169-81. He concluded that this, combined with the fact that there had been no consumer complaints or injuries linked to the disclosure of the 1718 file, indicated that there was little likelihood that the information in the file would be disclosed to additional individuals or would cause future harm. ID 60.

With respect to the Sacramento incident, the ALJ concluded that Complaint Counsel had failed to establish a causal connection between the incident and any failure of LabMD to reasonably protect data on its computer network as alleged in the Complaint. The ALJ noted that the documents were found in hard copy form and that no evidence had been presented establishing that the documents were maintained on, or taken from, LabMD’s computer network. ID 13, 71. Additionally, although the documents were discovered in the possession of identity thieves, the ALJ held that Complaint Counsel had not shown that the exposure of the Sacramento documents caused or was likely to cause substantial consumer harm. In particular, he highlighted the lack of evidence of consumer complaints or injuries resulting from the incident and reasoned that, because the documents had been booked into evidence by the Sacramento Police Department, there was also no likelihood of future injury. ID 13, 72.

The ALJ declined to address or make any findings of fact with respect to the other issues in the case, including the reasonableness of LabMD’s data security practices and the two other unfairness elements – whether the alleged harm was reasonably avoidable by consumers and whether it was outweighed by countervailing benefits to consumers or competition. ID 49, 55-56. He also concluded that, in light of his holding, it was unnecessary to address LabMD’s affirmative defenses. ID 14.

Opinion of the Commission

Complaint Counsel appeal the ALJ's ruling, arguing that the ALJ misconstrued Section 5(n) by applying an unduly stringent substantial injury standard and failing to recognize that economic and physical harm are not the only forms of cognizable injury. They contend further that he erred by placing undue emphasis on the lack of evidence of particular consumers who suffered actual injury. Complaint Counsel also argue that the ALJ erred by requiring that the probability that consumers will suffer injury be precisely quantified.

LabMD, in turn, urges us to adopt the standard set forth in the ALJ's Initial Decision and affirm his dismissal of the Complaint. As alternative bases for dismissal of the Complaint, LabMD argues that the Commission's unfairness standard is unconstitutionally void for vagueness and fails to provide due process and fair notice. LabMD also claims that dismissal is warranted because the information Complaint Counsel obtained regarding the 1718 file and "all derivative evidence" are based on "unreliable, if not false evidence" provided by Tiversa.

STANDARD OF REVIEW

The Commission reviews the ALJ's findings of fact and conclusions of law *de novo*, considering "such parts of the record as are cited or as may be necessary to resolve the issues presented." 16 C.F.R. §3.54. Our *de novo* review applies to "both findings of fact and inferences drawn from those facts." *McWane, Inc.*, Docket No. 9351, 2014 FTC LEXIS 28, at *30 (Jan. 30, 2014), *aff'd*, *McWane, Inc. v. FTC*, 783 F.3d 814 (11th Cir. 2015), *cert. denied*, 136 S. Ct. 1432 (2016). We have nonetheless carefully considered the ALJ's factual findings and analysis in the course of conducting our own review.¹⁸

18 TechFreedom moved for leave to file an *amicus curiae* brief in support of LabMD. That motion is hereby granted. Most of TechFreedom's arguments are similar to those raised by LabMD, and our discussion of LabMD's arguments incorporates our assessment of TechFreedom's related points. An additional argument TechFreedom raises is that the Commission must defer to the ALJ's Initial Decision absent an abuse of discretion and that the Commission lacks authority to overrule the decision. The contention is meritless. As noted above, the Commission reviews the ALJ's findings *de novo*.

Opinion of the Commission

ANALYSIS**I. The Unfairness Standard**

Section 5 of the FTC Act authorizes the Commission to challenge “unfair or deceptive acts or practices in or affecting commerce.” 15 U.S.C. §45(a). In 1994, Congress added Section 5(n) to the Act, providing that an act or practice may be deemed unfair if (1) it “causes or is likely to cause substantial injury to consumers”; (2) the injury “is not reasonably avoidable by consumers themselves”; and (3) the injury is “not outweighed by countervailing benefits to consumers or competition.” 15 U.S.C. § 45(n). This three-part test, derived from the Commission’s 1980 *Policy Statement on Unfairness*,¹⁹ codifies the analytical framework for the Commission’s application of its unfairness authority.

Our resolution of this case turns in significant part on the meaning of the first prong of Section 5(n) and the relationships that tie the various elements of the unfairness standard together. In construing and applying Section 5(n), we draw considerable guidance from the *Unfairness Statement* and the many Commission actions and federal court rulings applying the unfairness standard. Within the framework set out by Congress, it is up to the Commission to determine, on a case-by-case basis, which practices should be condemned as “unfair.” *See FTC v. Wyndham Worldwide, Inc.*, 799 F.3d 236, 243 (3d Cir. 2015) (“Congress designed the term as a ‘flexible concept with evolving content,’ and ‘intentionally left [its] development . . . to the Commission.’”); *Am. Fin. Servs. Ass’n v. FTC*, 767 F.2d 957, 966 (D.C. Cir. 1985) (noting the Commission may exercise its

¹⁹ *See* FTC, Commission Statement of Policy on the Scope of the Consumer Unfairness Jurisdiction (“*Unfairness Statement*”) (Dec. 17, 1980) (*appended to Int’l Harvester Co.*, 104 F.T.C. 949, 1070 (1984)), *available at* <https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness>; S. REP. NO. 103-130, at 12-13 (1993) (“SENATE REPORT”) (explaining that the amendments were “intended to codify . . . the principles of the FTC’s [*Unfairness Statement*]” and to “enable the FTC to proceed in its development of the law of unfairness with a firm grounding in the precedents decided under this authority, and consistent with the approach of the FTC and the courts in the past”).

Opinion of the Commission

discretion to ascertain which “acts or practices . . . injuriously affect the general public” and “to prevent” such acts) (quoting H.R. REP. NO. 75-1613, at 3 (1937)).

The central focus of any inquiry regarding unfairness is consumer injury. *See* FTC, Credit Practices Rule, Statement of Basis and Purpose, 49 Fed. Reg. 7740, 7743 (Mar. 1, 1984) (“*Credit Practices SBP*”), *aff’d*, *Am. Fin. Servs. Ass’n*, 767 F.2d 957. As reflected in the first prong of Section 5(n), a finding of unfairness requires that the injury in question be “substantial.” It is well established that substantial injury may be demonstrated by a showing of a small amount of harm to a large number of people, as well as a large amount of harm to a small number of people.²⁰ Additionally, in the *Unfairness Statement*, the Commission noted that most cases of unfairness involve economic harm or health and safety risks, and that “[e]motional impact and other more subjective types of harm . . . will not ordinarily make a practice unfair.” *Unfairness Statement*, 104 F.T.C. at 1073. The Commission, however, also recognized that, in extreme cases, subjective types of harm might well be considered as the basis for a finding of unfairness, citing as an example “harassing late-night telephone calls” from debt collectors. *Id.* at 1073 n.16; *see also* SENATE REPORT at 13 (legislative history of Section 5(n) referring to “abusive debt collection practices” and “high pressure sales tactics” as examples of contexts in which the unfairness standard may apply). Indeed, neither the *Unfairness Statement* nor Section 5(n) forecloses the possibility that an intangible but very real harm like a privacy harm resulting from the disclosure of sensitive health or medical information may constitute a substantial injury.

The first prong of Section 5(n) also includes a causation requirement that is satisfied where a practice “causes . . . substantial injury.” 15 U.S.C. § 45(n). The practice need not be the only or most proximate cause of an injury to meet this test. As the Third Circuit recently explained in *Wyndham*, “that a company’s conduct was not *the most* proximate cause of an injury

²⁰ *See* SENATE REPORT at 13; *Unfairness Statement*, 104 F.T.C. at 1073 n.12; *FTC v. Neovi, Inc.*, 604 F.3d 1150, 1157 (9th Cir. 2010) (*quoting Am. Fin. Servs. Ass’n*, 767 F.2d at 972); *Orkin Exterminating Co., Inc. v. FTC*, 849 F.2d 1354, 1365 (11th Cir. 1988).

Opinion of the Commission

generally does not immunize liability from foreseeable harms.” 799 F.3d at 246.

A practice may also meet the first prong of Section 5(n) if it is “likely to cause substantial injury.” Congress therefore expressly authorized the Commission to address injuries that have not yet manifested. *Id.* (“[T]he FTC Act expressly contemplates the possibility that conduct can be unfair before actual injury occurs.”). In determining whether a practice is “likely to cause a substantial injury,” we look to the likelihood or probability of the injury occurring and the magnitude or seriousness of the injury if it does occur. Thus, a practice may be unfair if the magnitude of the potential injury is large, even if the likelihood of the injury occurring is low. For example, in *Philip Morris, Inc.*, 82 F.T.C. 16 (1973), the Commission found unfair the unsolicited distribution of free sample razor blades in a manner that could lead the razors to fall into the hands of small children – even though no child had yet been injured. *See also Int’l Harvester Co.*, 104 F.T.C. at 1064 (failure to include a warning label on a tractor gas cap was unfair where the likelihood of harm was low but the injuries were severe). As is the case for analysis of unfairness generally, this evaluation does not require precise quantification. What is important is obtaining an overall understanding of the level of risk and harm to which consumers are exposed. *See FTC v. Wyndham Worldwide Corp.*, 10 F. Supp. 3d 602, 625 (D. N.J. 2014), *aff’d on other grounds*, 799 F.3d 236 (3d Cir. 2015); *see also Int’l Harvester Co.*, 104 F.T.C. at 1065 n.59; *Am. Fin. Servs. Ass’n*, 767 F.2d at 986; SENATE REPORT at 13.

Under the second and third prongs of Section 5(n), we ask whether consumers could have reasonably avoided the asserted injury and whether it is outweighed by countervailing benefits. *See Unfairness Statement*, 104 F.T.C. at 1073-74; *Orkin Exterminating Co., Inc. v. FTC*, 849 F.2d 1354, 1363-64 (11th Cir. 1988) (Commission’s “definition of ‘unfairness’ focuses upon *unjustified* consumer injury”) (emphasis added).

Among the types of acts or practices the Commission has long challenged under its unfairness authority are unreasonable and

Opinion of the Commission

inappropriate data security practices.²¹ The Third Circuit succinctly summarized how the three prongs of the unfairness test apply in the data security context in *Wyndham*, describing it as “a cost-benefit analysis” that “considers a number of relevant factors, including the probability and expected size of reasonably unavoidable harms to consumers given a certain level of cybersecurity and the costs to consumers that would arise from investment in stronger cybersecurity.” 799 F.3d at 255.

This framework dovetails with the analysis the Commission has consistently employed in its data security actions, which is encapsulated in the concept of “reasonable” data security. As the Commission has explained:

The touchstone of the Commission’s approach to data security is reasonableness: a company’s data security measures must be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. . . . [T]he Commission has made clear that it does not require perfect security; reasonable and appropriate security is a continuous process of assessing and addressing risks; there is no one-size-fits-all data security program; and the mere fact that a breach occurred does not mean that a company has violated the law.

21 To date, using both its deception and unfairness authority, the Commission has brought nearly 60 data security cases. *See, e.g.*, Commission Statement Marking the FTC’s 50th Data Security Settlement, at 1 (Jan. 31, 2014), *available at* <https://www.ftc.gov/system/files/documents/cases/140131gmrstatement.pdf>; *CardSystems Solutions, Inc.*, FTC File No. 052-3148, Docket No. C-4168 (2006), *available at* <https://www.ftc.gov/enforcement/cases-proceedings/052-3148/cardsystems-solutions-inc-solidus-networks-inc-dba-pay-touch>; *Nations Title Agency, Inc.*, FTC File No. 052-3117, Docket No. C-4161 (2006), *available at* <https://www.ftc.gov/enforcement/cases-proceedings/052-3117/nations-title-agency-inc-nations-holding-company-christopher>; *DSW, Inc.*, 141 F.T.C. 117 (2006); *BJ’s Wholesale Club, Inc.*, 140 F.T.C. 465 (2005).

Opinion of the Commission

Commission Statement Marking the FTC's 50th Data Security Settlement, at 1 (Jan. 31, 2014) ("50th Settlement Statement"); *see also* Comm'n Order Den. Mot. to Dismiss at 17-19.

Thus, we evaluate whether LabMD's data security practices, taken together, failed to provide reasonable and appropriate security for the sensitive personal information on its computer network, and whether that failure caused or was likely to cause substantial injury that consumers could not have reasonably avoided and that was not outweighed by benefits to consumers or competition.

We now present an overview of LabMD's data security practices and then apply each of the three prongs of Section 5(n) to the facts here.

II. LabMD's Data Security Practices

LabMD was entrusted with patients' sensitive medical and financial information, and was obligated to put reasonable security systems in place to guard against the risk of an unauthorized release of such information. As discussed below, LabMD did not employ basic risk management techniques or safeguards such as automated intrusion detection systems, file integrity monitoring software, or penetration testing. It also failed to monitor traffic coming across its firewalls. In addition, LabMD failed to provide its employees with data security training. And it failed to adequately limit or monitor employees' access to patients' sensitive information or restrict employee downloads to safeguard the network.

A. LabMD Failed to Protect its Computer Network or Employ Adequate Risk Assessment Tools

Widely known and accepted standards governing minimum reasonable data security practices have long established that risk assessment is an essential starting point. For example, as of 2003, regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936 (1996), have required covered entities like LabMD that transmit health information to "[c]onduct an accurate and

Opinion of the Commission

thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.”²² While the requirements imposed by HIPAA do not govern whether LabMD met its obligations under Section 5 of the FTC Act, they do provide a useful benchmark for reasonable behavior. Similarly, since at least 2002, National Institute of Science and Technology (“NIST”) guidelines provided a framework for risk management for information technology systems that included testing for the presence of vulnerabilities.²³ Additionally, since at least 2005, IT practitioners commonly used intrusion detection systems and file integrity monitoring products to assess whether there were risks on networks.²⁴ They also used “penetration tests,” which are a series of audits that check for conditions such as whether a server’s ports are unused and open or whether industry-known software bugs are unpatched, to spot vulnerabilities that criminals could exploit to obtain unauthorized access to sensitive information on the network.²⁵

22 45 C.F.R. 164.308 (a)(1)(ii)(A); *see also* CX0405 (HIPAA Security Series) at 1 (“The Security Rule requires covered entities to evaluate risks and vulnerabilities in their environments and to implement policies and procedures to address those risks and vulnerabilities.”). Throughout this proceeding LabMD has acknowledged that it is subject to HIPAA. *See, e.g.*, Motion to Dismiss at 4 (“LabMD’s patient-information data-security practices are, and were at all times relevant, regulated under HIPAA and HITECH.”).

23 *See* CX0400 at 17-18 (NIST Special Publication 800-30 (Risk Management Guide for Information Technology Systems) (2002)); *see also* National Research Council, FOR THE RECORD: PROTECTING ELECTRONIC HEALTH INFORMATION (1997) (“NRC Report”) (cited as a “comprehensive information security program[] concerning electronic health data,” CX0740 (Hill Expert Report) ¶ 60 and n.8) (noting that “[o]rganizations should formally assess the security and vulnerabilities of their information systems on an ongoing basis”), available at <http://www.nap.edu/catalog/5595.html>.

24 CX0740 (Hill Expert Report) ¶¶ 4, 48, 65, 69 n.22, 104(h). Intrusion detection systems analyze large amounts of network traffic and issue alerts and warnings about threats and suspicious activity. *Id.* ¶ 65. File integrity monitoring products identify changes in critical files that may indicate that malware is present on a network. *Id.*

25 CX0400 at 24-25; CX0740 (Hill Expert Report) ¶¶ 70-72.

Opinion of the Commission

Although LabMD had at least two IT employees on staff,²⁶ it did none of this. It had no intrusion detection system or file integrity monitoring at all, and it employed penetration testing only after Tiversa had notified it that the 1718 file was available through LimeWire.²⁷ The tools that LabMD used to help mitigate risk were antivirus programs, firewall logs, and manual computer inspections, which could identify only a limited scope of vulnerabilities and were often used in a manner that further reduced their effectiveness.²⁸ For example, LabMD did not consistently update virus definitions²⁹ or run and review scans.³⁰

26 *See, e.g.*, CX0707 (Bureau dep.) at 7; CX0717 (Howard dep.) at 7-11; CX0719 (Hyer dep.) at 46-47, 49; CX0735 (Kaloustian IH) at 7, 13-17; CX0724 (Maire dep.) at 10-11; CX0725-A (Martin dep.) at 9-10; CX0730 (Simmons dep.) at 7. LabMD objects to the introduction of testimony by former LabMD IT employee Curt Kaloustian, arguing that his testimony was obtained during an investigational hearing when LabMD counsel was not present and attorney-client privilege may not have been preserved. LabMD does not identify any particular testimony that purportedly reveals privileged information, and we find no factual basis for LabMD's objection. At the outset of the investigational hearing, the FTC investigator explained that he did not want Mr. Kaloustian "to reveal the content of any communication [he may have] had with an attorney" and offered Mr. Kaloustian the opportunity to proceed only with personal counsel or counsel for LabMD, which Mr. Kaloustian declined. CX0735 (Kaloustian IH) at 9-10. In any event, we rely on Mr. Kaloustian's testimony only for factual descriptions of LabMD's network, equipment, and applications, as well as the day-to-day actions and practices of LabMD's IT employees.

27 CX0731 (Truett dep.) at 122; CX0717 (Howard dep.) at 58, 140-41; CX0734 (Simmons IH) at 68-69; JX0001-A (Joint Stipulations) at 4; CX0735 (Kaloustian IH) at 92-93.

28 *See, e.g.*, CX0740 (Hill Expert Report) ¶ 68; CX0735 (Kaloustian IH) at 43-44, 126-27, 187-88.

29 *See, e.g.*, CX0035 (APT service invoice) at 3; CX0731 (Truett dep.) at 81-84; CX0735 (Kaloustian IH) at 91-92 (many LabMD servers did not receive new virus definitions), 126-32, 160-61 (LabMD relied on individual employees to download new virus definitions from manufacturer websites, but many lacked an internet connection).

30 LabMD relied on individual employees to run scans, but had no policy requiring them to do so or explaining how and when to conduct the scans. CX0735 (Kaloustian IH) at 126-32. In addition, the Symantec/Norton antivirus program did not automatically report the results of scans to LabMD's IT employees. CX0717 (Howard dep.) at 63-64, 70-71. Thus, LabMD's

Opinion of the Commission

Also, LabMD's manual inspections were not used to detect security risks but merely responded to complaints about computer performance.³¹

LabMD also failed to monitor its network for unauthorized intrusions or exfiltration, which is another common practice long employed by IT professionals.³² LabMD's firewalls were ineffective for the purpose of risk assessment for two reasons. First, they were not configured properly.³³ Second, no one at LabMD reviewed firewall logs or network activity logs except in connection with troubleshooting a problem, such as with Internet speed or connectivity. For example, there was no attempt to monitor outgoing traffic for items like social security numbers.³⁴

programs were incapable of determining and revealing whether new viruses had infected the servers and computers. *See* CX0731 (Truett dep.) at 83-84; CX0717 (Howard dep.) at 64-66.

31 CX0730 (Simmons dep.) at 104, 143-45; CX0707 (Bureau dep.) at 50-51, 89-90.

32 CX0740 (Hill Expert Report) ¶¶ 65, 68-69(b). This dovetails with HIPAA's requirement that covered entities "[i]mplement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports." 45 C.F.R. § 164.308(a)(1)(ii)(D).

33 Although properly configured firewalls should be in place at the network gateway *and* on employee workstations, CX0740 (Hill Expert Report) ¶¶ 31(c), 104(g), until the middle of 2010, LabMD relied only on a ZyWall firewall at the network level. CX0731 (Truett dep.) at 65. The type of network traffic information the ZyWall firewall could record and store was limited, and it could only log information for a few days of traffic. *Id.* at 68-69. Contrary to speculation by LabMD's expert, Mr. Fisk, that LabMD's router could provide significant additional network-level firewall protection, the record shows that, as configured, LabMD's router contributed little to data security. *See, e.g.*, CX0735 (Kaloustian IH) at 96-99; CX0678 at 10; CX0729. The Windows operating system used on the servers also had firewalls available, but LabMD often turned them off. CX0735 (Kaloustian IH) at 293-94.

34 CX0719 (Hyer dep.) at 167-69. *See also* CX0731 (Truett dep.) at 68-69; CX0717 (Howard dep.) at 98-99; CX0735 (Kaloustian IH) at 115-16. Indeed, the firewall logs were erased by overwriting as frequently as every few days. CX0731 (Truett dep.) at 68-69; CX0710-A (Daugherty, LabMD Designee, dep.) at 176-77.

Opinion of the Commission

One significant consequence of these failures by LabMD was that LimeWire ran undetected on the billing manager's computer between 2005 and 2008.³⁵ File integrity monitoring or a more complete walk-around inspection could have detected the program, but these safeguards were not in place.³⁶ Indeed, even after learning of the 1718 file breach in 2008, following which LabMD initiated daily "walk-around inspections," IT employees did not follow any written checklist and instead only asked employees if they were experiencing computer problems.³⁷

B. LabMD Failed to Provide Data Security Training to its Employees

Even where basic hardware and software data security mechanisms are in place, there is an increased likelihood of exposing consumers' personal information if employees are not adequately trained. HIPAA's Security Rule, for example, requires that covered entities "[i]mplement a security awareness and training program for all members of [the] workforce (including management)."³⁸

LabMD recognized the need for training, as acknowledged in its Compliance Manual which mandated that its compliance officer establish in-house training sessions regarding privacy and

35 Ans. ¶ 18(a); CX0755 at 4; CX0447 at 5-6; CX0730 (Simmons dep.) at 54-56; CX0735 (Kaloustian IH) at 269-70; CX0711 (Dooley dep.) at 117-19; CX0443 (LabMD Access Letter Response) at 13.

36 CX0735 (Kaloustian IH) at 92-93; CX0734 (Simmons IH) at 68-69; CX0705-A (Bradley dep.) at 46-47; Hill, Tr. 199-201; CX0740 (Hill Expert Report) ¶ 105; CX0707 (Bureau dep.) at 95-96. *See also* CX0719 (Hyer dep.) at 167-69 (If LabMD had monitored outgoing traffic for items like social security numbers, it could have detected the disclosure of the 1718 file.).

37 CX0445 at 1-2; CX0730 (Simmons dep.) at 143; CX0719 (Hyer dep.) at 98-99.

38 45 C.F.R. §164.308(a)(5)(i). Other IT industry guidance provides: "Organizations should establish education and training programs to ensure that all users of information systems receive some minimum level of training in relevant security practices and knowledge regarding existing confidentiality policies. All computer users should complete such training *before* being granted access to any information systems." NRC Report at 174.

Opinion of the Commission

security,³⁹ but it failed to provide such training to any of its employees including its IT personnel.⁴⁰ As a result, employees, including sales representatives and billing staff, did not receive training regarding data security, security mechanisms, or the consequences of reconfiguring security settings in applications.⁴¹ For example, the LabMD billing manager from May 2005 to May 2006 testified that she and other billing department employees did not receive any training from LabMD about protecting sensitive health data, stating that LabMD relied on the training that these employees received in their previous employment.⁴² Due in part to this lack of data security training, LabMD employees appear not to have understood the risk involved in using P2P file sharing software on LabMD's computers.

C. LabMD Failed to Adequately Restrict and Monitor the Computer Practices of Individuals Using Its Network

LabMD also did not adequately limit or monitor employees' access to the sensitive personal information of patients or restrict employee downloads to safeguard the network.

As the National Research Council has been emphasizing since 1997, "[p]rocedures should be in place that restrict users' access to only that information for which they have a legitimate need." NRC Report at 170. Similarly, HIPAA requires that covered entities implement policies and procedures for authorizing "access to electronic protected information" and "to prevent those workforce members who do not have access . . . from obtaining access to electronic protected health information." 45 C.F.R. §

39 CX0005 (LabMD Compliance Program, effective 2003) at 9.

40 See, e.g., CX0717 (Howard dep.) at 23-26; CX0711 (Dooley dep.) at 148-49; CX0707 (Bureau dep.) at 37-38, 105-06; CX0719 (Hyer dep.) at 130, 159-62; CX0735 (Kaloustian IH) at 208-20; CX0734 (Simmons IH) at 60-67.

41 See, e.g., CX0706 (Brown dep.) at 90-94; CX0711 (Dooley dep.) at 147-49; CX0714-A ([Former LabMD Employee] dep.) at 85-88; CX0734 (Simmons IH) at 61-62; CX0735 (Kaloustian IH) at 214-15; CX0708 (Carmichael dep.) at 25-26, 42.

42 CX0706 (Brown dep.) at 96-98.

Opinion of the Commission

164.308(a)(3)(i). LabMD's own 2004 employee handbook acknowledged that sharing health information unnecessarily was illegal and that the company was required to take "specific measures to ensure our compliance with this law."⁴³

Yet, LabMD failed to employ adequate measures to prevent employees from accessing personal information not needed to perform their jobs. In fact, LabMD turned off the feature of its laboratory information software, LabSoft, that allowed for distinct access settings for different users. CX0717 (Howard dep.) at 117. Even college students hired on a part-time basis could access patients' medical and other sensitive information. CX0706 (Brown dep.) at 98-102. In addition, LabMD's sales representatives were able to use physician-clients' login credentials to log in to LabSoft, which gave them access to patient information. CX0718 (Hudson dep.) at 73-74, 88-89, 183. Because LabMD had no data deletion policy and never destroyed any patient or billing information it received since it began operating,⁴⁴ the amount of information on its network was extensive and included copies of personal checks and credit and debit card account numbers in addition to medical information.⁴⁵

Nor did LabMD adequately restrict or monitor what employees downloaded onto their work computers. Throughout the period at issue, it was widely recognized that downloading unauthorized applications to a computer was dangerous, and P2P programs in particular "presented a well-known and significant risk that files would be inadvertently shared."⁴⁶ As the NRC also

43 CX0001 (LabMD Employee Handbook Rev. June 2004) at 6.

44 CX0710-A (Daugherty, LabMD Designee, dep.) at 215; CX0733 (Boyle, LabMD Designee, IH) at 39-40; CX0443 at 6; CX0717 (Howard dep.) at 113.

45 CX0716 (Harris dep.) at 19-25; CX0733 (Boyle IH) at 46.

46 CX0738 (Shields Rebuttal Report)¶ 49; *see also id.* ¶¶ 40-48; CX0874 (SANS Institute InfoSec Reading Room Peer-to-Peer File-Sharing Networks Security) (2002) at 6; CX0878 (US-CERT - Risks of File-Sharing Technology) (2005) at 1 ("By using P2P applications, you may be giving other users access to personal information. Whether it's because certain directories are accessible or because you provide personal information to what you believe to be a trusted person or organization, unauthorized people may be able to access your

Opinion of the Commission

advised, “Organizations should exercise and enforce discipline over user software. At a minimum, they should . . . limit the ability of users to download or install their own software.”⁴⁷

Until at least the fall of 2009, LabMD’s management employees were given administrative rights over their workstations and its sales employees had administrative rights over their laptop computers,⁴⁸ which allowed them to change security settings and download software applications and music files from the Internet.⁴⁹ LabMD’s Policy Manual included a Software Monitoring Policy that stated that users’ “‘add/remove’ programs file will be reviewed for the appropriate applications for the specific user.”⁵⁰ If followed, this policy would have led to detection of the LimeWire program. CX0740 (Hill Report) ¶ 61(b).

financial or medical data The availability of this information may increase your risk of identity theft”).

47 NRC Report at 173; see also FTC Staff Report, *Peer-to-Peer File-Sharing Technology: Consumer Protection and Competition Issues* (June 2005), available at <https://www.ftc.gov/sites/default/files/documents/reports/peer-peer-file-sharing-technology-consumer-protection-and-competition-issues/050623p2prpt.pdf> (noting the risk of inadvertent file-sharing on P2P platforms and methods for protecting against this risk).

48 See, e.g., CX0735 (Kaloustian IH) at 187-89; CX0705-A (Bradley dep.) at 147-49; CX0722 (Knox dep.) at 54-56; CX0719 (Hyer dep.) at 27- 31. In fact, at least until some point in 2005, all LabMD employees used the administrator’s user name and password for their credentials. Consequently, all LabMD employees had the ability to exercise administrative rights for their computers, although not all LabMD computers had Internet access. CX0717 (Howard dep.) at 19-20; CX0735 (Kaloustian IH) at 166-72.

49 CX0714-A ([Former LabMD Employee] dep.) at 38-40; CX0717 (Howard dep.) at 77; CX0735 (Kaloustian IH) at 167; CX0705-A (Bradley dep.) at 148-49.

50 CX0006 (LabMD Policy Manual) at 18. In addition, LabMD’s Employee Handbook stated “Personal internet or e-mail usage in the office is prohibited. . . . Computers in the office are property of LabMD and should only be used for company related reasons.” CX0001 (LabMD Employee Handbook Rev. June 2004) at 7.

Opinion of the Commission

In sum, if LabMD had followed proper data security protocols, LimeWire never would have been installed on the computer used by LabMD's billing manager in the first instance, or it would have been discovered and removed soon after downloading. Instead, LimeWire sat on the billing manager's computer for approximately three years and resulted in the exposure of the 1718 file.⁵¹

III. LabMD's Data Security Practices Were Unfair in Violation of Section 5(n)

We now turn to whether LabMD's data security practices were unfair within the meaning of Section 5(n). As discussed above, we find that LabMD's lax security practices resulted in the unauthorized sharing of the 1718 file on LimeWire, exposing sensitive medical information of 9,300 consumers to millions of Gnutella users. For the reasons discussed below, we further find that, due to the exposure of the 1718 file, LabMD's data security practices caused and were likely to cause substantial injury that was not avoidable by consumers or outweighed by countervailing benefits and thus that LabMD's data security practices were unfair.

We note that Complaint Counsel argues that LabMD's security practices risked exposing the sensitive information of all 750,000 consumers whose information is stored on its computer network and therefore that they create liability even apart from the LimeWire incident. We find that the exposure of sensitive medical and personal information via a peer-to-peer file-sharing application was likely to cause substantial injury and that the disclosure of sensitive medical information did cause substantial injury. Therefore, we need not address Complaint Counsel's broader argument.

⁵¹ See *supra* nn.4, 13.

Opinion of the Commission

A. LabMD's Data Security Practices Caused and Were Likely to Cause Substantial Injury

1. LabMD's Unauthorized Disclosure of the 1718 File Itself Caused Substantial Injury

We address first whether the unauthorized disclosure of the 1718 file caused actual “substantial injury” to consumers. The ALJ held that “privacy harms, allegedly arising from an unauthorized exposure of sensitive medical information . . . unaccompanied by any tangible injury such as monetary harm or health and safety risks, [do] not constitute ‘substantial injury’ within the meaning of Section 5(n).” ID 85 n.43. We disagree.

It is undisputed that the 1718 file contained names, dates of birth, social security numbers, insurance company names, policy numbers, and codes for laboratory tests performed, including tests for HIV, herpes, prostate cancer, and testosterone levels. IDF 82. We also know that the file was downloaded by at least one unauthorized third-party – Tiversa – and then shared with an academic researcher.

Complaint Counsel introduced evidence of a range of harms that can and often do result from the unauthorized disclosure of sensitive personal information of the types contained in the 1718 file. One category encompasses economic harms resulting from identity theft and medical identity theft. This includes monetary losses due to financial fraud and time and resources expended by consumers in resolving fraud-related disputes.⁵² Medical identity theft associated with data breaches can also result in misdiagnosis or mistreatment of illness, and can thereby harm consumers’ physical health and safety.⁵³ There is no dispute that these economic and health and safety harms fall squarely within the types of injury encompassed by Section 5(n).

Because LabMD never notified any of the consumers identified in the 1718 file that their information had been

⁵² See nn.71-72 and accompanying text, *infra*.

⁵³ ID 49-50; CX0742 (Kam Expert Report) at 15.

Opinion of the Commission

disclosed, we do not know whether the breach of the 1718 file resulted in actual identity theft, medical identity theft, or physical harm for any of the consumers whose information was disclosed. *See* Daugherty, Tr. 1087; CX0710-A (Daugherty dep.) at 48, 50. We therefore evaluate whether the disclosure of sensitive medical information alone, in the absence of proven economic or physical harm, satisfies the “substantial injury” requirement.

We conclude that the disclosure of sensitive health or medical information causes additional harms that are neither economic nor physical in nature but are nonetheless real and substantial and thus cognizable under Section 5(n). For instance, Complaint Counsel’s expert, Rick Kam, testified that disclosure of the mere fact that medical tests were performed irreparably breached consumers’ privacy, which can involve “embarrassment or other negative outcomes, including reputational harm.”⁵⁴ Mr. Daugherty himself recognized the sensitivity of personal medical data and the gravity of its unauthorized disclosure.⁵⁵ In fact, the protection of personal health information was seen as part of the service LabMD delivered to its customers, and the company trained its sales representatives to assure physician clients that their data would be maintained on secure servers (despite not following through with such protections).⁵⁶ As LabMD’s Vice President for Operations noted, it is vital for a lab to protect sensitive patient information.⁵⁷

Indeed, the Commission has long recognized that the unauthorized release of sensitive medical information harms consumers. The Commission brought its very first data security case against Eli Lilly to address lax security practices that resulted in the inadvertent disclosure of the email addresses of Prozac users.⁵⁸ *FTC v. Eli Lilly & Co.*, 133 F.T.C. 763, 767-68 (2002)

54 CX0742 (Kam Expert Report) at 21; *see also id.* at 16; Kam, Tr. 411-12.

55 *See* Daugherty, Tr. 989; CX0710-A (Daugherty Designee dep.) at 45.

56 CX0704-A (Boyle dep.) at 128-29; CX0718 (Hudson dep.) at 67-68.

57 CX0704-A (Boyle dep.) at 128-29.

58 This was brought as a deception case, but still demonstrates the Commission’s concern with protecting sensitive medical information.

Opinion of the Commission

(complaint and consent order). A more recent example involving sensitive medical information is *GMR Transcription Services*. There we alleged that the failure of GMR's service provider to implement reasonable security measures harmed consumers due to the disclosure of files containing notes from medical examinations on the Internet, which included information about psychiatric disorders, alcohol and drug abuse, and pregnancy loss. *GMR Transcription Services, Inc.*, 2014 WL 4252393, *4 (Aug. 14, 2014) (complaint and consent order).⁵⁹ And just last month we announced a settlement with Practice Fusion, a cloud-based electronic health record company, for soliciting consumer healthcare reviews in a manner that we alleged failed to adequately disclose that the reviews would be posted on the Internet. We alleged that these practices resulted in the unauthorized disclosure of some patients' sensitive personal and medical information, including health conditions, medications taken, medical procedures performed, and treatments received. Complaint, *In re Practice Fusion, Inc.*, FTC File No. 142-3039 (June 8, 2015).⁶⁰

There is also broad recognition in federal and state law of the inherent harm in the disclosure of sensitive health and medical information. Section 5(n) expressly authorizes us to look to "established public policies" as additional evidence in support of a determination about whether a practice is unfair, including whether it causes substantial injury, and we do so here.⁶¹ Federal

59 Available at <https://www.ftc.gov/enforcement/cases-proceedings/122-3095/gmr-transcription-services-inc-matter>.

60 Available at <https://www.ftc.gov/enforcement/cases-proceedings/142-3039/practice-fusion-inc-matter>.

61 In highlighting the public policies about sensitive health and medical information established in these laws, we are not saying that practices are unfair simply because they offend those policies. Rather, such laws support our conclusion that the unauthorized exposure of sensitive health and medical information causes substantial consumer injury. See 15 U.S.C. § 45(n) ("In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence;" however, public policy considerations may not "serve as a primary basis for [an unfairness] determination").

Opinion of the Commission

statutes such as HIPAA and the Health Information Technology for Economic and Clinical Health (“HITECH”) Act, as well as state laws, establish the importance of maintaining the privacy of medical information in particular. *See, e.g.*, HIPAA, 42 U.S.C. §§ 1320 *et seq.* (directing HHS to promulgate privacy and security rules for health information); 45 C.F.R. Parts 160 & 164 (privacy, data security, and related rules); HITECH Act, Pub. L. No. 111-5, 123 Stat. 226 (2009), *codified at* 42 U.S.C. §§ 300jj *et seq.*; §§ 17901 *et seq.*, and revisions to 42 U.S.C. §§ 1320d—1320d(8); Freedom of Information Act, 5 U.S.C. § 552(b)(6) (restricting agencies from disclosing “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy”); Fair Credit Reporting Act, 15 U.S.C. §§ 1681a(i) & 1681b(g)(1) (generally prohibiting reporting agencies from releasing “a consumer report that contains medical information . . . about a consumer” for employment, credit, or insurance purposes); *id.* § 1681a(i) (defining “medical information”); Ga. Code Ann. § 31-33-2(d) (forbidding release of medical records without patient’s signed written authorization); *id.* § 31-22-4(c) (restricting clinical labs’ disclosure of test results); *id.* §§ 31-22-9.1(a)(2)(D), 24-12-21(b)(1) (limiting the release of “AIDS confidential information,” including the fact that a person has submitted to an HIV test); *id.* § 24-12-21(o), (u) (imposing criminal liability for intentional or knowing disclosure of AIDS confidential information and permitting civil liability for “gross negligence”).

Federal courts have similarly acknowledged the importance of protecting the confidentiality of sensitive medical information. *See, e.g., Maracich v. Spears*, 133 S. Ct. 2191, 2202 (2013) (recognizing that an individual’s “medical and disability history” is among “the most sensitive kind of information” and characterizing its use in attorney solicitations as a “substantial . . . intrusion on privacy”); *Harris v. Thigpen*, 941 F.2d 1495, 1513-14 (11th Cir. 1991) (expressing view that prison inmates’ interest in preventing non-consensual disclosure of their HIV-positive diagnoses, although not absolute, is “significant” and “constitutionally-protected”). State courts, including those in Georgia, also have long recognized a right to privacy in sensitive medical information. *See, e.g., Multimedia WMAZ, Inc. v.*

Opinion of the Commission

Kubach, 443 S.E. 2d 491 (Ga. App. 1994) (en banc) (affirming verdict awarding damages for public disclosure of AIDS diagnosis).

Tort law also recognizes privacy harms that are neither economic nor physical. As explained by the Restatement of Torts, when “intimate details of [one’s] life are spread before the public gaze in a manner highly offensive to the ordinary reasonable man, there is an actionable invasion of his privacy, unless the matter is one of legitimate public interest.” RESTATEMENT (SECOND) OF TORTS § 652D, Comment b (1977). Thus, one can be held liable for invasion of privacy if “the matter publicized is of a kind that[:] (a) would be highly offensive to a reasonable person, and (b) is not of legitimate concern to the public.” *Id.* § 652D (summarizing tort of “publicity given to private life”).⁶²

We therefore conclude that the privacy harm resulting from the unauthorized disclosure of sensitive health or medical information is in and of itself a substantial injury under Section 5(n), and thus that LabMD’s disclosure of the 1718 file itself caused substantial injury.

2. LabMD’s Unauthorized Exposure of the 1718 File Was Likely to Cause Substantial Injury

We now address whether, independent of our holding that the disclosure of sensitive medical information caused substantial injury under Section 5(n), the unauthorized exposure of the 1718 file for more than 11 months on LimeWire was also “likely to

⁶² According to a Comment to this section, “if [a] record is one not open to public inspection, as in the case of income tax returns, it is not public, and there is an invasion of privacy when it is made so.” *Id.* at Comment b. The D.C. Circuit has also affirmed the FTC’s determination that certain debt-collection techniques are “unfair acts and practices” because they “invade the consumer’s right of privacy, causing embarrassment and humiliation,” and often harm consumers’ reputations for financial stability and degrade their relationships with employers. *Credit Practices SBP*, 49 Fed. Reg. at 7744; see *Am. Fin. Servs. Ass’n*, 767 F.2d at 975 (affirming FTC’s adoption of rule and finding such intangible consumer injuries were “neither trivial[,] speculative nor based merely on notions of subjective distress or offenses to taste”).

Opinion of the Commission

cause substantial injury.” The ALJ interpreted “likely to cause” as requiring a showing that substantial consumer injury was “probable.” ID 54, 90. He relied principally on the Merriam Webster dictionary’s statement that “the word ‘likely’ is ‘used to indicate the chance that something will happen,’ and is primarily defined as ‘having a high probability of occurring or being true.’” ID 54. On that basis, he concluded that Section 5(n) requires a showing that it is “probable that something will occur,” not merely “possible,” and that “at best, Complaint Counsel has proven the ‘possibility’ of harm.”⁶³ ID 14, 54. The ALJ’s analysis does not withstand scrutiny.

As an initial matter, we are unpersuaded by the ALJ’s reliance on a single dictionary definition to determine the meaning of the phrase “likely to cause” in Section 5(n). Different dictionaries define the phrase differently. *See, e.g.*, Dictionary.com (defining “likely” as “reasonably to be believed or expected”). Some dictionaries define “likely” more broadly when used, as in Section 5(n), with an infinitive (“likely to cause”). Thus, Black’s Law Dictionary defines “likely” in the phrase “likely to show” as “[s]howing a strong tendency; reasonably expected.” *Black’s Law Dictionary* (10th ed. 2014). Similarly, Collins English Dictionary defines “likely” when used as an adjective as “probable,” but when used with an infinitive as “tending to or

⁶³ LabMD argues for an even higher threshold to assess likely causation, based on law used to determine whether a plaintiff has suffered an “injury in fact” for purposes of Article III standing. The standing doctrine “developed in our case law to ensure that federal courts do not exceed their authority as it has been traditionally understood” by “limit[ing] the category of litigants empowered to maintain a lawsuit in federal court” and, thereby, “prevent[ing] the judicial process from being used to usurp the powers of the political branches.” *Spokeo, Inc. v. Robins*, 136 S.Ct. 1540, 1547 (2016). Standing doctrine has no application here, where the issue is the authority of an executive branch agency to enforce the law, rather than the authority of federal courts to entertain a private party’s lawsuit. Similarly, LabMD is wrong when asserting that the Commission must satisfy standing requirements before imposing a cease and desist order. The Commission, as an independent agency within the executive branch, is simply carrying out its duty to “take Care that the Laws be faithfully executed.” U.S. Const. art. II, § 3. Indeed, the “injury in fact” prerequisite for standing is particularly inappropriate given Congress’ empowerment of the FTC to “tak[e] preemptive action,” consistent with “Section 5’s prophylactic purpose.” *FTC v. Freecom Communications, Inc.*, 401 F.3d 1192, 1203 (10th Cir. 2005).

Opinion of the Commission

inclined.”⁶⁴ None of these dictionary definitions is dispositive. Where there is disagreement about the meaning of an important statutory term, dictionary definitions may not be particularly helpful. *Bullock v. BankChampaign, N.A.*, 133 S. Ct. 1754, 1758 (2014). “It is a fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn” from the “specific context in which that language is used, and the broader context of the statute as a whole.” *Yates v. United States*, 135 S. Ct. 1074, 1082 (internal quotations omitted).

Unlike the ALJ, we agree with Complaint Counsel that showing a “significant risk” of injury satisfies the “likely to cause” standard.⁶⁵ In arriving at his interpretation of Section 5(n), the ALJ found that Congress had implicitly “considered, but rejected,” text in the *Unfairness Statement* stating that an injury “may be sufficiently substantial” if it “raises a significant risk of concrete harm.” ID 54-55 (citing *Unfairness Statement*, 104 F.T.C. at 1073 n.12). Yet the legislative history of Section 5(n) contains no evidence that Congress intended to disavow or reject this statement in the *Unfairness Statement*. Rather, it makes clear that in enacting Section 5(n) Congress specifically approved of the substantial injury discussion in the *Unfairness Statement* and existing case law applying the Commission’s unfairness authority. See SENATE REPORT at 12-13; H.R. REP. NO. 103-617, at 12 (1994) (Conf. Rep.).

We conclude that the more reasonable interpretation of Section 5(n) is that Congress intended to incorporate the concept of risk when it authorized the Commission to pursue practices “likely to cause substantial injury.” This reading is supported by prior Commission cases applying the unfairness standard, which also teach that the likelihood that harm will occur must be evaluated together with the severity or magnitude of the harm

64 See *Collins English Dictionary Online*, available at <http://www.collinsdictionary.com/dictionary/english/likely>.

65 Complaint Counsel also argues that an act or practice that creates a “significant risk of concrete harm” thereby *causes* a substantial injury. We believe the practices in this case creating a significant risk of injury are more properly analyzed under the “likely to cause” portion of Section 5(n).

Opinion of the Commission

involved. In other words, contrary to the ALJ's holding that "likely to cause" necessarily means that the injury was "probable," a practice may be unfair if the magnitude of the potential injury is large, even if the likelihood of the injury occurring is low. For example, in *International Harvester* – the quintessential unfairness case – the Commission found the failure to include a warning label on a tractor gas cap to be unfair where harmful fuel geysering accidents had occurred at a "rate of less than .001 percent," but the injuries involved included death and severe disfigurement. *Int'l Harvester Co.*, 104 F.T.C. at 1063; see also *Philip Morris*, 82 F.T.C. at 16 (finding unfairness based on severe health hazards without alleging any injuries had yet occurred).

The Third Circuit interpreted Section 5(n) in a similar way in *Wyndham*. It explained that defendants may be liable for practices that are likely to cause substantial injury if the harm was "foreseeable," *Wyndham*, 799 F.3d at 246, focusing on both the "probability and expected size" of consumer harm. *Id.* at 255. This approach is consistent with the standard applied in negligence cases. As described in the Restatement of Torts, a "negligent act or omission may be one which involves an unreasonable risk of harm to another through . . . the foreseeable action of . . . a third person." RESTATEMENT (SECOND) OF TORTS § 302 (1965).

In this case, there was a significant risk of substantial injury. First, there was a high likelihood of harm because the sensitive personal information contained in the 1718 file was exposed to millions of online P2P users, many of whom could have easily found the file. The ALJ's contrary determination that the 1718 file could only have been found by a search of the file's exact name, IDF 77, was in error. Complaint Counsel's expert on the Gnutella network, Dr. Clay Shields, convincingly explained how the 1718 file could have been found through a variety of commonly-used search techniques that would not have required searching for its exact file name or components thereof.

For instance, Dr. Shields pointed out that malicious users can and do search for P2P users whose computers are misconfigured. CX0738 (Shields Rebuttal Report) at ¶¶ 65-66. As he explained,

Opinion of the Commission

a computer may be misconfigured to share files that the user does not intend to share, such as all the files in the “My Documents” directory. Shields, Tr. 868. Users do not need to have any information about the names of the files they hope to find; rather, they can look for common files that are placed in particular directories when installed (*e.g.*, in “My Documents”). CX0738 (Shields Rebuttal Report) at ¶ 65. Finding such files suggests a high probability that the computer is misconfigured and is exposing files that the user does not intend to share. *Id.* at ¶ 66. The searcher who locates such a computer can then use LimeWire’s “browse host” function – which permits the searcher to see all the files the host computer is sharing, *id.* at ¶¶ 56-57 – to identify and download potentially sensitive files being inadvertently shared. *Id.* at ¶ 66; Shields, Tr. 844-45. “The LabMD computer, which was running LimeWire, would have been vulnerable to being found in this manner.” CX0738 (Shields Rebuttal Report) at ¶ 67.

Dr. Shields explained further that these methods, including use of the browse host functionality, were not speculative – that P2P networks are often used by malicious persons who use these types of simple techniques to seek out information that has been inadvertently shared. *Id.* at ¶ 65. A user could have received a search hit for some other file that was present on the billing manager’s computer and then used the browse host function to examine and download other files. Dr. Shields explained that because LabMD’s billing manager was using LimeWire to download and share popular music that could result in many search hits, her behavior “could easily have led to the 1,718 File being downloaded through browse host.” *Id.* at ¶ 57. He continued:

In addition, the shared folders on [the billing manager’s] computer contained other files that might have drawn the interest of potential thieves and could have been found through the basic search. For example, there was a file named “W-9 Form” being shared. A person who was interested in identity theft might have been searching [for] that term to find addresses and Social Security numbers. The browse host function could then be used to view and

Opinion of the Commission

download the 1,718 File that was contained in the same shared folders.

Id. at ¶ 58.

Dr. Shields' conclusions are borne out by what actually occurred. Mr. Wallace did not discover the 1718 file by searching for its exact name. Rather, he located the 1718 file while conducting a general search for sensitive information on P2P networks, using standard P2P software. Wallace, Tr. 1342-43, 1372, 1440-41; IDF 122. There is nothing in Mr. Wallace's testimony to suggest that he was searching for LabMD files specifically or that he knew – or even could have known – the 1718 file's exact name.

Dr. Shields also opined that “[w]hile it may be unlikely that any random user would choose to download the 1,718 File, this low probability must be balanced against the enormous number of users on the Gnutella system.” CX0738 (Shields Rebuttal Report) at ¶ 59. In particular, he quotes the estimate of LabMD's expert, Adam Fisk, that “[a]t any one time on the LimeWire network there would be approximately 2 to 5 million users online,” and opines that “[o]ver an extended period of time, such as weeks or months, even a 1 in 1,000,000 chance of someone downloading the 1,718 file would therefore result in it being downloaded many times.” *Id.* at ¶¶ 60-61. Dr. Shields' opinion, in combination with Mr. Wallace's actual experience, is persuasive evidence that LabMD's exposure of the 1718 file and other documents⁶⁶ for sharing on the Gnutella network created a significant likelihood that sensitive medical and other information would be disclosed.⁶⁷

66 See IDF 127 (“Using the ‘browse host’ function, Mr. Wallace also downloaded 18 other LabMD documents in addition to the 1718 File, three of which contained Personal Information.”). One of those documents contained names and passwords of LabMD employees; others contained the names and social security numbers or the names and insurance information for specific patients. See Wallace, Tr. 1405; RX645 at 39-43 (*in camera*).

67 The ALJ found that LabMD had searched P2P networks for other users in possession of the 1718 file and found nothing. IDF 95-97. Neither the ALJ nor LabMD, however, have identified any evidence suggesting that a malicious user who downloaded the 1718 file would further share that file, rather than simply keep it for his or her own malicious use.

Opinion of the Commission

Indeed, the sensitivity of the data in LabMD's possession made a breach particularly likely to occur. As Complaint Counsel's expert Mr. Van Dyke noted, the types of sensitive personal information found on the 1718 file are very attractive to identity thieves. CX0741 (Van Dyke Expert Report) at 5-6, 12-13.

The ALJ nonetheless discounted Complaint Counsel's evidence that LabMD's practices were "likely to cause" harm in light of what he characterized as the "inherently speculative nature of predicting 'likely' harm." ID 53. He placed great weight on the fact that Complaint Counsel had "not . . . identified even one consumer that suffered any harm as a result of Respondent's alleged unreasonable data security" and concluded that this "undermines the persuasiveness of Complaint Counsel's claim that such harm is nevertheless 'likely' to occur." ID 52; *see also id.* at 14, 64, 88.

The ALJ's reasoning comes perilously close to reading the term "likely" out of the statute. When evaluating a practice, we judge the likelihood that the practice will cause harm at the time the practice occurred, not on the basis of actual future outcomes. This is particularly true in the data security context. Consumers typically have no way of finding out that their personal information has been part of a data breach. CX0742 (Kam Expert Report) at 17; Kam, Tr. 400-02; *see also* ID 52. Furthermore, even if they do learn that their information has been exposed, it is very difficult for identity theft victims to find out which company was the source of the information that was used to harm them absent notification from the company. Kam, Tr. 398-99. Here, given the absence of notification by LabMD, a lack of evidence regarding particular consumer injury tells us little about whether LabMD's security practices caused or were likely to cause substantial consumer injury.⁶⁸ Moreover, Section 5 very clearly has a "prophylactic purpose" and authorizes the

⁶⁸ Significantly, LabMD typically interacted only with physicians' offices and had no direct dealings with consumers, other than billing when insurance did not pay. Even consumers whose samples were tested by LabMD may not have known that the company was retaining their sensitive personal data. See CX0726 (Maxey dep.) at 78-81; CX0728 (Randolph dep.) at 67.

Opinion of the Commission

Commission to take “preemptive action.” *FTC v. Freecom Commc’ns*, 401 F.3d 1192, 1203 (10th Cir. 2005).⁶⁹ We need not wait for consumers to suffer known harm at the hands of identity thieves.

In addition to demonstrating a significant risk of harm in this case, Complaint Counsel also proved that the severity and magnitude of potential harm was high. As noted above, Complaint Counsel’s expert witnesses identified a range of harms that can and do result from the unauthorized disclosure of consumers’ sensitive personal information of the type maintained by LabMD on its computer network.

Mr. Kam focused on the consumer harms caused by medical identity theft, *i.e.*, the unauthorized use of a consumer’s personal health information such as health insurance policy information, test codes, and diagnosis codes, to fraudulently obtain medical services, prescription drugs, or other products or services, or to fraudulently bill health insurance providers.⁷⁰ In particular, Mr. Kam reported the results of a Survey on Medical Identity Theft by the Ponemon Institute in 2013, showing the substantial out-of-pocket expenses that medical identity theft victims typically incur, including “reimbursement to healthcare providers for services received by the identity thief”; costs of “identity protection, credit counseling and legal counsel”; and “payment for medical services

69 See also *FTC v. Gratz*, 253 U.S. 421, 435 n.6 (1920) (Brandeis, J., dissenting) (“The purpose of this bill . . . is to seize the offender before his ravages have gone to the length necessary in order to bring him within the law that we already have.”) (quoting 51 CONG. REC. 11455 (July 1, 1914) (statement of Sen. Albert Cummins, co-sponsor of the legislation ultimately enacted as the FTC Act)).

70 CX0742 at 11-12. The risks of medical identity theft and its potentially serious consequences were well-known during the relevant time frame. See, e.g., *Medical Identity Theft Environmental Scan*, available at https://www.healthit.gov/sites/default/files/hhs_onc_medid_theft_envscan_101_008_final_cover_note_0.pdf (prepared by Booz, Allen, Hamilton for HHS and ONC for Health Information Technology, Oct. 2008); P. Dixon, *Medical Identity Theft: The Information Crime That Can Kill You*, available at <https://www.worldprivacyforum.org/2006/05/report-medical-identity-theft-the-information-crime-that-can-kill-you/>.

Opinion of the Commission

and prescriptions because of a lapse in healthcare coverage.”⁷¹ He observed that victims typically have to spend significant time to resolve problems caused by medical identity theft, and often give up because the process is so difficult and time-consuming. CX0742 at 15. He also noted that because “[t]here is no central ‘medical identity bureau’ where a consumer can set up a fraud alert, like they can with the credit bureaus,” and as a result, “identity thieves can continue to use a consumer’s medical identity to commit identity crimes” for long periods of time. *Id.* at 14.

Mr. Van Dyke emphasized that information like names, addresses, and Social Security numbers cannot be readily changed so that, once compromised, these types of personal information can often be used by malicious actors for an extended period and “could result in affected consumers suffering fraud in perpetuity.” CX0741 at 5, 12. Mr. Van Dyke also cited data from a survey conducted by his firm, Javelin, showing the average amount of money that identity thieves steal, the average number of hours that victims spend to resolve specific categories of fraud, and the out-of-pocket costs that victims incur in the course of resolving them. *Id.* at 9-11.⁷²

In addition, medical identity theft associated with data breaches can result in misdiagnosis or mistreatment of illness, and can thereby harm consumers’ physical health and safety. ID 49-50; CX0742 at 15. Mr. Kam explained that a “victim of medical identity theft may have the integrity of [his or her] electronic health record compromised if the health information of the identity thief has merged with that of the victim,” and that “[t]he resulting inaccuracies may cause serious health and safety risks to the victim, such as the wrong blood type or life-threatening drug allergies.” CX0742 at 15; Kam Tr. 426-27. Medical identity theft victims have also reported other types of health and safety harms

71 CX0742 at 15. According to the Ponemon Survey and Mr. Kam, loss of insurance coverage as a result of medical identity theft is a serious problem. *Id.*

72 Although Mr. Van Dyke bases his report primarily on the Javelin consumer survey conducted in 2013, Javelin has been conducting similar surveys for the past ten years.

Opinion of the Commission

caused by the theft, such as delay in receiving medical treatment and incorrect pharmaceutical prescriptions. CX0742 at 16. All of these types of harms are cognizable under Section 5(n).

Finally, given that we have found that the very disclosure of sensitive health or medical information to unauthorized individuals is itself a privacy harm, LabMD's sharing of the 1718 file on LimeWire for 11 months was also highly likely to cause substantial privacy harm to thousands of consumers, in addition to the harm actually caused by the known disclosure.⁷³

Having found that the unauthorized exposure of the 1718 file created a high likelihood of a large harm to consumers, we conclude that the unauthorized exposure of the 1718 file was "likely to cause substantial injury to consumers."

3. The Sacramento Incident

We do not find, however, that the security incident involving the Sacramento documents provides additional evidence that LabMD's computer security practices caused or were likely to cause substantial injury. LabMD does not dispute that the Sacramento Police Department discovered the documents in the possession of identity thieves. However, unlike with the 1718 file incident, the evidence does not establish any causal link between the exposed documents, which were found in hard copy form, and LabMD's computer security practices.

The fact that the documents were found in the hands of identity thieves strongly suggests that they viewed the information contained therein (including names and social security numbers) as valuable for their purposes. It also raises concerns that LabMD's lax security practices may not have been confined to its computers. Nonetheless, like the ALJ, we conclude that Complaint Counsel have not established that the Sacramento security incident was caused by deficiencies in LabMD's *computer* security practices, which were the sole practices challenged in the Complaint. *See* Comp. ¶ 10.

⁷³ *See* nn.54-62 and accompanying text, *supra*.

Opinion of the Commission

B. Consumers Could Not Reasonably Avoid the Injuries Resulting from LabMD's Data Security Practices

Turning to the second prong of Section 5(n), we find that consumers had no ability to avoid the harms caused by LabMD's practices. LabMD's clients were physicians or other health care providers. Most patients who provided blood or tissue samples for testing were not notified that their specimens would be given to LabMD for testing, or that LabMD would receive and retain other sensitive personal information as well. CX0726 (Maxey, SUN Designee, dep.) at 78; CX0728 (Randolph, Midtown Designee, dep.) at 67.⁷⁴ While some consumers eventually learned of LabMD's existence during the billing or collections process, even these consumers lacked any information about LabMD's data security practices, CX0726 (Maxey, SUN Designee, dep.) at 80-81, 100-01, and thus had no opportunity to avoid injuries caused by these practices. In sum, victims of a LabMD data breach would have "no chance whatsoever to avoid the injury before it occurred." *FTC v. Neovi, Inc.*, 598 F. Supp. 2d 1104, 1115 (S.D. Cal. 2008), *aff'd*, 604 F.3d 1150 (9th Cir. 2010).

LabMD nonetheless argues that consumers were reasonably capable of mitigating any injury "after the fact." We disagree. Our inquiry centers on whether consumers can avoid harm *before* it occurs.⁷⁵ Second, even assuming *arguendo* that the ability to mitigate harm does factor into its avoidability, there is nothing LabMD has pointed to that demonstrates mitigation after the fact would have been possible here. Without notice of a breach, consumers can do little to mitigate its harms. CX0742 (Kam Expert Report) at 17; Kam, Tr. 398-402. LabMD would be the entity to provide such notice if a breach occurred on its network,

74 Moreover, LabMD also holds personal data of approximately 100,000 consumers for whom it never performed tests. JX0001-A (Joint Stipulations) at 3; CX0710-A (Daugherty dep.) at 185-90, 192-93, 198.

75 See, e.g., *In re Orkin Exterminating Co.*, 108 F.T.C. at 366 (holding that "[a]nticipatory avoidance through consumer choice was impossible" when consumers had no "reason to anticipate the impending harm" and respondent did not give most consumers information on "the means to avoid it") (quoted with approval in *Orkin*, 849 F.2d at 1365).

Opinion of the Commission

yet it did not notify the relevant 9,300 consumers that their medical and other sensitive personal information had been exposed in the 1718 file. CX0710-A (Daugherty Designee dep.) at 48; Daugherty, Tr. 1087. Moreover, even if consumers do receive notice that their information was involved in a breach, it may be difficult or impossible to mitigate or avoid further harm, since they have “little, if . . . any, control over who may access that information” in the future,⁷⁶ and tools such as credit monitoring and fraud alerts cannot foreclose the possibility of future identity theft over a long period of time.⁷⁷ Furthermore, consumers cannot avoid or fully reverse certain categories of non-economic injury that may accompany the exposure of sensitive medical information. In short, there was no way for consumers to avoid the injury that was caused or likely to be caused by LabMD’s inadequate data security practices.

C. The Injuries Were Not Outweighed by Countervailing Benefits to Consumers or to Competition

Finally, we must consider whether the consumer injury resulting from LabMD’s data security practices is “outweighed by countervailing benefits to consumers or to competition.” 15 U.S.C. § 45(n). A “benefit” can be in the form of lower costs and then potentially lower prices for consumers, and the Commission “will not find that a practice unfairly injures consumers unless it is injurious in its net effects.” *Unfairness Statement*, 104 F.T.C. at 1073. This cost-benefit inquiry is particularly important in cases where the allegedly unfair practice consists of a party’s failure to take actions that would prevent consumer injury or reduce the risk of such injury. *Int’l Harvester Co.*, 104 F.T.C. at 1064. When a case concerns the failure to provide adequate data security in particular, “countervailing benefits” are the foregone costs of “investment in stronger cybersecurity” by comparison

⁷⁶ For example, in the case of an unauthorized release of information through a P2P network, “once a file has been shared on a P2P network it can be difficult or impossible to remove it from the network.” CX0738 (Shields Rebuttal Report) ¶ 21.

⁷⁷ Kam, Tr. at 402; CX0742 (Kam Expert Report) at 22-23.

Opinion of the Commission

with the cost of the firm's existing "level of cybersecurity." *Wyndham*, 799 F.3d at 255.

Here, we conclude that whatever savings LabMD reaped by forgoing the expenses needed to remedy its conduct do not outweigh the "substantial injury to consumers" caused or likely to be caused by its poor security practices. For the data security failures we described above, the record contains detailed evidence of low-cost solutions that LabMD could have adopted to cure the deficiencies and render its practices reasonable and appropriate. LabMD has not disputed Complaint Counsel's showing as to the availability and cost of these alternatives.

For example, there were many free or low cost software tools and hardware devices available for detecting vulnerabilities, including antivirus programs, firewalls, vulnerability scanning tools, intrusion detection devices, penetration testing programs,⁷⁸ and file integrity monitoring tools.⁷⁹ CX0740 (Hill Expert Report) ¶ 65. LabMD could have maintained and updated operating systems of computers and other devices on its network at relatively low cost. Hill, Tr. 194; CX0740 (Hill Expert Report) ¶ 101. Remediation processes and updates for vulnerabilities were widely available. CX0740 (Hill Expert Report) ¶ 99. These processes included free notifications from vendors, as well as the Computer Emergency Response Team ("CERT"), the Open Source Vulnerability Data Base, NIST, and others. *Id.*

In addition, LabMD could have adequately trained employees to safeguard personal information at relatively low cost. Hill, Tr.

⁷⁸ Since 1997, several well-respected and free penetration test and network analysis mechanisms have been available. Examples include Wireshark (released in 1998 under a different name), Nessus (free until 2008), and nmap (released in 1997). Hill, Tr. 162; CX0740 (Hill Expert Report) ¶ 71. When LabMD hired outside IT service provider ProviDyn to conduct penetration tests after the FTC investigation began, in May 2010, the cost for nine tests was \$450. CX0044 at 4; CX0048; CX0488 at 4.

⁷⁹ LabMD could have implemented SNORT, a respected and widely used intrusion detection system, which has been available at no cost since 1998. CX0740 (Hill Expert Report) ¶¶ 69 n.22, 104(h). Free file integrity monitoring products, such as Stealth and OSSEC, were also available to LabMD during the relevant time period. CX0740 (Hill Expert Report) ¶ 69 n.22.

Opinion of the Commission

173-76; CX0740 (Hill Expert Report) ¶ 92. Several nationally recognized organizations provided low-cost or free IT security training courses. Hill, Tr. 173-74; CX0740 (Hill Expert Report) ¶ 89 & n.30. For example, the SysAdmin Audit Network Security (SANS) Institute, formed in 1989, provides free security training webcasts. Additional free resources could be found online, and CERT at Carnegie Mellon University offered e-learning courses for IT professionals for as little as \$850. Hill, Tr. 174-75; CX0740 (Hill Expert Report) ¶ 89 n.30.

LabMD also could have limited employees' access to only the types of personal information that they needed to perform their jobs at relatively low cost. Hill, Tr. 166-67; CX0740 (Hill Expert Report) ¶ 85. Because operating systems and applications already have access controls embedded in them, rectifying this issue would have required only the time of trained IT staff. Hill, Tr. 166-67; CX0740 (Hill Expert Report) ¶ 85. In addition, LabMD could have purged the personal information of consumers for whom it never performed testing at relatively low cost. This could have been accomplished using LabMD's database applications, and would have required only the time of trained IT staff. Hill, Tr. 164; CX0740 (Hill Expert Report) ¶ 80(b). We recognize that the time of trained IT staff can amount to a real cost, but LabMD already had multiple IT personnel on staff. Any such additional costs would be far outweighed by the likely adverse consequences to consumers of LabMD's lax security practices.

Finally, LabMD readily could have prevented the installation of LimeWire by simply providing the billing manager and other employees non-administrative accounts on their workstations. CX0740 (Hill Expert Report) ¶¶ 85, 104(a). The Windows operating system that LabMD used included this functionality; LabMD could have made use of it with no monetary expense. *Id.*

Consequently, the benefits resulting from LabMD's flawed practices are negligible because the costs to provide the appropriate data security would have been relatively low. The cost-benefit test "is easily satisfied 'when a practice produces clear adverse consequences for consumers that are not accompanied by an increase in services or benefits to consumers

Opinion of the Commission

or by benefits to competition.” *Neovi*, 598 F. Supp. 2d at 1116 (quoting *FTC v. J.K. Publications, Inc.*, 99 F. Supp. 2d 1176, 1201 (C.D. Cal. 2000)). That is the case here.

IV. None of LabMD’s Affirmative Defenses or Other Objections Has Merit

A. Fair Notice and Due Process

LabMD’s First Amended Answer raised six affirmative defenses, most of which we have already addressed in prior rulings or elsewhere in this Opinion.⁸⁰ Our discussion here focuses on LabMD’s fifth affirmative defense: that this proceeding violates its Fifth Amendment due process rights and the Administrative Procedure Act because the Commission failed to provide adequate notice of what data security practices are required by Section 5. Although we addressed essentially the same arguments and explained why they are meritless in our January 16, 2014 order, LabMD reiterates and expands on them in the present appeal.

First, LabMD contends that our unfairness standard is “void for vagueness,” in violation of the Fifth Amendment. As we noted in our January 16, 2014 order, the Supreme Court and courts of appeals have rejected comparable due process challenges on many occasions and affirmed agency and lower court decisions imposing liability for violations of statutes that, like the FTC Act, use broad terms such as “unfair,” “unjust,” or “unreasonable” to define which practices are prohibited. *See*

⁸⁰ We rejected LabMD’s first, second, and third affirmative defenses – respectively, the failure to state a claim upon which relief can be granted, absence of subject matter jurisdiction, and an absence of statutory authority to regulate the acts or practices alleged – in our January 16, 2014 order. We also rejected LabMD’s contention that its acts and practices were not “in or affecting commerce,” as defined in Section 4 of the FTC Act. Comm’n Order Denying Motion to Dismiss at 17. LabMD’s fourth defense is that the acts or practices alleged in the Complaint do not constitute a violation of Section 5(n). That assertion is addressed throughout this Opinion, in which we analyze the evidence establishing that LabMD’s data security practices satisfied each of the elements in Section 5(n). Finally, we rejected LabMD’s sixth affirmative defense (challenging the ALJ’s role as presiding officer) in our September 14, 2015 order.

Opinion of the Commission

Comm'n Order Denying Motion to Dismiss at 15. For example, courts and agencies often evaluate restraints of trade under Sections 1 and 2 of the Sherman Act, as well as under the FTC Act's prohibition of "unfair methods of competition," 15 U.S.C. §§ 1, 2, 45(a), using a fact-specific "rule of reason." *See, e.g., FTC v. Indiana Fed. of Dentists*, 476 U.S. 447, 457-59 (1986). For over a century, courts have held that this flexible "rule of reason" standard does not violate defendants' due process rights. *See, e.g., Standard Oil Co. v. United States*, 221 U.S. 1, 66-69 (1911). Similarly, courts have held that agencies may, "consistent[] with the obligations of due process," enforce the prohibitions of "unjust" or "unreasonable" rates or practices in various public utility and common carrier regulatory statutes. *See Permian Basin Area Rate Cases*, 390 U.S. 747, 784 (1968); *see also FPC v. Hope Natural Gas Co.*, 320 U.S. 591, 601-02 (1944); *Verizon Commc'ns, Inc. v. FCC*, 535 U.S. 467, 477, 481 (2002).

LabMD's vagueness challenge relies heavily on *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307 (2012), in which the Federal Communications Commission imposed substantial monetary forfeitures on broadcasters for violating a statute that prohibited broadcast "indecenty." But *Fox* is distinguishable from this case in a number of important respects. The regulatory action in *Fox*, penalizing broadcasters based on the content of the language in their programs, directly implicated their First Amendment right to free speech. 132 S. Ct. at 2317. No comparable fundamental right is at issue here. LabMD cannot plausibly contend that it had a constitutional right to manage its computer networks in a manner that was likely to expose sensitive personal information to unauthorized third parties. *See Wyndham*, 799 F.3d at 255 (lower level of statutory notice was required because "[S]ection 45(a) does not implicate any constitutional rights") (citing *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982)).

Moreover, in *Fox*, the agency applied a criminal statute, 18 U.S.C. § 1464, and imposed monetary penalties. By contrast, Section 5 of the FTC Act is a civil statute and only injunctive relief is at issue in this case, not criminal or "quasi-criminal" fines. *Wyndham*, 799 F.3d at 255 & n.20 (citing *Flipside*, 455 U.S. at 498-99, and *Ford Motor Co. v. Texas Dept. of Transp.*,

Opinion of the Commission

264 F.3d 493, 508 (5th Cir. 2001)). Section 5 therefore is “subject to a less strict vagueness test.” *Flipside*, 455 U.S. at 498.

Additionally, in *Fox*, the agency abruptly reversed a more lenient interpretation to which it had adhered for decades, and imposed liability in a manner that “failed to provide . . . fair notice of what is prohibited.” 132 S. Ct. at 2318 (internal quotations omitted). The Court has faulted other abrupt changes of policy for similar reasons in other cases. *See, e.g., Christopher v. SmithKline Beecham Corp.*, 132 S. Ct. 2156, 2167 (2012) (invalidating agency’s “interpretation of ambiguous regulations [that] impose[d] potentially massive liability on respondent for conduct that occurred well before that interpretation was announced” – which was “precisely the kind of ‘unfair surprise’ against which our cases have long warned”); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 146-47 (2000) (overturning rules in part because agency had repeatedly and consistently stated that it lacked authority to regulate tobacco products). By contrast, here the FTC is imposing the same basic data security standard it has consistently articulated for nearly fifteen years.

LabMD challenges this enforcement proceeding next on the ground that the Commission had “not prescribed regulations or legislative rules under Section 5 establishing medical data security standards” before issuing the complaint against LabMD. In our January 16, 2014 order, we noted that “longstanding case law confirm[s] that administrative agencies may – indeed, must – enforce statutes that Congress has directed them to implement, regardless whether they have issued regulations addressing the specific conduct at issue.” Comm’n Order Denying Motion to Dismiss at 14 (citing *SEC v. Chenery*, 332 U.S. 194, 201-02 (1947), and *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 292 (1974)). Indeed, “complex questions relating to data security practices in an online environment are particularly well-suited to case-by-case development in administrative adjudications or enforcement proceedings.” *Id.* at 14-15. By the same token, “it is well-established that the common law of negligence does not violate due process simply because the standards of care are uncodified,” and thus “courts and juries [routinely] subject

Opinion of the Commission

companies to tort liability for violating uncodified standards of care.” *Id.* at 16-17.

Fundamentally, Section 5(n) provides reasonably clear and intelligible guidelines for companies to follow in designing their own data security programs. *See Wyndham*, 799 F.3d at 255. As discussed above, the FTC Act simply requires a company that maintains personal information about consumers to assess the risks that its actions could cause harm to those consumers and to implement reasonable measures to prevent or minimize such foreseeable harm.

We provided ample notice to the public of our expectations regarding reasonable and appropriate data security practices by issuing numerous administrative decisions finding specific companies liable for unreasonable data security practices. Our complaints, as well as our decisions and orders accepting consent decrees, which are published on our website and in the Federal Register, make clear that the failure to take reasonable data security measures may constitute an unfair practice. Those complaints, decisions, and orders also flesh out the specific types of security lapses that may be deemed unreasonable.⁸¹ These

⁸¹ *See, e.g., BJ's Wholesale Club, Inc.*, 140 F.T.C. 465 (2005); *CardSystems Solutions, Inc.*, 71 Fed. Reg. 10686 (FTC, Mar. 2, 2006) ([available at http://www.ftc.gov/enforcement/cases-proceedings/052-3148/cardsystems-solutions-inc-solidus-networks-inc-dba-pay-touch](http://www.ftc.gov/enforcement/cases-proceedings/052-3148/cardsystems-solutions-inc-solidus-networks-inc-dba-pay-touch)); *DSW Inc.*, 141 F.T.C. 117 (2006); *Reed Elsevier, Inc.*, (FTC, July 29, 2008) ([available at http://www.ftc.gov/enforcement/cases-proceedings/052-3094/reed-elsevier-inc-seisint-inc-matter](http://www.ftc.gov/enforcement/cases-proceedings/052-3094/reed-elsevier-inc-seisint-inc-matter)); *TJX Companies, Inc.*, (FTC, July 29, 2008) ([available at http://www.ftc.gov/enforcement/cases-proceedings/072-3055/tjx-companies-inc-matter](http://www.ftc.gov/enforcement/cases-proceedings/072-3055/tjx-companies-inc-matter)). The FTC has also provided substantial public guidance outside the litigation context. *See* CX0771 at 2 (Press Release: Press Council of Better Business Bureaus, National Cyber Security Alliance, Federal Trade Commission, offer Businesses Tips For Keeping Their Computer Systems Secure (Apr. 2, 2004)) (recommending that businesses “prohibit[] [their] employees from installing file-sharing programs on their computers”); FTC, PROTECTING PERSONAL INFORMATION: A GUIDE FOR BUSINESS (2007) (announced in FTC’s press release “FTC Unveils Practical Suggestions for Businesses on Safeguarding Personal Information” (Mar. 8, 2007), [available at https://www.ftc.gov/news-events/press-releases/2007/03/ftc-unveils-practical-suggestions-businesses-safeguarding](https://www.ftc.gov/news-events/press-releases/2007/03/ftc-unveils-practical-suggestions-businesses-safeguarding)) (advising companies, *inter alia*, to “[k]eep sensitive data in your system only as long as you have a business reason to have it”; “[a]ssess the vulnerability of each connection to commonly known or reasonably foreseeable attacks”; “[s]can computers on your network

Opinion of the Commission

widely available materials “constitute a body of experience and informed judgment to which . . . [parties] may properly resort for guidance.” *Gen. Elec. Co. v. Gilbert*, 429 U.S. 125, 141-42 (1976). And even though they “are neither regulations nor ‘adjudications on the merits,’” they are sufficient to afford fair notice of what was needed to satisfy Section 5(n). See *Wyndham*, 799 F.3d at 257 (citing *United States v. Lachman*, 387 F.3d 42, 57 (1st Cir. 2004); *Sec’y of Labor v. Beverly Healthcare-Hillview*, 541 F.3d 193, 202 (3d Cir. 2008); and *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1329 (D.C. Cir. 1995)). LabMD cannot seriously contend that it lacked notice that its security failures, which led to at least one documented breach of thousands of consumers’ sensitive personal information – practices similar to those committed by other companies against which the FTC has taken action – could trigger Section 5 liability.⁸²

B. Exclusion of All Evidence as Claimed “Fruit of the Poisoned Tree”

We concur with the ALJ’s conclusions that the testimony of Robert Boback, CEO of Tiversa, was not credible or reliable. IDF 160, 166-68; ID 60. In particular, we agree that Mr. Boback’s assertion that Tiversa had gathered evidence showing that the 1718 file had spread to multiple Internet locations by means of LimeWire was false and that the document that purported to list

to identify and profile the operating system and open-network services”; “[m]onitor outgoing traffic for signs of a data breach”; and “[t]ake time to explain the rules to your staff, and train them to spot security vulnerabilities”). See also 16 C.F.R. Part 314 (FTC standards for safeguarding consumers’ financial information, promulgated pursuant to the Gramm-Leach-Bliley Act); 65 Fed. Reg. 54186 (Sept. 7, 2000) (advance notice of proposed rulemaking and request for comment on Part 314 rules); 66 Fed. Reg. 41162 (Aug. 8, 2001) (proposed rule); 67 Fed. Reg. 36484 (May 23, 2002) (final Part 314 rule and Statement of Basis and Purpose).

⁸² See, e.g., *BJ’s Wholesale Club*, 140 F.T.C. at 467, ¶ 7(4) (2005) (alleging that BJ’s “failed to employ sufficient measures to detect unauthorized access or conduct security investigations”); *DSW, Inc.*, 141 F.T.C. at 119, ¶ 7(5) (2006) (alleging that DSW “failed to employ sufficient measures to detect unauthorized access”); Comp. ¶ 10(g) (alleging that LabMD “did not employ readily available measures to prevent or detect unauthorized access to personal information on its computer networks”).

Opinion of the Commission

Internet locations where the 1718 file had been found (CX0019) was unreliable. IDF 129, 148-49, 153-54; ID 60. Complaint Counsel do not take issue with these conclusions in their appeal. They represent that they have not relied on Mr. Boback's testimony or on CX0019 here or in their pre- or post-trial briefs before the ALJ.

LabMD nonetheless argues that all of the evidence obtained by Complaint Counsel should have been excluded from the record. According to LabMD, Complaint Counsel "knew, or should have known" that Tiversa was not authorized to obtain the 1718 file, that all of Complaint Counsel's evidence was the direct "fruit" of the 1718 file, and thus that the entire case should have been dismissed. RAB 64. This argument fails.

First, the record does not show that Tiversa, whatever its motives, unlawfully obtained the 1718 file; LabMD made the file freely available for public viewing through LimeWire. Moreover, even evidence improperly obtained by private individuals and provided to law enforcement officials is not excluded unless the private actors served as agents of the government. *See, e.g., United States v. Clutter*, 914 F.2d 775, 778 (6th Cir. 1990) ("[T]he exclusionary rule of the Fourth Amendment does not apply to a search and seizure by a private person not acting in collusion with law enforcement officials in order to circumvent the requirements of a search warrant.").

As the Court of Appeals for the Eleventh Circuit has explained, "the exclusionary rule is designed to deter police misconduct, rather than to punish the errors of others," so that "[m]isconduct by other actors is a proper target of the exclusionary rule only insofar as those others are adjuncts to the law enforcement team." *United States v. Herring*, 492 F.3d 1212, 1217 (11th Cir. 2007) (internal quotations omitted). Accordingly, the exclusionary rule applies only in "those areas where its remedial objectives [*i.e.*, deterring law enforcement agents from violating the Fourth Amendment] are thought most efficaciously served." *United States v. Calandra*, 414 U.S. 338, 348 (1974). Furthermore, the Supreme Court has made clear that the government does not violate due process by reason of improper private conduct so long as the agency did not "exercise[] coercive

Opinion of the Commission

power or . . . provide[] such significant encouragement, either overt or covert,” to induce the private actors to commit such purportedly unlawful conduct. *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982).

There is no evidence that Tiversa acted as an “agent” or “adjunct” to the FTC in obtaining the 1718 file, much less that anyone at the FTC “exercised coercive power” compelling Tiversa to do so. Consequently, even granting that Tiversa was financially motivated to obtain confidential information, there was nothing improper about Commission staff’s receipt of the information via a civil investigative demand in a law enforcement matter.⁸³

This case is thus entirely distinguishable from the principal case on which LabMD relies, *Knoll Associates, Inc. v. FTC.*, 397 F.2d 530 (7th Cir. 1968), in which the court concluded that Complaint Counsel’s “use of . . . stolen documents render[ed] the Commission’s order unenforceable.” *Id.* at 533-34. In that case, undisputed evidence showed that a former sales representative had stolen the documents “for the purpose of assisting the Commission counsel in the prosecution of the proceeding,” and that Complaint Counsel “knowingly gave its approval to [his] unlawful act.” *Id.* at 533. None of those factors is present here. No proceeding against LabMD was pending when Tiversa obtained the 1718 file and nothing in the record indicates that Tiversa was acting at the direction or behest of FTC staff.⁸⁴

83 LabMD’s assertion that the use of the Privacy Institute “as a PHI conduit made the government a party to conduct which violated HIPAA,” RAB 64, is unclear. As described in the Initial Decision, the FTC issued its civil investigative demand to the Privacy Institute, a Tiversa affiliate created for the purpose of receiving the CID. IDF 136-38. LabMD does not explain why directing the CID to a Tiversa affiliate, rather than to Tiversa itself, made the FTC a party to a HIPAA violation. We see no factual or logical relationship between the manner in which the FTC staff obtained information from Tiversa and the manner in which Tiversa obtained the information in the first place.

84 The ALJ found, based on Mr. Wallace’s testimony, that after the meeting between Tiversa and FTC staff in the fall of 2009, Mr. Boback directed Mr. Wallace to generate false information purporting to show that the 1718 file had spread to multiple locations on the Internet and could be downloaded from those locations. IDF 146-49. LabMD apparently asks us to infer that FTC staff asked Tiversa to generate such false information in order to use it as evidence

Opinion of the Commission

C. Miscellaneous Objections and Defenses

Over the course of the proceeding, LabMD raised a number of objections to the procedures that the Commission used to conduct this administrative proceeding. None of these objections has merit. First, LabMD challenged the participation of Chief Administrative Law Judge D. Michael Chappell and Chairwoman Edith Ramirez. The Commission rejected both challenges.

Similarly, LabMD argued before the ALJ that the Commission as a whole has infringed LabMD's due process rights because the Commission purportedly has prejudged the outcome of the case. Specifically, LabMD claimed that it was denied due process because there was a "statistical certainty" that the Commission would "find LabMD's data security practices are unfair under Section 5(n) no matter what [the ALJ] does," and that "[t]his clear inevitability of outcome transforms the adjudicatory process into punishment." Resp't's Post-Trial Br. at 58. The argument is meritless. LabMD submitted no evidence that the Commission had "made up [its] mind about important and specific factual questions and [was] impervious to contrary evidence" before deciding this case. *Metro. Council of NAACP Branches v. FCC*, 46 F.3d 1154, 1165 (D.C. Cir. 1995) (internal quotations omitted). Nor did LabMD show that the Commission had "in some measure adjudged the facts as well as the law of a particular case in advance of hearing it." *Cinderella Career & Finishing Sch., Inc. v. FTC*, 425 F.2d 583, 591 (D.C. Cir. 1970) (internal quotations omitted). Rather, as is evidenced by this Opinion, we have decided the contested factual and legal issues

against LabMD. However, there is no basis whatsoever for such an inference. At trial, Mr. Wallace thoroughly discussed both his contacts with the FTC and Mr. Boback's directions regarding creation of evidence that the 1718 file had spread to multiple locations. At no time did he suggest that FTC staff knew of, or in any way acquiesced in, Mr. Boback's direction, much less that FTC staff had asked or suggested that such evidence be generated. *See* Wallace Tr. 1347, 1369-70, 1380, 1383-90, 1408-09, 1447. LabMD's related argument – that the FTC knew or should have known that Mr. Boback's testimony was untruthful, so that any continuation of this proceeding violates LabMD's due process rights – is similarly flawed. LabMD presents no factual basis for the assertion that Complaint Counsel knew or should have known that Mr. Boback's testimony was false, and no explanation why continuation of the proceeding *without* continued reliance on Mr. Boback's testimony violates due process.

Opinion of the Commission

on their merits, based on a careful analysis of the record. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 493, 496-97 (1951); *see also FTC v. Cement Inst.*, 333 U.S. 683, 701-02 (1948) (rejecting claim that FTC's prior conclusions about legal issues denied respondent due process); *Kennecott Copper Corp. v. FTC*, 467 F.2d 67, 79 (10th Cir. 1972) (noting "the courts have uniformly held" that the fact that "the Federal Trade Commission combines the functions of investigator, prosecutor and judge and that Congress designed it in that manner . . . does not make out an infringement of the due process clause of the Fifth Amendment").

Finally, we find that any defenses or arguments not raised on appeal by LabMD have been waived.⁸⁵ *See United States v. Jernigan*, 341 F.3d 1273, 1283 n.8 (11th Cir. 2003) ("a party seeking to raise a claim or issue on appeal must plainly and prominently so indicate"; otherwise, the issue "will be considered abandoned").

V. The Remedy is Appropriate and Required to Prevent Further Consumer Injury

Having found that LabMD violated the FTC Act, we enter an order that will ensure LabMD reasonably protects the security and confidentiality of the personal consumer information in its possession. 15 U.S.C. § 45(b); *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957). "The Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past." *FTC v. Colgate-Palmolive Co.*, 380 U.S.

⁸⁵ In a single sentence in its post-trial brief before the ALJ, LabMD asserted that the FTC violated its First Amendment rights when it issued the Complaint in order "to retaliate against LabMD for speaking out against government overreach." Resp't's Post-Trial Br. 59. Apart from this one sentence, LabMD submitted no explanation of the basis for this argument. The single case LabMD cited in support of this contention, *Trudeau v. FTC*, 456 F.3d 178, 190-91 & n.22 (D.C. Cir. 2006), is inapposite. In that case, the D.C. Circuit affirmed the lower court's dismissal of a party's First Amendment claim against the FTC, but held that the court mistakenly dismissed the case for lack of subject-matter jurisdiction when it should have dismissed it for failure to state a claim. In any case, LabMD has cited no evidence in support of its argument. LabMD has therefore waived any possible First Amendment argument.

Opinion of the Commission

374, 395 (1965) (internal quotations omitted). Rather, “[t]he Commission has wide latitude in fashioning orders to prevent . . . respondents from pursuing a course of conduct similar to that found to have been unfair.” *Thompson Med. Co.*, 104 F.T.C. 648, 832-33 (1984), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986). This discretion is subject to two constraints, however. First, the order must be sufficiently clear and precise to be understood by the violator. *See, e.g., Colgate-Palmolive*, 380 U.S. at 392. Second, the order must bear a reasonable relationship to the unlawful practice found to exist. *See, e.g., Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946).

We enter an order similar to the Notice Order that was attached to the Complaint. The Order contains three provisions to prevent future violations by LabMD and remediate the risk of harm to consumers.

Part I of the Order requires LabMD to establish, implement, and maintain a comprehensive information security program that is reasonably designed to protect the security and confidentiality of consumers’ personal information. The program must be in writing, and should contain administrative, technical, and physical safeguards appropriate to LabMD’s size and complexity, the nature and scope of its activities, and the sensitive personal information maintained on LabMD’s network. In light of the discussion in our opinion and the availability of guidance about comprehensive information security programs from HIPAA and organizations such as NIST and the SANS Institute,⁸⁶ this provision is sufficiently clear and precise that its requirements can be readily understood and met.

Part II of the Order requires LabMD to obtain initial and then biennial assessments and reports regarding its implementation of the information security program. Each assessment must set forth the safeguards that LabMD implemented and maintained during the reporting period and certify that LabMD’s security program is operating with sufficient effectiveness to provide reasonable

⁸⁶ The FTC also offers guidance. *See, e.g., FTC, Start with Security: A Guide for Business* (2015), available at www.ftc.gov/system/files/documents/plain-language/pdf0205-startwithsecurity.pdf.

Opinion of the Commission

assurance that the security, confidentiality, and integrity of personal information is protected. The assessments and reports must be provided by a qualified, objective, independent third-party professional. This provision will ensure that LabMD implements information security practices that are appropriate for LabMD's size, complexity, and the nature and scope of its activities and the sensitive personal information maintained on its network, and thereby complies with the Order. Courts have upheld the use of extensive assessment and monitoring requirements by an independent third party in final injunction orders. *See, e.g., United States v. Apple, Inc.*, 992 F.Supp.2d 263 (S.D.N.Y. 2014), *aff'd*, 787 F.3d 131 (2d Cir. 2015).

These two provisions are reasonably related to the unlawful practices that form the basis for LabMD's liability – the failure by LabMD to implement reasonable and appropriate data security practices to protect consumers' sensitive medical and other information – and seek to ensure that this failure is remedied. The FTC has required these types of provisions in numerous final orders to settle actions involving data security practices that it charged were violations of Section 5(n). *See, e.g., FTC v. Cornerstone & Co., LLC*, Case No. 1:14-cv-01479-RC, at 5-6, Sec. II (Stip. Final Order for Permanent Inj.) (D.D.C. Apr. 21, 2015), *available at* <https://www.ftc.gov/enforcement/cases-proceedings/142-3211-x150005/cornerstone-company-llc>; *FTC v. Bayview Solutions, LLC*, Case No. 1:14-cv-01830-RC, at 4-6, Sec. II (Stip. Final Order for Permanent Inj.) (D.D.C. Apr. 20, 2015), *available at* <https://www.ftc.gov/enforcement/cases-proceedings/142-3226-x140062/bayview-solutions-llc>.

Part III of the Order requires LabMD to notify individuals whose personal information LabMD has reason to believe was or could have been exposed about the unauthorized disclosure of their personal information. LabMD must also notify the health insurance companies for these individuals of the information disclosure. Without notification, consumers would not know about the unauthorized disclosure of their sensitive information and would not know to take actions to reduce their risk of harm from identity or medical identity theft. LabMD acknowledges that this type of notice is required under HIPAA for disclosures of personal medical information that have occurred since 2010.

Opinion of the Commission

Daugherty, Tr. 1020-21. Similarly, notice to affected consumers' insurance companies enables these insurers to protect consumers' identities from misuse. These notification requirements are consistent with relief obtained in other cases. See *FTC v. Cornerstone & Co., LLC*, Case No. 1:14-cv-01479-RC, at 7, Sec. IV (Stip. Prelim. Inj.) (D.D.C. Apr. 21, 2015), available at <https://www.ftc.gov/enforcement/cases-proceedings/142-3211-x150005/cornerstone-company-llc>; *FTC v. Bayview Solutions, LLC*, Case No. 1:14-cv-01830-RC, at 7, Sec. IV (Stip. Prelim. Inj.) (D.D.C. Apr. 20, 2015), available at <https://www.ftc.gov/enforcement/cases-proceedings/142-3226-x140062/bayview-solutions-llc>.

The remaining parts of the Order are standard recordkeeping and sunset provisions that are included in most Commission orders. Part IV is a record-keeping requirement. Part V establishes that copies of the Order be distributed to, among others, principals, managers, and employees of LabMD. Part VI requires that LabMD file notifications about changes in corporate structure. Part VII establishes compliance reporting requirements. See, e.g., *FTC v. Direct Mktg. Concepts, Inc.*, 648 F. Supp. 2d 202, 213 (D. Mass. 2009) (“Courts have also included monitoring provisions in final orders in FTC cases to ensure compliance with permanent injunctions.”); *FTC v. Think Achievement Corp.*, 144 F. Supp. 2d 1013, 1018 (N.D. Ind. 2000) (ordering record retention, notification of changed employment or residence, access to premises, and monitoring); *FTC v. U.S. Sales Corp.*, 785 F. Supp. 737, 753 (N.D. Ill 1992) (“The order should also require Defendants to report their addresses and places of employment or business, and any subsequent changes in this information to the F.T.C.”). Part VIII provides that the Order will terminate in 20 years. See *U.S. Sales Corp.*, 785 F. Supp. at 754 (explaining that a complex case “may require a sustained period of monitoring by the F.T.C. to ensure adequate compliance”).

Complaint Counsel also seek a provision to require notice to the medical insurance companies for the consumers identified in the day sheets that were recovered in Sacramento. (LabMD has already provided notice to the individuals whose information was disclosed in the Sacramento incident.) We do not include this provision from the Notice Order that was attached to the

Opinion of the Commission

Complaint because such relief is not reasonably related to the violation in this case. LabMD's liability is not based on the Sacramento security incident, because we, like the ALJ, conclude that Complaint Counsel have not established that the Sacramento security incident was caused by deficiencies in LabMD's computer security practices. In addition, the day sheets included consumers' names, social security numbers, and copies of personal checks, but did not include medical or insurance information. IDF 182, 183, 185. The absence of medical or insurance information in this unauthorized disclosure provides further reason not to require notice to consumers' medical insurers.

LabMD contends that the relief in the Order is unnecessary and punitive. We disagree. Although LabMD stopped accepting specimen samples and conducting tests in January 2014, LabMD continues to exist as a corporation and has not ruled out a resumption of operations. IDF 36, 40-41; CX0709 (Daugherty dep.) at 15; Daugherty Tr., 1049-54. Moreover, LabMD continues to maintain the personal information of approximately 750,000 consumers on its computer system. IDF 42. Because LabMD continues to hold consumers' personal information and may resume operations at some future time, the Order is appropriate and necessary. *See, e.g., Direct Mktg. Concepts, Inc.*, 648 F. Supp. 2d at 215 (imposing injunction "[e]ven though the . . . defendants currently have no employees and are not engaged in any business, they could resume such activities in the future"); *United States v. Bldg. Inspector of Am., Inc.*, 894 F. Supp. 507, 521 (D. Mass. 1995) (finding injunction appropriate where company had ceased operation but "remains a going concern and could resume at any time"); *cf. Int'l Harvester Co.*, 104 F.T.C. at 1067 ("[A]n obligation should ordinarily extend as long as the risk of harm exists.").

In addition, the Order takes account of LabMD's current limited operations. The Order requires that LabMD establish and implement a comprehensive information security program that provides administrative, technical and physical safeguards that are appropriate for the nature and scope of LabMD's activities. Order, ¶ 1. A reasonable and appropriate information security program for LabMD's current operations with a computer that is

Final Order

shut down and not connected to the Internet will undoubtedly differ from an appropriate comprehensive information security program if LabMD resumes more active operations.

Finally, we reject LabMD's claim that the Order is punitive. The Order merely requires measures reasonably necessary to ensure the protection of the personal information on its computer system and notice related to its unfair practices. An order that is purely remedial and preventative is not a penalty or forfeiture. *See Riordan v. SEC*, 627 F.3d 1230, 1234 (D.C. Cir. 2010).

CONCLUSION

For the foregoing reasons, the Commission concludes that LabMD's data security practices were unreasonable and constitute an unfair act or practice in violation of Section 5 of the FTC Act. Consequently, we vacate the ALJ's Initial Decision and issue a Final Order requiring that LabMD notify affected individuals, establish a comprehensive information security program, and obtain assessments regarding its implementation of the program.

FINAL ORDER

The Commission has heard this matter upon the appeal of Complaint Counsel from the Initial Decision of the Administrative Law Judge, and upon briefs and oral argument in support thereof and in opposition thereto. For the reasons stated in the accompanying opinion of the Commission, the Commission has concluded that LabMD's data security practices were unreasonable and constitute an unfair act or practice that violates Section 5 of the Federal Trade Commission Act. The Commission has therefore determined to vacate the Initial Decision and issue the following order:

Final Order

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- B. Unless otherwise specified, “respondent” shall mean LabMD, Inc., and its successors and assigns.
- C. “Affected Individual” shall mean any consumer whose personal information LabMD has reason to believe was, or could have been, accessible to unauthorized persons before July 28, 2016, including, but not limited to, consumers listed in the Insurance File and other documents available to a peer-to-peer file sharing network, but excluding consumers whom LabMD has notified, before July 28, 2016, of a data security breach.
- D. “Insurance File” shall mean the file containing personal information about approximately 9,300 consumers, including names, dates of birth, Social Security numbers, health insurance company names and policy numbers, and medical test codes, that was available to a peer-to-peer file sharing network through a peer-to-peer file sharing application installed on a computer on respondent’s computer network.
- E. “Personal information” shall mean individually identifiable information from or about an individual consumer including, but not limited to: (a) first and last name; (b) telephone number; (c) a home or other physical address, including street name and name of city or town; (d) date of birth; (e) Social Security number; (f) medical record number; (g) bank routing, account, and check numbers; (h) credit or debit card information, such as account number; (i) laboratory

Final Order

test result, medical test code, or diagnosis, or clinical history; (j) health insurance company name and policy number; or (k) a persistent identifier, such as a customer number held in a “cookie” or processor serial number.

I.

IT IS ORDERED that the respondent shall, no later than the date this order becomes final and effective, establish and implement, and thereafter maintain, a comprehensive information security program that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers by respondent or by any corporation, subsidiary, division, website, or other device or affiliate owned or controlled by respondent. Such program, the content and implementation of which must be fully documented in writing, shall contain administrative, technical, and physical safeguards appropriate to respondent’s size and complexity, the nature and scope of respondent’s activities, and the sensitivity of the personal information collected from or about consumers, including:

- A. the designation of an employee or employees to coordinate and be accountable for the information security program;
- B. the identification of material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management; (2) information systems, including network and software design, information processing, storage, transmission, and disposal; and (3) prevention, detection, and

Final Order

response to attacks, intrusions, or other systems failures;

- C. the design and implementation of reasonable safeguards to control the risks identified through risk assessment, and regular testing or monitoring of the effectiveness of the safeguards' key controls, systems, and procedures;
- D. the development and use of reasonable steps to select and retain service providers capable of appropriately safeguarding personal information they receive from respondent, and requiring service providers by contract to implement and maintain appropriate safeguards; and
- E. the evaluation and adjustment of respondent's information security program in light of the results of the testing and monitoring required by Subpart C, any material changes to respondent's operations or business arrangements, or any other circumstances that respondent knows or has reason to know may have a material impact on the effectiveness of its information security program.

II.

IT IS FURTHER ORDERED that, in connection with its compliance with Part I of this order, respondent shall obtain initial and biennial assessments and reports ("Assessments") from a qualified, objective, independent third-party professional, who uses procedures and standards generally accepted in the profession. Professionals qualified to prepare such assessments shall be: a person qualified as a Certified Information System Security Professional (CISSP) or as a Certified Information Systems Auditor (CISA); a person holding Global Information Assurance Certification (GIAC) from the SysAdmin, Audit, Network, Security (SANS) Institute; or a similarly qualified person or organization approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580. The reporting period for the Assessments shall cover: (1) the first one hundred and eighty

Final Order

(180) days after July 28, 2016, for the initial Assessment, and (2) each two (2) year period thereafter for twenty (20) years after July 28, 2016, for the biennial Assessments. Each Assessment shall:

- A. set forth the specific administrative, technical, and physical safeguards that respondent has implemented and maintained during the reporting period;
- B. explain how such safeguards are appropriate to respondent's size and complexity, the nature and scope of respondent's activities, and the sensitivity of the personal information collected from or about consumers;
- C. explain how the safeguards that have been implemented meet or exceed the protections required by Part I of this order; and
- D. certify that respondent's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of personal information is protected, and has so operated throughout the reporting period.

Each Assessment shall be prepared and completed within sixty (60) days after the end of the reporting period to which the Assessment applies. Respondent shall provide the initial Assessment to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, within ten (10) days after the Assessment has been prepared. All subsequent biennial Assessments shall be retained by respondent until the order is terminated and provided to the Associate Director for Enforcement within ten (10) days of request. Unless otherwise directed by a representative of the Commission, the initial Assessment, and any subsequent Assessments requested, shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580, with the subject line *In the Matter of LabMD, Inc.*, FTC Docket No. 9357. *Provided, however*, that in lieu of overnight courier, Assessments

Final Order

may be sent by first-class mail, but only if an electronic version of any such Assessment is contemporaneously sent to the Commission at Debrief@ftc.gov.

III.

IT IS FURTHER ORDERED that respondent shall provide notice to Affected Individuals and their health insurance companies within 60 days of the date this order becomes final and effective unless an appropriate notice has already been provided, as follows:

- A. Respondent shall send the notice to each Affected Individual by first class mail, only after obtaining acknowledgment from the Commission or its staff that the form and substance of the notice satisfies the provisions of the order. The notice must be easy to understand and must include:
1. a brief description of why the notice is being sent, including the approximate time period of the unauthorized disclosure, the types of personal information that were or may have been disclosed without authorization (*e.g.*, insurance information, Social Security numbers, etc.), and the steps respondent has taken to investigate the unauthorized disclosure and protect against future unauthorized disclosures;
 2. advice on how Affected Individuals can protect themselves from identity theft or related harms. Respondent may refer Affected Individuals to the Commission's identity theft website (www.ftc.gov/idtheft), advise them to contact their health care providers or insurance companies if bills don't arrive on time or contain irregularities, or to obtain a free copy of their credit report from www.annualcreditreport.com and monitor it and their accounts for suspicious activity, or take such other steps as respondent deems appropriate; and

Final Order

3. methods by which Affected Individuals can contact respondent for more information, including a toll-free number for 90 days after notice to Affected Individuals, an email address, a website, and mailing address.
- B. Respondent shall send a copy of the notice to each Affected Individual's health insurance company by first class mail.
 - C. If respondent does not have an Affected Individual's mailing address in its possession, it shall make reasonable efforts to find such mailing address, such as by reviewing online directories, and once found, shall provide the notice described in Subpart A, above.

IV.

IT IS FURTHER ORDERED that respondent shall maintain and, upon request, make available to the Federal Trade Commission for inspection and copying:

- A. for a period of five (5) years, a print or electronic copy of each document relating to compliance, including, but not limited to, notice letters required by Part III of this order and documents, prepared by or on behalf of respondent, that contradict, qualify, or call into question respondent's compliance with this order; and
- B. for a period of three (3) years after the date of preparation of each Assessment required under Part II of this order, all materials relied upon to prepare the Assessment, whether prepared by or on behalf of respondent, including, but not limited to, all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, and any other materials relating to respondent's compliance with Parts I and II of this order, for the compliance period covered by such Assessment.

Final Order

V.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this order to: (1) all current and future principals, officers, directors, and managers; (2) all current and future employees, agents, and representatives having responsibilities relating to the subject matter of this order; and (3) any business entity resulting from any change in structure set forth in Part VI. Respondent shall deliver this order to such current personnel within thirty (30) days after the date this order becomes final and effective, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities. For any business entity resulting from any change in structure set forth in Part VI, delivery shall be at least ten (10) days prior to the change in structure.

VI.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any change in respondent that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor company; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in either corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580, with the subject line *In the Matter of LabMD, Inc.*, FTC Docket No. 9357. *Provided, however,* that in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of any such notice is contemporaneously sent to the Commission at Debrief@ftc.gov.

Final Order

VII.

IT IS FURTHER ORDERED that respondent, within sixty (60) days after the date this order becomes final and effective, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, D.C. 20580, with the subject line *In the Matter of LabMD, Inc.*, FTC Docket No. 9357. *Provided, however*, that in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of any such notice is contemporaneously sent to the Commission at Debrief@ftc.gov.

VIII.

This order will terminate on July 28, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. any Part in this order that terminates in less than twenty (20) years;
- B. this order's application to any respondent that is not named as a defendant in such complaint; and
- C. this order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that each respondent did not violate any provision of

Final Order

the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Complaint

IN THE MATTER OF

**SUPERIOR PLUS CORP.
AND
CANEXUS CORPORATION**COMPLAINT AND FINAL ORDER IN REGARD TO ALLEGED
VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION
ACT AND SECTION 7 OF THE CLAYTON ACT

*Docket No. 9371; File No. 161 0020
Complaint, June 27, 2016 – Decision, August 2, 2016*

This case addresses the \$982 million acquisition by Superior Plus Corp. of Canexus Corporation. The complaint alleges that the acquisition would violate Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act by significantly reducing competition in the market for sodium chlorate in North America. The Order dismisses the Complaint, on the ground that Superior has abandoned its proposed acquisition of Canexus, and that both Respondents have withdrawn their respective Hart-Scott-Rodino Notification and Report Forms.

Participants

For the *Commission: Cem Akleman, Stephen Antonio, Mac Conforti, Stephen Dahm, Llewellyn Davis, Meredith Levert, Sean Sullivan, and Robert Tovsky.*

For the *Respondents: Paul Cuomo, Baker Botts; Pamela Taylor, Jones Day.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (“FTC Act”), and by the virtue of the authority vested in it by the FTC Act, the Federal Trade Commission (“Commission”), having reason to believe that Respondents Superior Plus Corp. (“Superior”) and Canexus Corporation (“Canexus”) have executed an acquisition agreement in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, which if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public

Complaint

interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

I. NATURE OF THE CASE

1. Superior's proposed acquisition of Canexus (the "Acquisition") would combine two of the three major producers of sodium chlorate in North America. Sodium chlorate is a commodity chemical whose primary use is for bleaching wood pulp for paper, tissues, and other products. Superior and Canexus account for more than 50 percent of the sodium chlorate production capacity in North America.

2. In Superior's own words, the North American sodium chlorate market is an "oligopoly" that is "dominated by a small number of players." Absent injunctive relief, two firms, Superior and AkzoNobel ("Akzo"), will control approximately 80 percent of North American sodium chlorate capacity, resulting in post-Acquisition market shares that easily exceed the market concentration levels presumed likely to result in anticompetitive effects under the Federal Trade Commission and U.S. Department of Justice Horizontal Merger Guidelines ("Merger Guidelines") and under the relevant case law.

3. The Acquisition would substantially lessen competition in the market for sodium chlorate. First, by placing more than 50 percent of all production capacity into the hands of Superior—a company long focused on careful capacity management as a means of maintaining profitability—the Acquisition would increase the likelihood of future anticompetitive output reductions to increase price. Second, by consolidating more than 80 percent of total production capacity in the hands of the two most disciplined producers, and by removing Canexus, a uniquely disruptive, low-cost competitor, the Acquisition would increase the likelihood of coordination in an already vulnerable market.

4. New entry or expansion by existing producers would not be timely, likely, or sufficient to counteract the anticompetitive effects of the acquisition. Superior noted in an internal business presentation that "barriers to entry are high." Likewise, Canexus

Complaint

observed that barriers to entry are “significant” and that [REDACTED] [REDACTED] Constructing a new sodium chlorate manufacturing facility is expensive and time-consuming, making entry unlikely in this market characterized by declining demand. The newest sodium chlorate facility in North America opened in 2002. Similarly, expansion by the remaining firms sufficient to offset the Acquisition’s anticompetitive effects is unlikely. Since 2005, the sodium chlorate industry has removed capacity, not added it.

5. Respondents cannot show cognizable efficiencies that would offset the likely and substantial competitive harm from the Acquisition.

II. JURISDICTION

6. Respondents are, and at all relevant times have been, engaged in commerce or in activities affecting “commerce” as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

7. The Acquisition constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

III. RESPONDENTS

8. Superior is a publicly traded company based in Toronto, Ontario. It divides its business into three operating segments: (1) Specialty Chemicals, sold under the ERCO brand name; (2) Energy Services; and (3) Construction Products Distribution. In 2014, Superior had C\$3.976 billion in global sales. The ERCO business, which manufactures and sells sodium chlorate and chlor-alkali chemicals, generated C\$652 million in revenue in 2014, with the North American sodium chlorate business generating C\$382 million in revenue. Superior owns six sodium chlorate plants in North America: five in Canada, and one in the United States.

9. Canexus is a publicly traded chemical company based in Calgary, Alberta. It reported total 2014 revenue of C\$539 million, with sodium chlorate accounting for revenue of C\$233

Complaint

million. Canexus operates three sodium chlorate plants in Canada. Its Brandon, Manitoba facility is by far the largest and the lowest-cost sodium chlorate plant in North America.

IV. THE ACQUISITION

10. Under an agreement dated October 5, 2015 (“Acquisition Agreement”), Superior proposes to acquire all of the outstanding shares of Canexus in a transaction valued at \$982 million, including the assumption of \$618 million in debt.

V. BACKGROUND**A. Sodium Chlorate**

11. Sodium chlorate is a commodity chemical, manufactured by running electric current through purified salt water. It can be produced in either crystal or solution form. The vast majority of sodium chlorate sold in North America is in crystal form.

12. Sodium chlorate is widely used as a key process-chemical for bleaching wood pulp, which accounts for more than 90 percent of North American chlorate consumption. Pulp mills perform on-site conversion of sodium chlorate into chlorine dioxide — the actual bleaching agent. Because chlorine dioxide is volatile and expensive to ship and handle, most mills must produce it on-site. In turn, bleached pulp is the foundation of a variety of paper products, including coated sheet paper, tissues, and diaper liners.

13. Producers mainly ship sodium chlorate crystal by rail or truck, though a few customers located adjacent to sodium chlorate plants can also receive the solution form by pipeline. Industry practice is for producers to quote delivered prices. The largest cost components of sodium chlorate are electricity, which accounts for approximately 70-80 percent of production costs, salt, and freight.

Complaint

B. Market Participants and Industry Dynamics

14. Over the past decade, the North American sodium chlorate industry has experienced declining demand and capacity rationalization because of lower demand for paper products.

15. Because pulp and paper manufacturing is the primary end use for sodium chlorate, the decline in demand for paper in the digital age has caused a corresponding decline in demand for sodium chlorate. As Superior explained in an internal business document, sodium chlorate producers have responded to declining demand by removing capacity from the market and increasing exports in order to protect prices and producer profits:

[T]he market has adjusted to demand reduction with supply side management. Production capacity has been removed from the market as demand decreased. Additionally an increasing amount of sodium chlorate is being exported from North America to the extent that [REDACTED] of the North American production is now exported. ... Despite the declining market, producers have consistently achieved growing and stable profit margins . . .

16. As Superior's own documents state, the sodium chlorate market is an "oligopoly" with three "dominant market players": Superior, Canexus, and Akzo. The two smaller players — Kemira and Chemtrade — have much less capacity and a limited effect on competition.

17. Although 70 percent of North American production capacity is located in Canada, U.S. customers account for roughly 75 percent of North American chlorate sales. There is no production capacity or meaningful consumption of sodium chlorate in Mexico.

18. Superior operates five sodium chlorate plants in Canada (Buckingham, Quebec; Vancouver, British Columbia; Grand Prairie, Alberta; Hargrave, Manitoba; and Saskatoon, Saskatchewan) and one in the U.S. (Valdosta, Georgia), with an overall capacity of [REDACTED] metric tons. In addition to the North

Complaint

American sales from these facilities, Superior exports approximately [REDACTED] percent of its total annual production to Europe, Asia, and South America. Since 2006, Superior has closed chlorate plants in Bruderheim, Alberta, and Thunder Bay, Ontario, and contributed to the closure of former competitor Tronox's plant in Hamilton, Mississippi.

19. Canexus operates three plants in Canada (Brandon, Manitoba; Beauharnois, Quebec; and Nanaimo, British Columbia), with an overall capacity of [REDACTED] metric tons. At a production capacity of [REDACTED] metric tons, Canexus's Brandon plant is by far the largest, lowest-cost plant in North America. Brandon's position as the lowest-cost production facility in North America is the result of its operating in Manitoba, the lowest-cost electricity jurisdiction in North America, and of its significant economies of scale. Canexus ships from Brandon to customers throughout North America. Its two other plants are smaller and higher cost. Canexus exports some sodium chlorate [REDACTED]

[REDACTED]. Since 2007, Canexus has closed chlorate plants at Amherstburg, Ontario, and Bruderheim, Alberta.

20. Akzo, under the brand name Eka, operates two sodium chlorate plants in Canada (Magog, Quebec and Valleyfield, Quebec) and two in the U.S. (Columbus, Mississippi and Moses Lake, Washington), with an overall practical capacity of [REDACTED] metric tons. [REDACTED]

21. Kemira is the bigger of the two smallest competitors. It operates two plants in the southeast U.S. (Augusta, Georgia and Eastover, South Carolina), with an overall capacity of [REDACTED] metric tons. [REDACTED]

Complaint

[REDACTED]

22. Chemtrade has a single sodium chlorate plant in western Canada (Prince George, British Columbia), with a practical capacity of [REDACTED] metric tons. [REDACTED]

23. In 2013, Superior entered into an agreement with sodium chlorate producer Tronox, whose only North American sodium chlorate facility was in Hamilton, Mississippi. Under the agreement, Superior paid Tronox for the exclusive right to purchase all of Tronox's sodium chlorate production and customer contracts. Therefore, from 2013-2015, Superior was the exclusive seller of sodium chlorate produced by Tronox. Superior's goal, stated both internally and to investors, was to use the agreement it entered with Tronox to "help reduce [the] North American supply" of sodium chlorate in order to make the market "more conducive to price increase[s]." Last year, Superior announced that it was electing to purchase no volume from Tronox in 2016, meaning that Superior is paying Tronox about [REDACTED] million to produce no sodium chlorate. Tronox responded by closing its facility and exiting the market at the end of 2015, with Superior assisting Tronox in decommissioning the plant.

VI. RELEVANT PRODUCT MARKET

24. The relevant product market in which to analyze the Acquisition's effects is the manufacture and sale of sodium chlorate. Superior describes sodium chlorate as "the technology of choice for pulp bleaching." Customers (paper mills) have no viable substitute for sodium chlorate in the bleaching process, and could not realistically switch to other products in the face of a small but significant and non-transitory increase in price ("SSNIP") for sodium chlorate.

Complaint

25. Other products do not constrain the price of sodium chlorate. Customers play sodium chlorate producers against each other to obtain lower pricing and better contractual terms. Superior's outgoing vice president of its sodium chlorate business testified that customers rarely threaten to switch away from sodium chlorate when facing a price increase, and that never in his memory had Superior actually lowered its price or offered better terms to any customer in direct response to a threat to substitute another chemical or processes for sodium chlorate. Customers also state that they do not threaten to switch to alternative products or processes.

26. Respondents themselves recognize that other products are not meaningful substitutes for sodium chlorate. Canexus's business documents stated that demand for sodium chlorate is "fairly price inelastic" and that there are "no economically viable substitutes" for sodium chlorate in the pulp bleaching process. Superior similarly stated in its internal business documents that "demand is inelastic."

VII. RELEVANT GEOGRAPHIC MARKET

27. The relevant geographic market in which to assess the Acquisition is North America. Customers in the U.S. account for roughly 75 percent of all North American chlorate sales, and receive product from plants throughout both the U.S. and Canada. North American freight costs are low, typically accounting for approximately 10 percent of the delivered price, which allows North American plants to profitably ship to customers throughout the continent.

28. While some North American chlorate producers export sodium chlorate outside of the North American market, almost no sodium chlorate is imported. Customers report that imports are prohibitively expensive and complicated by special handling requirements — limiting their realistic sourcing options to North American producers.

29. Respondents operate their plants as part of an integrated North American supply network, optimizing supply across multiple plants and customers. Customers' supply contracts are

Complaint

not tied to specific plants. Although there is substantial variability in pricing across customers, there are no persistent regional pricing patterns. Consistent with this, the Respondents' internal business documents consistently refer to a "North American" sodium chlorate market.

30. Indeed, documentary evidence and testimony make clear that industry participants develop strategies, take actions, and understand pricing dynamics to operate at the North American level. For example, an internal Superior presentation discussed "North American Sodium Chlorate Supply and Demand," and noted that "[e]xports are critical to maintaining North American balance." On a Superior earnings call, Superior's CEO explained why it was choosing not to sell any more Tronox chlorate: "The potential to remove 130,000 ton of sodium chlorate supply from the North American market would largely balance the North American supply and demand fundamentals, which should provide Superior an improved opportunity to recover production costs." Likewise, in describing its competitive position, Canexus stated, "The North American sodium chlorate market is efficient and favors low cost producers ... [C]ost curve positioning is paramount, as low cost plants compete most effectively on a delivered cost basis across North America." Canexus' Vice President of Sales and Marketing testified under oath that Canexus "look[s] at the market more in a continental basis, than a regional basis."

VIII. MARKET CONCENTRATION AND THE ACQUISITION'S PRESUMPTIVE ILLEGALITY

31. Post-acquisition, the sodium chlorate market in North America would be highly concentrated, with Superior alone accounting for more than 50 percent of market share by any measure (i.e., capacity, sales volume, or sales revenue), and two firms, Superior and Akzo, controlling more than 80 percent of the market.

32. The Merger Guidelines and courts measure concentration using the Herfindahl-Hirschman Index ("HHI"). The HHI is calculated by totaling the squares of the market shares of each firm in the relevant market. Under the Merger Guidelines, a

Complaint

merger is presumed likely to create or enhance market power—and is presumptively illegal—when the post-merger HHI exceeds 2,500 and the merger increases the HHI by more than 200 points.

33. Because sodium chlorate is a homogenous, commodity chemical product, relative production capacities are the best measure of market shares. Whether measured by production capacity, production volume, or sales revenue, however, Superior's acquisition of Canexus would result in a post-merger HHI exceeding 3,800, with an increase in the HHI of more than 1,300. Thus, by any measurement, the acquisition would result in concentration well above the amount necessary to establish a presumption of competitive harm.

34. The acquisition is presumptively unlawful under relevant case law and the Merger Guidelines.

**IX. THE ACQUISITION WOULD INCREASE
SUPERIOR'S INCENTIVE AND ABILITY TO CURTAIL
OUTPUT**

35. The Acquisition is likely to cause output curtailment. In Superior's own words, "[i]n an Oligopoly, Supply Side management is the key to maintaining profitability." Canexus identifies "excess capacity which is impeding pricing appreciation for producers" [REDACTED]. Allowing Superior to acquire Canexus would increase Superior's incentive and ability to decrease output, thus leading to higher prices.

36. Respondents' documents make clear the relationship between available sodium chlorate capacity and prices: when competitors have underutilized capacity, competition intensifies and prices either stagnate or fall, but when supply becomes tight, competition softens and prices increase. For example, in 2013, Superior's CEO informed investors that a "small supply demand [im]balance in chlorate has resulted in negative overall pressure on selling prices." Similarly, in an internal planning document Canexus observed that "[t]he North American chlorate industry requires higher operating rates [REDACTED] in order to achieve

Complaint

upward pricing momentum.” Given this correlation, Respondents closely monitor North American industry capacity utilization.

37. Superior has a history of attempting to use output curtailment as a means to support higher prices. These efforts include reducing production, increasing exports from North America, closing sodium chlorate production facilities, and shutting down production lines.

38. Curtailing output at a sodium chlorate plant can be accomplished simply by turning down a dial that controls electric current. Individual lines and entire plants can be shut down for periods as short as only a few hours at a time. Superior’s documents show that Superior has curtailed output at its plants to support higher pricing. For instance, in May 2013 the President of Superior’s ERCO business wrote in an internal email, “the market is declining and if we do not take steps to restructure the supply side, the result will be reduced volume or price,” and that Superior felt that “reduced volume to maintain pricing is the prudent path to take.” In February 2015, Superior’s CEO explained that given the “race to the bottom” pricing by some of its competitors, Superior was reducing capacity in 2015 and intended to “continue on that pace into the 2016 years and on.”

39. Increasing exports can also serve as a means of limiting supply to North American customers. Superior views exports as “critical” to maintaining a balanced market in North America, and uses exports as additional means of supporting pricing in North America. For example, Superior observed in internal documents that it [REDACTED] “have always used exports as a means to maintain an equilibrium in the market” and that its pricing has benefited from “tightening supply caused by greater exports and curtailed production.” Canexus, on the other hand, [REDACTED].

40. Since 2005, Superior, Canexus, and Akzo each has permanently removed capacity from the market. The smaller producers, Kemira and Chemtrade, have not followed suit, but as Superior recognized in an internal presentation, these smaller players “cannot curtail without exiting the business.”

Complaint

41. When Superior has removed capacity from the market, it has done so with the clear expectation that prices will increase as a result. For example, in a board proposal, Superior stated that its 2005 announcement that it was closing its Thunder Bay facility would “prepare the market in advance for [a] planned, very significant, sodium chlorate price increase announcement” and that the reduction in capacity would “permit the increase of prices in the range of \$50 per [metric ton].”

42. Superior’s most recent initiative to reduce North American capacity was its purchase agreement with sodium chlorate producer Tronox. That agreement culminated in Superior electing to purchase no volume from Tronox in 2016 (and paying Tronox [REDACTED] million not to produce any sodium chlorate), and assisting Tronox with decommissioning its plant at the end of 2015. Superior made clear that a purpose of the Tronox agreement was to allow Superior to manage North American chlorate supply in order to support higher prices. An internal Superior document dating from the inception of the Tronox agreement in 2013 stated that, “[t]hrough management of the Tronox arrangement, [Superior] will bring the Sodium Chlorate market back into equilibrium, improving earnings through its pricing impact.” Superior’s senior executives likewise informed investors of its intention to reduce volumes under the Tronox agreement in order to “reduce North American supply” of sodium chlorate so that “the market should be more conducive to price increase[s].” Ultimately, Superior elected not to buy any volume from Tronox in 2016 in expectation that this would lead the Tronox facility to close, thereby increasing industry capacity utilization and positioning the company for price increases. Superior went so far as to inform investors that it expected price increases to occur in 2016 as a result of Tronox’s exit. Contemporaneous [REDACTED] Canexus business documents [REDACTED].

43. Allowing Superior, which is already focused on managing its capacity in light of overall market-wide capacity, to acquire one of the other two large chlorate producers would increase the likelihood of future output reductions. Consistent with Merger Guidelines § 6.3, this merger of homogenous-good producers is

Complaint

likely to incentivize the merged entity to engage in unilateral output curtailment because:

- the merged firm would have a high market share (more than 50 percent by any measure);
- the merged firm would have relatively little output already committed at fixed pricing (many contracts open each year and many allow for price escalations);
- the margin on curtailed output would be relatively low (the merged entity would have a portfolio that would include several of the higher-cost plants in the market);
- the supply responses of rivals would be relatively small (capacity constraints quickly bind competitors, and entry and/or expansion is slow, expensive, and unlikely); and
- the market elasticity of demand is relatively low (the Respondents themselves assume demand to be price-inelastic).

44. Consistent with this, Superior's documents indicate a desire to curtail output post-Acquisition. As early as 2009, when Superior first contemplated a possible merger with Canexus, it listed among the benefits of the merger that "[s]ome of the smaller plants could be rationalized." In 2014, an internal email among Superior management explained that "[t]he picture we painted on the chlorate market has [our CEO] thinking about the Canexus merger and [REDACTED] high cost plants." In the fall of 2014, Superior's CEO told the Chairman of Canexus's Board that he viewed a merger with Canexus as a means of [REDACTED] [REDACTED] rationalization in the market.

X. THE ACQUISITION WOULD INCREASE THE LIKELIHOOD OF ANTICOMPETITIVE COORDINATION

45. The sodium chlorate market has a number of characteristics that make it vulnerable to coordination, including significant transparency into competitive activities, opportunities

Complaint

for communication between competitors, and strong interdependence among competitors. Allowing Superior to acquire Canexus would make anticompetitive coordination more likely going forward by eliminating a large, low-cost, uniquely disruptive competitor. Post-Acquisition, the only remaining major suppliers of sodium chlorate would be Superior and Akzo,

46. Sodium chlorate is a homogenous product with a market characterized by declining demand, stable market shares, and high barriers to entry. In addition, suppliers have considerable transparency into the businesses of their competitors. Competitors track a wealth of information about each other, including

Competitively sensitive information is accessible to competitors through published price increase announcements and public statements such as earnings calls. Competitors also obtain competitively sensitive information from a variety of other sources, including

In addition to significant market transparency, competitors have ample opportunities to communicate with each other, including discussions at trade association meetings, conversations about product swaps, and

Internal documents show that Superior executives have at least contemplated

In May 2015, upon receiving a copy of a Superior price increase letter that was ready to be sent out, Superior's CEO emailed the president of chemical sales,

In June 2014, Superior's president of chemical sales emailed its CEO,

Complaint

48. Sodium chlorate producers also use [REDACTED] consulting firm [REDACTED]

[REDACTED]. In July 2015, Superior's head of chlorate sales asked [REDACTED] for information about a possible [REDACTED] price increase. [REDACTED] responded by providing the specific amount of [REDACTED] price increases, [REDACTED]. In the same email exchange, [REDACTED] asked Superior's head of chlorate sales to provide information about the average price increase Superior had achieved on its formula-based accounts, and he responded that they should talk via phone. [REDACTED]

[REDACTED] Despite confirming that at least some of the pricing information received [REDACTED] was not public, Superior's management included the information in a report circulated to its Board of Directors.

49. The three major players recognize their mutual interdependence and aligned incentives today. [REDACTED]

[REDACTED]. Respondents' ordinary course documents reflect a desire to support competitors' efforts to raise prices, and show that Respondents give careful consideration to how their potential bids might disrupt market stability. For instance, in internal emails, Canexus executives express concern about inciting "price wars" with competitors. Superior's internal documents are blunt about the speed and certainty with which producers respond to each other's actions, observing that "[t]he market is dominated by a small number of players . . . the actions of any one firm will affect overall market conditions and spur[s] an immediate response by other competitors."

50. Removing Canexus from a market that is already vulnerable to coordination would make coordination more likely going forward. Despite its concerns about creating market instability, Canexus's large, low-cost Brandon facility has enabled

Complaint

it to be a frequently aggressive competitor who is uniquely able to disrupt potential coordination:

- In 2014, [REDACTED]
- In 2014, [REDACTED]
- In 2015, [REDACTED]
- In 2015, Superior attempted a price increase at [REDACTED], but eventually agreed to delay the price increase because Canexus [REDACTED]

Complaint

[REDACTED]

- In 2015, [REDACTED]

- For 2016, [REDACTED]

51. Contemporaneous business documents from chlorate suppliers reflect the importance of Canexus as an independent competitor. In its own business documents, Canexus observed that it has the “[s]trongest competitive positioning in North America due to Brandon” and that it “can compete on price with any other producer in North America and remain highly profitable.” Superior [REDACTED] describe Canexus as aggressive and a constraint on pricing, [REDACTED]

52. In the period leading up to the announcement of the proposed Acquisition, Superior documents reflect a growing frustration and concern about the ability of Canexus to disrupt sales patterns and undermine price increases:

- In July 2013, the President of Superior’s ERCO business complained about Canexus trying to steal Superior accounts: “We have seen [Canexus] very aggressively trying to renew [our] contracts coming open at year end with lower pricing.”

Complaint

- In July 2014, the President of Superior's ERCO business told the President of Superior, "My long term worry is that [Canexus] will significantly expand Brandon ... [That] could destroy the chlorate business model."
- In a September 2014 email to fellow Board members, Superior's CEO wrote, "Canexus pricing of chlorate has been [REDACTED] lower than ours. We have announced price increases and they did not follow. Canexus should be gaining on margins since they are not [hedged] instead of making the extra margins they are selling at lower prices. They are really out of touch with the market. They are price takers instead of being marketers."
- The next week, a senior executive at Superior lamented that Canexus was "disruptive in the market" noting that Canexus was "dropping prices for volume." Superior's CEO echoed these sentiments in an October 2014 earnings call when he told investors that the competition (Canexus) "just wants to fill up their plant and are not really looking at pricing properly to maximize their opportunity." On the same earnings call, Superior's CFO noted that Canexus was "being very, very aggressive" which was "causing pressure on some of the pricing in chlorate."
- Subsequently, in November 2014, the president of Superior's ERCO business expressed further frustration with Canexus' disruptive approach to Superior's CEO, noting "I can't believe Canexus is being so aggressive [...] ERCO raises the price only to have Canexus come in and mess things up."
- In May 2015, while anticipating making price increase announcements for the second half of 2015 and 2016, Superior's CEO considered holding off making such announcements as he "wonder[ed] if

Complaint

Canexus will be more aggressive if so we should wait to see what they will do.”

53. Testimony from Superior’s CEO given under oath underscores the impact that Canexus has in the market. Superior’s CEO testified that Canexus’ lower pricing, failure to follow price increases, and passing foreign exchange gains through to customers all prevent Superior from raising chlorate prices to its customers.

54. By the summer of 2015, Superior’s concern about Canexus’s unique disruptive potential motivated it to pursue the present Acquisition. At that time, Superior’s CEO fretted in an email that Canexus was “reducing prices looks like they have no sense of the Business.” In response, Superior’s Treasurer suggested that it might make sense to pursue an acquisition of Canexus “if they are going to continue to be so irrational.” By July, Superior was in negotiations to acquire Canexus.

55. Post-Acquisition, Superior’s remaining competitors would be unlikely to replicate Canexus’s uniquely disruptive role in the market.

Once they do so, they can no longer compete for additional sales opportunities, and therefore can no longer act as constraints on pricing. Superior itself recognizes this reality, with a Superior executive observing in an internal email that

56. Akzo has [REDACTED] but Superior and Canexus describe the company as

[REDACTED]. In 2003, Akzo requested immunity from the European Commission for violations of European competition laws for attempting to raise

Complaint

sodium chlorate prices by setting target prices, allocating customer volumes, and exchanging information with European sodium chlorate competitors.

XI. LACK OF COUNTERVAILING FACTORS**A. Barriers to Entry and Expansion**

57. Respondents cannot demonstrate that new entry or expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Acquisition.

58. As Superior recognizes in its own business documents, there are high barriers to entry in the sodium chlorate market. Building a new sodium chlorate plant would take multiple years and a large capital investment that Canexus estimates would exceed [REDACTED]. Entry is unlikely given the ongoing decline in demand for sodium chlorate. Over the past ten years, multiple sodium chlorate plants have closed, but no new plants have been built. Expansion by the remaining firms post-Acquisition that would defeat anticompetitive effects is unlikely.

B. Efficiencies

59. Respondents cannot demonstrate cognizable efficiencies that would be sufficient to rebut the strong presumption and evidence that the Acquisition likely would substantially lessen competition in the North American market for sodium chlorate.

XII. VIOLATION**Count I – Illegal Agreement**

60. The allegations of Paragraphs 1 through 59 above are incorporated by reference as though fully set forth.

61. The Acquisition Agreement constitutes an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

Complaint

Count II—Illegal Acquisition

62. The allegations of Paragraphs 1 through 59 above are incorporated by reference as though fully set forth.

63. The Acquisition, if consummated, may substantially lessen competition in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the twenty-ninth day of November, 2016, at 10 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the

Complaint

proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Merger challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Acquisition is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant market, with the ability to offer such products and services as

Final Order

Superior and Canexus were offering and planning to offer prior to the Acquisition.

2. A prohibition against any transaction between Superior and Canexus that combines their businesses in the relevant market, except as may be approved by the Commission.
3. A requirement that, for a period of time, Superior and Canexus provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant market with any other company operating in the relevant markets.
4. A requirement to file periodic compliance reports with the Commission.
5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to restore Canexus as a viable, independent competitor in the relevant market.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this twenty-seventh day of June, 2016.

By the Commission.

ORDER DISMISSING COMPLAINT

On June 27, 2016, the Commission issued an administrative Complaint alleging that an acquisition agreement between Respondents Superior Plus Corp. and Canexus Corporation violates Section 5 of the FTC Act, 15 U.S.C. § 45, as amended, and that if the acquisition were consummated, it would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, as well

Final Order

as Section 5 of the FTC Act. Complaint Counsel and Respondents now jointly seek dismissal of the Complaint, on the ground that Superior has abandoned its proposed acquisition of Canexus, and that both Respondents have withdrawn their respective Hart-Scott-Rodino Notification and Report Forms.¹

The Commission has determined to dismiss the Complaint without prejudice, in light of Respondents' decision to abandon the proposed transaction and their withdrawal of their respective Hart-Scott-Rodino Notification and Report Forms. Respondents would not be able to effectuate the proposed transaction without filing new Hart-Scott-Rodino Notification and Report Forms. The Commission has therefore determined that the public interest warrants dismissal of the Complaint in this matter.² Accordingly,

IT IS ORDERED THAT the Complaint in this matter be, and it hereby is, dismissed without prejudice.

By the Commission.

¹ See Joint Motion to Dismiss Complaint (July 15, 2016).

² See, e.g., *Staples Inc.*, Docket No. 9367, Order Dismissing Complaint (May 18, 2016), available at <https://www.ftc.gov/system/files/documents/cases/160519staplesrorder.pdf>; *Sysco Corp.*, Docket No. 9364, Order Dismissing Complaint (June 30, 2015), available at <https://www.ftc.gov/system/files/documents/cases/150630syscoorder.pdf>.

Complaint

IN THE MATTER OF

PRACTICE FUSION, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4591; File No. 142 3039
Complaint, August 15, 2016 – Decision, August 15, 2016

This consent order addresses Practice Fusion, Inc.'s solicitation of patients to take surveys to rate and review their provider. The complaint alleges that Practice Fusion violated Section 5(a) of the Federal Trade Commission Act from April 2012 through April 2013 by failing to adequately disclose that survey responses would be made publicly available on Patient Fusion's healthcare provider review website. The consent order requires Practice Fusion, prior to making any consumer's covered information publicly available, to (A) clearly and conspicuously disclose to the consumer, separate and apart from "privacy policy," "terms of use" page, or similar document, that such information is being made publicly available; and (B) obtain the consumer's affirmative express consent. The order also prohibits Practice Fusion from displaying any healthcare provider review information obtained from consumers between April 5, 2012 and April 8, 2013.

Participants

For the *Commission: Allison Lefrak, Kristin Madigan, Ryan Mehm, and Jennifer Nagle.*

For the *Respondents: Joseph Molosky, Lydia Parnes, and Seth Silber, Wilson Sonsini Goodrich & Rosati, PC; Timothy Muris, Kirkland & Ellis LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Practice Fusion, Inc. ("Respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Practice Fusion, Inc. ("Practice Fusion" or "Respondent") is a Delaware corporation with its principal office or place of business at 650 Townsend Street, Suite 500, San Francisco, California 94103.

Complaint

2. The acts and practices of Respondent as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

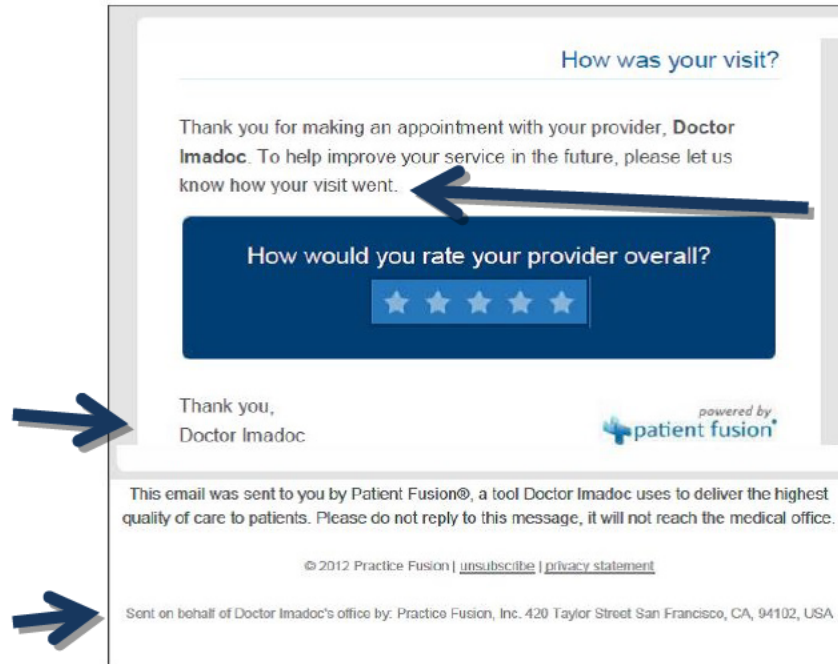
RESPONDENT’S BUSINESS PRACTICES

3. Since 2007, Respondent has provided services for healthcare providers. Its core service is a cloud-based electronic health record (“EHR”) that allows healthcare providers in the ambulatory/out-patient setting to store and utilize health information.

4. In 2009, Respondent launched the Patient Fusion website, www.patientfusion.com (“Patient Fusion”), with an online portal that allows patients, who have been granted access by their healthcare providers, to view, download, and transmit to other providers their health information and send and receive secure messages directly to and from their providers. Respondent planned to launch a public-facing healthcare provider directory portion of the Patient Fusion website in 2013. The directory would allow current and prospective patients to search for providers by specialty or in a specific geographic area, read patient reviews of providers, and request appointments with providers through the website.

5. In order to populate the Patient Fusion website with provider reviews, starting in April 2012, Respondent emailed healthcare providers’ patients post-visit satisfaction surveys seeking reviews of the providers’ service. Practice Fusion described these surveys as a tool to “help improve your service in the future,” (as depicted below). The emails asked the patient to “please let us know how your visit went,” with a closing stating “Thank you, [Healthcare Provider’s Name]” at the end of the email. A disclosure at the bottom stated that the “email was sent to you by Patient Fusion®, a tool Doctor [Healthcare Provider’s Name] uses to deliver the highest quality of care to patients.” The email also indicated that it was “Sent on behalf of Doctor [Healthcare Provider’s Name]’s office” by Practice Fusion.

Complaint




6. A link at the bottom of the email labeled “privacy statement” took the consumer to Practice Fusion’s Privacy Policy. The Privacy Policy included a section titled “Surveys, questionnaires, and polls.” Until April 8, 2013, Respondent did not indicate in this section or elsewhere in its privacy policy that it would publicly post reviews by patients of their providers.

7. Consumers who clicked on the stars in the email message were taken to the survey form, which among other things included a free text box at the bottom of the page prompting consumers to “Please leave a review for your provider:” (as depicted below). In light grey type just above the text box, the survey form indicated, “For your protection, do not include any personal information.” Below the free text box was a pre-checked box next to the phrase “Keep this review anonymous.” Leaving this box checked did not anonymize anything a consumer wrote in the free text box, including a consumer’s identifying information. Instead, the “Keep this review anonymous” selection only affected whether a review was posted on the Patient Fusion website under the handle “Anonymous” or under a patient’s first name. A button at the bottom of the survey enabled the consumer to “Submit my feedback.”

Complaint

How was your visit?





Your overall rating for **Francis Toan**: ★ ★ ★ ★ ★


How would you rate the following:


Bedside manner	★ ★ ★ ★ ★
Clarity & Communication	★ ★ ★ ★ ★
Scheduling an appointment	★ ★ ★ ★ ★


How long did you have to wait for your appointment?


under 10min


10-20min


20-30min


30-40min


over 40min

Was your medical concern addressed?

Would you recommend your provider to your family or friends?

Please leave a review for your provider:

For your protection, do not include any personal information

255 chars remaining.

Keep this review anonymous

I agree to the terms of the [Patient Authorization](#)

8. Consumers were required to check the box next to the phrase, “I agree to the terms of the Patient Authorization,” in order to submit their feedback, but were not required to *view* the Patient Authorization. Consumers who clicked through to the Patient Authorization would have seen the following statements: “I authorize my provider and Practice Fusion, Inc. to publish my review on the Practice Fusion website The purpose of publishing my review is to make it available to patients and prospective patients of my provider, and other members of the public.” The Patient Authorization also stated that information

Complaint

submitted by the consumer would not be protected under the Health Insurance Portability and Accountability Act, or HIPAA.

9. Since survey information was collected for a full year before the Patient Fusion website went live, consumers who visited Respondent's website would not have found any posted reviews, so they would not have any historical or contextual reference to alert them to the fact that their feedback would be publicly posted rather than provided to their physician, mental health specialist, or other healthcare provider for his or her sole use.

10. In April 2013, Practice Fusion publicly launched the healthcare provider directory portion of the www.patientfusion.com website. At that time, Practice Fusion posted approximately 613,000 reviews it had collected from consumers during the previous year. At the same time, Respondent revised its email communications to consumers soliciting survey responses to indicate that reviews they submitted "may be publicly visible on Patient Fusion to help patients find doctors in the area." Respondent also revised the section on "Surveys and Ratings" in the Patient Fusion privacy policy to state for the first time that survey responses would be made public: "From time to time we ask users to submit surveys or ratings to assist healthcare providers and others in improving their operations or to assist other users in making informed choices. The content of such surveys or ratings, therefore, should be presumed public."

11. Based on the highly sensitive content of some consumers' survey responses, combined with identifying information, they likely believed the communication was private. Consumers submitted hundreds of survey responses where they disclosed identifying information such as their full name or phone number combined with a sensitive health condition, medications taken, medical procedures performed, or treatments received. Examples of responses publicly posted include:

- a. "Dr [healthcare provider name intentionally redacted by FTC staff], My Xanax prescription that I received on Monday was for 1 tablet a day but usually it's for 2

Complaint

tablets a day. I have not taken it to the pharmacy yet. Can I pick up a new one, or can I get a prescription called into a pharmacy? Thanks, [patient name intentionally redacted by FTC staff]" Date: May 21, 2012 (Xanax (alprazolam) is a medication typically prescribed to treat anxiety disorders, panic disorders, and anxiety caused by depression.)

- b. "I was pleased with Dr. [healthcare provider name intentionally redacted by FTC staff]'s information on getting a facelift. I will call if I have further questions. Thank you, [patient name intentionally redacted by FTC staff]" Date: May 5, 2012
- c. "I called today and left a message regarding my daughter and no one has returned my call. I think she is depressed and has stated several times this week that she wishes she was dead. Could someone please call me [phone number intentionally redacted by FTC staff]" Date: September 27, 2012
- d. "The cefuroxime axetil does not seem to be doing anything for me. I did a little research and I think I have a yeast infection called candida. Not sure what to do about it yet. I guess I will first try to change my diet. Medication? [patient name intentionally redacted by FTC staff]" Date: June 9, 2012
- e. "My left foot was so much better after the wart was removed from under the callus! There may be one growing on the right foot.....we'll see! My feet always feel so much better when leaving the office. [patient name intentionally redacted by FTC staff]" Date: July 12, 2012
- f. "I would like to make an appointment for my back pain and possible shingles. Can you please call me @[phone number intentionally redacted by FTC staff] Thank you! [patient name intentionally redacted by FTC staff]" Date: December 31, 2012

Complaint

- g. "I HAVE NO INFECTION [healthcare provider name intentionally redacted by FTC staff] EVERYTHING WENT FINE AFTER MY VISIT, SO IT'S A GO FOR MY CHEMO DAY.....THANKS HOPEFULLY I WILL SEE YOU TOMARROW AT METHODIST HOSPITAL.....THANKS... [patient name intentionally redacted by FTC staff]" Date: March 15, 2013

12. An October 21, 2013 article in *Forbes Technology Blog* highlighted the sensitive nature of some of the information posted on the Patient Fusion website (*available at* <http://www.forbes.com/sites/kashmirhill/2013/10/21/practice-fusion-patient-privacy-explicit-reviews/>).

13. In November 2013, Respondent for the first time implemented automated procedures to identify reviews where consumers had entered personal information in the open text fields in the survey. Respondent did not post reviews that contained such personal information; Respondent also used this process to take down reviews containing personal information that had already been posted on the website.

14. Communications between healthcare providers and Practice Fusion indicate that some healthcare providers were surprised that feedback they received was also posted publicly. Others were surprised that patients were being asked for feedback in the first place.

**PRACTICE FUSION'S DECEPTIVE FAILURE TO
DISCLOSE**

15. As described in Paragraphs 5-9, from April 5, 2012 through April 8, 2013, Respondent represented, directly or indirectly, expressly or by implication, that responses to a healthcare provider satisfaction survey would be communicated to the consumer's healthcare provider.

16. Respondent failed to disclose adequately that, if consumers provided responses to the satisfaction survey, Respondent would also publish the responses on its public

Decision and Order

healthcare provider review website, as described in Paragraphs 10-14. This fact would be material to consumers in deciding whether or how to respond to the survey, including, for example, what type of information to include in their responses.

17. Respondent's failure to disclose adequately the material information described in Paragraph 16, in light of the representation set forth in Paragraph 15, is a deceptive act or practice.

VIOLATIONS OF SECTION 5

18. The acts and practices of Respondent as alleged in this complaint constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this fifteenth day of August, 2016, has issued this complaint against Respondent.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission ("Commission" or "FTC"), having initiated an investigation of certain acts and practices of the Respondent named in the caption hereof, and the Respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45 *et seq.*;

Decision and Order

The Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), which includes: a statement by Respondent that it neither admits nor denies any of the allegations in the draft complaint, except as specifically stated in the Consent Agreement, and, only for purposes of this action, admits the facts necessary to establish jurisdiction; and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the Respondent has violated the FTC Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed Consent Agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments filed by an interested person, now in further conformity with the procedure prescribed in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and enters the following Order:

1. Respondent Practice Fusion, Inc. (“Practice Fusion”) is a Delaware corporation with its principal office or place of business at 650 Townsend Street, Suite 500, San Francisco, CA 94103.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

ORDER**Definitions**

For purposes of this Order, the following definitions apply:

- A. “Covered information” means the following information obtained from an individual consumer: (a) a first and last name; (b) a physical address (c) an

Decision and Order

email address or other online contact information, such as an instant messaging user identifier or a screen name; (d) a telephone number; (e) a Social Security number; (f) a driver's license or other government-issued identification number; (g) a financial institution account number; (h) credit or debit card information; (i) a persistent identifier, such as a customer number held in a "cookie," a static Internet Protocol ("IP") address, a mobile device ID, or processor serial number that is combined with other available data that identifies an individual consumer; (j) health information, including demographic data, that relates to the individual's past, present, or future physical or mental health or condition, the provision of healthcare to the individual, or the past, present, or future payment for the provision of healthcare to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual; or (k) any other information that is individually identifiable.

- B. "Healthcare provider review information" means feedback gathered by Respondent from consumers on Respondent's own behalf or on behalf of Respondent's healthcare provider customers regarding healthcare services provided by said healthcare provider customers (or their agents, contractors, or assigns) in response to the healthcare satisfaction survey that Respondent emailed to consumers from either Practice Fusion or Patient Fusion domains from April 5, 2012 through April 8, 2013. "Healthcare provider review information" does not include information recorded or documented by one of Respondent's healthcare provider customers (or their agents, contractors, or assigns) utilizing the services of Respondent.
- C. "Publicly available" means widely disseminated to the general public through a broadly accessible medium, such as wide dissemination on the Internet or in other printed, audio, visual, or digital media.

Decision and Order

- D. “Respondent” means Practice Fusion, Inc. and its successors and assigns.
- E. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- F. “Clearly and conspicuously” means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means.
 2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
 3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
 4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
 5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.

Decision and Order

6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
8. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, “ordinary consumers” includes reasonable members of that group.

Provisions**I. Prohibition against Misrepresentations**

IT IS ORDERED that Respondent and Respondent’s officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with any product or service must not misrepresent in any manner, expressly or by implication:

- A. the extent to which Respondent uses, maintains, and protects the privacy and confidentiality of any covered information, including: the extent to which covered information shall be made publicly available, including by posting on the Internet.

II. Notice and Affirmative Express Consent Provision

IT IS FURTHER ORDERED that Respondent and Respondent’s officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive notice of this Order, whether acting directly or indirectly, prior to making any consumer’s covered information publicly available, including by posting on the Internet, must:

Decision and Order

- A. clearly and conspicuously disclose to the consumer, separate and apart from “privacy policy,” “terms of use” page, or similar document, that such information is being made publicly available, including by posting on the Internet; and
- B. obtain the consumer’s affirmative express consent.

III. Disposition of Healthcare Provider Review Information

IT IS FURTHER ORDERED that Respondent and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, website, or other device or affiliate owned or controlled by Respondent, in or affecting commerce, must not publicly display any healthcare provider review information, and must not maintain any healthcare provider review information, except for review and retrieval by its healthcare provider customers, or their respective agents, contractors, assigns, or as permitted to comply with applicable law, regulation, or legal process. Within sixty (60) days after the effective date of the Order, Respondent must provide a written statement to the Commission, sworn under penalty of perjury, confirming the foregoing.

IV. Acknowledgements of the Order

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

- A. Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.
- B. Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives having direct supervisory responsibilities over the conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in

Decision and Order

the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

- C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

V. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondent make timely submissions to the Commission:

- A. Ninety (90) days after the effective date of this Order, Respondent must submit a compliance report, sworn under penalty of perjury, in which:
 - 1. Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the extent to which covered information is made publicly available; (d) describe in detail whether and how Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgments of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

Decision and Order

- B. Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
1. (a) any designated point of contact; or (b) the structure of any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
- C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.
- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: “I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____” and supplying the date, signatory’s full name, title (if applicable), and signature.
- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re *Practice Fusion, Inc.*

Decision and Order

VI. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records and retain each such record for 5 years. Specifically, Respondent must create and retain the following records:

- A. accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;
- B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;
- C. copies or records of all consumer complaints concerning the subject matter of the Order, whether received directly or indirectly, such as through a third party, and any response;
- D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;
- E. all forms, websites, and other methods used by Respondent to obtain feedback from consumers on Respondent's own behalf or on behalf of Respondent's healthcare provider customers regarding healthcare services provided by said healthcare provider customer (or their agents, contractors, or assigns);
- F. a copy of each widely disseminated representation by Respondent that describes the extent to which Respondent maintains or protects the privacy and confidentiality of any covered information, including any representation concerning a change in any website or other service controlled by Respondent that relates

Decision and Order

to the privacy and confidentiality of covered information; and

- G. for 5 years from the date created or received, all records, whether prepared by or on behalf of Respondent, that tend to show any lack of compliance by Respondent with this Order.

VII. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

- A. Within 10 days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.
- B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.
- C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

Decision and Order

VIII. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate on August 15, 2036, or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Provision in this Order that terminates in less than 20 years;
- B. This Order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision. If such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an agreement containing a consent order from Practice Fusion, Inc. (“Practice Fusion”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

Since 2007, Practice Fusion has provided services for healthcare providers. Since 2007, its core service has been a cloud-based electronic health record (“EHR”) that allows healthcare providers in the ambulatory/out-patient setting to store and utilize health information. In 2009, Practice Fusion launched the Patient Fusion website, www.patientfusion.com (“Patient Fusion”), with an online portal that allows patients, who have been granted access by their healthcare providers, to view, download, and transmit to other providers their health information and send and receive secure messages directly to their providers.

Practice Fusion planned to launch a public-facing healthcare provider directory portion of the Patient Fusion website in 2013. The directory would, among other things, allow current and prospective patients to read patient reviews of providers. To populate this website with reviews, starting on April 5, 2012, Practice Fusion sent emails to the patients of its healthcare provider clients soliciting those patients to take surveys to rate and review their provider. The email – and the survey itself – suggested that the health care provider was directly seeking the survey responses to improve the consumer’s experience on future visits. Neither the email nor the survey clearly indicated that the reviews would be posted publicly. Practice Fusion solicited reviews for a full year – collecting information from over 600,000 patients during that time – before launching the review service on April 8, 2013, at which time all of the reviews previously

Analysis to Aid Public Comment

collected were posted publicly on the Internet. Many of the reviews contained highly sensitive information, combined with identifying information, indicating that many patients likely thought they were communicating directly with their doctors, and did not intend for their feedback to be posted publicly.

The Commission's proposed complaint alleges that Practice Fusion violated Section 5(a) of the Federal Trade Commission Act from April 2012 through April 2013 by failing to adequately disclose that survey responses would be made publicly available on Patient Fusion's healthcare provider review website. This fact, according to the proposed complaint, would be material to consumers in deciding whether or how to respond to the survey. The Commission's complaint alleges that Practice Fusion's failure to adequately disclose this material information is a deceptive act or practice in violation of Section 5.

The proposed order contains provisions designed to prevent Practice Fusion from engaging in the same or similar acts or practices in the future. Part I of the proposed order prohibits Practice Fusion from misrepresenting the extent to which it uses, maintains, and protects the privacy and confidentiality of any covered information, including the extent to which covered information is made publicly available.

Part II of the proposed order requires Practice Fusion, prior to making any consumer's covered information publicly available, to (A) clearly and conspicuously disclose to the consumer, separate and apart from "privacy policy," "terms of use" page, or similar document, that such information is being made publicly available; and (B) obtain the consumer's affirmative express consent.

Part III of the proposed order prohibits Practice Fusion from displaying any healthcare provider review information obtained from consumers between April 5, 2012 and April 8, 2013. Part III of the proposed order also prohibits Practice Fusion from maintaining such information, except for review and retrieval by its healthcare provider customers, or their respective agents, contractors, assigns, or as permitted to comply with applicable law, regulation, or legal process.

Analysis to Aid Public Comment

Parts IV through VIII of the proposed order are reporting and compliance provisions. Part IV requires acknowledgment of the order and dissemination of the order now and in the future to persons with supervisory responsibilities relating to the subject matter of the order. Part V ensures notification to the FTC of changes in corporate status and mandates that Practice Fusion submit an initial compliance report to the FTC. Part VI requires Practice Fusion to retain documents relating to its compliance with the order for a five-year period. Part VII mandates that Practice Fusion make available to the FTC information or subsequent compliance reports, as requested. Part VIII is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order’s terms.

Complaint

IN THE MATTER OF

**BALL CORPORATION
AND
REXAM PLC**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4581; File No. 151 0088
Complaint, June 28, 2016 – Decision, August 15, 2016*

This consent order addresses the £5.4 billion, or \$8.4 billion acquisition by Ball Corporation of certain assets of Rexam PLC. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening competition in the markets for standard 12-ounce aluminum beverage cans and specialty aluminum beverage cans in the United States. The consent order requires Ball and Rexam to divest seven aluminum can body plants, one aluminum can end plant, and other innovation and support functions in order to preserve competition in the relevant markets in the United States.

Participants

For the *Commission*: James Abell, Cem Akleman, Monica Castillo van Panhuys, Leonor V. Davila, Eric Elmore, David Laing, Joonsuk Lee, Michael Lovinger, and Steven Wilensky.

For the *Respondents*: Nicholas Gaglio and John Harkrider, Axinn, Veltrop & Harkrider LLP; Mary Lehner and Paul Yde, Freshfields Bruckhaus Deringer US LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Ball Corporation (“Ball”), a corporation subject to the jurisdiction of the Commission, agreed to acquire Respondent Rexam PLC (“Rexam”), a public limited liability company subject to the jurisdiction of the Commission, in violation of Section 7 of the

Complaint

Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Ball is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Indiana with its headquarters and principal place of business located at 10 Longs Peak Drive, Broomfield, Colorado.

2. Respondent Rexam is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the United Kingdom with its headquarters and principal place of business located at 4 Millbank, London, United Kingdom.

II. JURISDICTION

3. Respondents, and each of their relevant operating subsidiaries and parent entities, are, and at all times relevant herein have been, engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. § 12, and Section 4 of the FTC Act, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

4. Pursuant to a Recommended Cash and Share Offer (the “Merger Agreement”) dated as of February 19, 2015, Ball proposes to purchase all issued and outstanding common stock of Rexam in a transaction valued at approximately \$8.4 billion (“the Acquisition”), including the assumption of debt.

IV. THE RELEVANT PRODUCT MARKETS

5. The relevant lines of commerce in which to analyze the effects of the Acquisition are standard 12-ounce aluminum beverage cans (“Standard Cans”), and specialty aluminum

Complaint

beverage cans (“Specialty Cans”), which come in a variety of dimensions that differ from Standard Cans.

6. Standard Cans are used to package beverages such as carbonated soft drinks, beer, tea, and sparkling water in 12-ounce containers. Standard Cans are sold to consumers primarily for future consumption in multipacks, but are also sold for immediate consumption in vending machines and other establishments. Standard Cans are the most widely available and consumed beverage cans and represent approximately 75% of beverage cans produced in the United States today.

7. Beverage producers would not switch from Standard Cans to other package types such as Specialty Cans, polyethylene terephthalate (“PET”) bottles, or glass bottles in response to a small but significant and non-transitory increase in price in Standard Cans. Beverage producers have made substantial investments in infrastructure that specializes in filling Standard Cans and cannot be used to fill PET bottles or glass bottles. Moreover, beverage producers package in Standard Cans to meet consumer demand, and would risk a loss in sales if they switched to other packaging substrates.

8. Specialty Cans consist of an assortment of beverage cans in different shapes and sizes, including 7.5-ounce slim cans, 8-ounce slim cans, 12-ounce sleek cans, 16-ounce cans, 24-ounce cans, and others. Beverage producers purchase Specialty Cans to reach different consumers and consumption occasions than Standard Cans. For example, carbonated soft drink companies use 7.5-ounce cans to reach consumers who prefer a more convenient, portion-controlled product in a sub-100 calorie package. Similarly, many energy drink producers have adopted the 16-ounce can to differentiate their products from competition and appeal to their target customers.

9. Although one type of Specialty Can is not a substitute for another, it is appropriate to evaluate the Acquisition’s likely effects through an analysis of the assortment of Specialty Cans because each of the products in the assortment is offered under similar competitive conditions. Grouping the many different

Complaint

types of Specialty Cans into an assortment, or cluster, enables the efficient evaluation of competitive effects.

10. Beverage producers would not switch from Specialty Cans to other package types such as Standard Cans, PET bottles, or glass bottles in response to a small but significant and non-transitory increase in price in Specialty Cans. Beverage producers package in specific shapes and sizes of Specialty Cans to maximize sales and attract certain customers who would not purchase their products in a different package type. Moreover, beverage producers have made substantial investments in infrastructure used to fill Specialty Cans and that cannot be used to fill PET bottles or glass bottles.

V. THE RELEVANT GEOGRAPHIC MARKETS

11. The relevant geographic markets in which to analyze the competitive effects of the Acquisition for Standard Cans are regional. Driven by high freight costs and large production volumes, customers purchase Standard Cans from suppliers that are located within the same general region as the customers' filling plants. There are at least three regional markets in the United States in which competition between Ball and Rexam would be lessened for the sale of Standard Cans: (1) the South/Southeast; (2) the Midwest; and (3) the West Coast, consisting primarily of California. Imports of Standard Cans from outside the United States would not be a viable option because of the significant shipping times and shipping costs that imports would entail.

12. The relevant geographic market in which to analyze the competitive effects of the Acquisition on Specialty Cans is the United States. Specialty Cans are shipped much greater distances than Standard Cans, sometimes even cross country, because Specialty Cans have lower volumes and significantly fewer supply locations than Standard Cans. Imports of Specialty Cans into the United States would not be a viable option for customers because of the significant shipping times and shipping costs that such imports would entail.

Complaint

VI. ENTRY CONDITIONS

13. Entry into the relevant markets would not be timely, likely, or sufficient to prevent or deter the expected anticompetitive effects of the Acquisition. Considerable entry barriers exist in the manufacture of aluminum beverage cans, including significant volume requirements necessary to manufacture efficiently; high capital costs to construct a can plant; and length of time to begin manufacturing aluminum beverage cans efficiently. Moreover, there would be little incentive for new entry given a consistent decline in demand for aluminum beverage cans in the United States, which has led to a steady removal of beverage can production for over 20 years.

14. Likewise, the threat of vertical integration by beverage producers would not be timely, likely, or sufficient to prevent or deter the expected anticompetitive effects of the Acquisition. A typical beverage can plant must produce over a billion Standard Cans and/or Specialty Cans a year in order to be competitive, which precludes the vast majority of beverage producers from contemplating vertical integration because they would not have the necessary scale. Even for the largest beverage producers, vertical integration would not be a credible threat due to significant capital costs and technical requirements, and the fact that they would have to continue to rely on incumbent beverage can manufacturers for at least part of their Standard Can and Specialty Can needs.

VII. EFFECTS OF THE ACQUISITION

15. The Acquisition, if consummated, is likely to substantially lessen competition in the relevant lines of commerce in the following ways, among others:

- a. by eliminating direct and substantial competition between Respondents Ball and Rexam;
- b. by increasing the likelihood that Ball will unilaterally exercise market power; and

Complaint

- c. by increasing the likelihood of coordinated interaction among competitors in the relevant markets.

16. The ultimate effects of the Acquisition would be to increase the likelihood that prices of Standard Cans and Specialty Cans will rise, and that quality, selection, service, and innovation will be lessened.

VIII. VIOLATIONS CHARGED

17. The allegations contained in Paragraphs 1 through 16 above are hereby incorporated by reference as though fully set forth here.

18. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

19. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

20. The Merger Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-eighth day of June, 2016, issues its complaint against said Respondents.

By the Commission.

Order to Maintain Assets

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Ball Corporation (“Ball”) of the voting securities of Respondent Rexam PLC (“Rexam”), collectively “Respondents,” and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Ball Corporation, is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Indiana with its executive offices and principal place of business at 10 Longs Peak Drive, Bloomfield, CO 80021.

Order to Maintain Assets

2. Respondent Rexam PLC, is a public limited company organized, existing, and doing business under, and by virtue of, the laws of England and Wales with its principal executive offices located at 4 Millbank, London SW1P 3XR, United Kingdom, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, Rexam Beverage Can Company, 4201 Congress Street, Suite 340, Charlotte, NC 28209.
3. The Commission has jurisdiction over the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS HEREBY ORDERED that, as used in this Order to Maintain Assets, the following definitions, and all other definitions used in the Consent Agreement and proposed Decision and Order (and when made final, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Ball” means Ball Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates in each case controlled by Ball Corporation, including, but not limited to, Ball UK Acquisition Ltd., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Ball includes Rexam, after the Acquisition Date.
- B. “Rexam” means Rexam PLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates in each case controlled by Rexam PLC, including, but not

Order to Maintain Assets

limited to, Rexam Beverage Can Company (“RBCC”), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Respondents” means Ball and Rexam, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Decision and Order” means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- F. “Acquirer” means:
 - 1. Ardagh; or
 - 2. A Person approved by the Commission to acquire the Aluminum Beverage Cans Business pursuant to the Decision and Order.
- G. “Aluminum Beverage Cans Business” means all of RBCCs assets, including Tangible Personal Property and intangible assets, businesses and goodwill, related to the research, development, manufacture, distribution, marketing or sale of Aluminum Beverage Cans Products including, but not limited to:
 - 1. The Aluminum Beverage Cans Manufacturing Facilities;
 - 2. The Aluminum Beverage Cans Corporate Facility;

Order to Maintain Assets

3. The Aluminum Beverage Cans Technical and Engineering Facility;
4. The Aluminum Beverage Cans Contracts;
5. An upfront, paid up, perpetual and royalty-free license to all Intellectual Property relating to the research, development, manufacture, distribution, marketing or sale of Aluminum Beverage Cans Products; *provided, however*, this license shall include rights to all of Respondent Rexam's Intellectual Property related to the Aluminum Beverage Cans Products worldwide;
6. All inventories relating to Aluminum Beverage Cans Products, affiliated with an Aluminum Beverage Cans Manufacturing Facility, wherever located;
7. All consents, licenses, certificates, registrations, or permits issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement relating to the research, development, manufacture, distribution, marketing or sale of Aluminum Beverage Cans Products, and all pending applications therefor or renewals thereof;
8. All Business Records relating to the research, development, manufacture, distribution, marketing or sale of Aluminum Beverage Cans Products; *provided, however*, that where documents or other materials included in the Business Records to be divested contain information: (a) that relates both to the Aluminum Beverage Cans Business to be divested and to the Retained Business or other products or businesses and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Aluminum Beverage Cans Business to be divested; or (b) for which the relevant party has a legal obligation to retain the

Order to Maintain Assets

original copies, the relevant party shall be required to provide only copies or relevant excerpts of the documents and materials containing this information, then Respondents may keep such records and provide copies with appropriate redactions to the Acquirer. In instances where such copies are provided to the Acquirer, the relevant party shall provide the Acquirer access to original documents under circumstances where copies of the documents are insufficient for evidentiary or regulatory purposes.

Provided, however, assets contained in Schedules 1.2(c), 1.2(m), 1.2(n)(i), 1.2(n)(ii), and 1.2(v) of the Divestiture Agreement shall be excluded.

- H. “Aluminum Beverage Cans Designated Employee” means any person employed by RBCC (1) at the Aluminum Beverage Cans Manufacturing Facilities; (2) working at or out of the Aluminum Beverage Cans Corporate Facility; (3) at the Aluminum Beverage Cans Technical and Engineering Facility; (4) who has spent over twenty-five percent (25%) of his or her time, from January 2015 to December 2015, working for or on behalf of the Aluminum Beverage Cans Business, wherever located; or (5) identified by agreement between Respondent Rexam and an Acquirer and made a part of a Divestiture Agreement including, but not limited to, the Aluminum Beverage Cans Divestiture Employees.
- I. “Aluminum Beverage Cans Divestiture Employees” are certain employees working at or out of the Aluminum Beverage Cans Corporate Facility and the Aluminum Beverage Cans Technical and Engineering Facility, and are identified in Non-Public Confidential Appendix C attached to the Decision and Order.
- J. “Ardagh” means Ardagh Group S.A., a limited liability corporation organized, existing, and doing business under, and by virtue of, the laws of

Order to Maintain Assets

Luxembourg with its office and principal executive offices located at 56, rue Charles Martel, Luxembourg, and its United States address for business operations is 401 E. Jackson Street, Suite 2800, Tampa, FL 33062.

- K. “Confidential Business Information” means information owned by, or in the possession or control of, RBCC that is not in the public domain and that is directly related to the conduct of the Aluminum Beverage Cans Business. The term “Confidential Business Information” *excludes* the following:
1. information specifically excluded from the Aluminum Beverage Cans Business conveyed to the Acquirer;
 2. information that is contained in documents, records, or books of RBCC that is provided to an Acquirer that is unrelated to the Aluminum Beverage Cans Business acquired by that Acquirer or that is exclusively related to businesses or products retained by Respondent Rexam;
 3. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition law; and
 4. information that Respondent Rexam demonstrates to the satisfaction of the Commission, in the Commission’s sole discretion:
 - a. Was or becomes generally available to the public other than as a result of disclosure by Respondent Rexam;
 - b. Is necessary to be included in Respondent Rexam’s mandatory regulatory filings; *provided, however,* that Respondent Rexam shall make all reasonable efforts to maintain

Order to Maintain Assets

the confidentiality of such information in the regulatory filings;

- c. Was available, or becomes available, to Respondent Ball on a non-confidential basis, but only if, to the knowledge of Respondent Ball, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information;
- d. Is information the disclosure of which is consented to by the Acquirer;
- e. Is necessary to be exchanged in the course of consummating the Acquisition or the transaction under the Divestiture Agreement or any Remedial Agreement;
- f. Is disclosed in complying with the Order;
- g. Is information the disclosure of which is necessary to allow Respondents to comply with the requirements and obligations of the laws of the United States and other countries, and decisions of Government Entities; or
- h. Is disclosed in obtaining legal advice.

L. “Divestiture Agreement” means:

- 1. the Equity and Asset Purchase Agreement by and among Ardagh Group S.A., Ball Corporation, and Rexam PLC, dated April 22, 2016, and all amendments, exhibits, attachments, agreements, and schedules thereto, attached to the Decision and Order as Non-public Confidential Appendix A; or
- 2. any agreement that receives the prior approval of the Commission between Respondents (or between a Divestiture Trustee appointed pursuant to

Order to Maintain Assets

Paragraph IV. of this Order) and an Acquirer to purchase the Aluminum Beverage Cans Business, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission.

- M. “Divestiture Date” means the date on which Respondent Rexam (or a Divestiture Trustee) closes on the divestiture of the Aluminum Beverage Cans Business as required by Paragraph II (or Paragraph IV) of the Decision and Order.
- N. “Employee Access Period” means one (1) year from the Divestiture Date.
- O. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- P. “Monitor Agreement” means the Monitor Agreement dated February 25, 2016, between ING Financial Markets LLC, and Ball Corporation. The Monitor Agreement is attached to the Decision and Order as Public Appendix E.
- Q. “Orders” means the Decision and Order and the Order to Maintain Assets.
- R. “Remedial Agreement(s)” means:
 - 1. Any agreement between Respondents and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, and divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final; and/or

Order to Maintain Assets

2. Any agreement between Respondents and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order.
- S. “Transition Services” means any transitional services required by the Acquirer for the operation of the divested business including, but not limited to administrative assistance (including, but not limited to, order processing, shipping, accounting, and information transitioning services), technical assistance, and supply agreements.
- T. “Transitional Services Agreement(s)” means:
1. The agreements between Respondents and Ardagh for the provision of Transition Services and attached to the Decision and Order as Non-Public Confidential Appendix B; or
 2. Any agreement entered into between Respondents and an Acquirer (or the Divestiture Trustee and an Acquirer) for the provision of Transition Services.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the Aluminum Beverage Cans Business, to minimize any risk of loss of competitive potential for such Aluminum Beverage Cans Business,

Order to Maintain Assets

and to prevent the destruction, removal, wasting, deterioration, or impairment of the Aluminum Beverage Cans Business except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Aluminum Beverage Cans Business (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the related Aluminum Beverage Cans Business.

- B. Respondents shall maintain the operations of the Aluminum Beverage Cans Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; customers; employees; and others having business relations with the Aluminum Beverage Cans Business. Respondents' responsibilities shall include, but are not limited to, the following:
1. Providing the Aluminum Beverage Cans Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business, and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for the Aluminum Beverage Cans Business;
 2. Continuing, at least at their scheduled pace, any additional expenditures for the Aluminum Beverage Cans Business authorized prior to the date the Consent Agreement was signed by Respondents, including, but not limited to, all research, development, manufacturing, distribution, marketing, and sales expenditures;
 3. Providing such resources as may be necessary to respond to competition against the Aluminum

Order to Maintain Assets

Beverage Cans Business and/or to prevent any diminution in sales of each of the Aluminum Beverage Cans Products prior to the divestiture;

4. Making available for use by the Aluminum Beverage Cans Business funds sufficient to perform all routine maintenance and other maintenance as may be necessary to, and all replacements of, the assets related to the Aluminum Beverage Cans Business;
 5. Providing the Aluminum Beverage Cans Business with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of the Aluminum Beverage Cans Business;
 6. Providing such support services to the Aluminum Beverage Cans Business as were being provided by Respondents as of the date the Consent Agreement was signed by Respondents; and
 7. Maintaining a work force at least equivalent in size, training, and expertise to what has been associated with the Aluminum Beverage Cans Business for the last fiscal year.
- C. Until the Divestiture Date, Respondents shall provide all Aluminum Beverage Cans Designated Employees with reasonable financial incentives to continue in their positions and to research, develop, manufacture, and/or market the Aluminum Beverage Cans Products consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Aluminum Beverage Cans Business pending divestiture. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the divestiture of the Aluminum Beverage Cans Business has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted

Order to Maintain Assets

by law), and additional incentives as may be necessary to prevent any diminution of the competitiveness of the Aluminum Beverage Cans Business.

- D. From the date Respondents execute the Divestiture Agreement until the Employee Access Period terminates, Respondents shall provide a proposed Acquirer with the opportunity to recruit and employ any Aluminum Beverage Cans Designated Employee in conformance with the following:
1. No later than ten (10) days after a request from a proposed Acquirer, or staff of the Commission, Respondents shall provide a proposed Acquirer with the following information for each Aluminum Beverage Cans Designated Employee, as and to the extent permitted by law:
 - a. name, job title or position, date of hire and effective service date;
 - b. a specific description of the employee's responsibilities;
 - c. the base salary or current wages;
 - d. the most recent bonus paid, aggregate annual compensation for RBCC's last fiscal year, and current target or guaranteed bonus, if any;
 - e. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
 - f. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly-situated employees; and
 - g. at a proposed Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant

Order to Maintain Assets

Aluminum Beverage Cans Designated
Employee(s);

2. No later than ten (10) days after a request from a proposed Acquirer, Respondents shall provide the proposed Acquirer with:
 - a. an opportunity to meet, personally and outside the presence or hearing of any employee or agent of Respondents, with any Aluminum Beverage Cans Designated Employee;
 - b. an opportunity to inspect the personnel files and other documentation relating to any such employee, to the extent permissible under applicable laws; and
 - c. to make offers of employment to any Aluminum Beverage Cans Designated Employee;
3. Respondents shall (i) not interfere, directly or indirectly, with the hiring or employing by a proposed Acquirer of any Aluminum Beverage Cans Designated Employee, (ii) not offer any incentive to any Aluminum Beverage Cans Designated Employee to decline employment with a proposed Acquirer, (iii) not make any counteroffer to any Aluminum Beverage Cans Designated Employee who receives a written offer of employment from a proposed Acquirer, and (iv) remove any impediments within the control of Respondents that may deter any Aluminum Beverage Cans Designated Employee from accepting employment with a proposed Acquirer, including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts with Respondents that would affect the ability of such employee to be employed by a proposed Acquirer; *provided, however*, that nothing in this Order shall be construed to require

Order to Maintain Assets

Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee.

- E. Respondents shall provide reasonable financial incentives to the Aluminum Beverage Cans Divestiture Employees as needed to facilitate the employment of such employees by the Acquirer; *provided, however*, (i) if the proposed Acquirer has made a written offer of employment to an Aluminum Beverage Can Divestiture Employee, and (ii) such employee has declined employment with the proposed Acquirer, then Respondents, in consultation with the Monitor (if one is appointed), shall make available a substitute employee with substantially the same skills and job function to the Acquirer for employment.
- F. For a period of two (2) years after the Divestiture Date, Respondents shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Person employed by an Acquirer of the Aluminum Beverage Cans Business, to terminate his or her employment relationship with an Acquirer;

Provided, however, Respondents may: (1) advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, so long as these actions are not targeted specifically at any Aluminum Beverage Cans Designated Employees; and (2) hire employees of the Aluminum Beverage Cans Business who apply for employment with Respondents, so long as such individuals were not solicited by Respondents in violation of this paragraph;

Provided, further, however, that this Paragraph shall not prohibit Respondents from making offers of employment to or employing any employee of the Aluminum Beverage Cans Business if an Acquirer has notified Respondents in writing that an Acquirer does not intend to make an offer of employment to that

Order to Maintain Assets

employee, or where such an offer has been made and the employee has declined the offer, or where the individual's employment has been terminated by an Acquirer.

- G. Respondents shall ensure that employees of the Respondents' Retained Business shall not receive, have access to, use or continue to use, or disclose any Confidential Business Information pertaining to the Aluminum Beverage Cans Business except in the course of:
1. Performing their obligations as permitted under this Order to Maintain Assets or the Decision and Order;
 2. Performing their obligations under any Remedial Agreement; or
 3. Complying with financial reporting requirements or environmental, health, and safety policies and standards, ensuring the integrity of the financial and operational controls on the Aluminum Beverage Cans Business, obtaining legal advice, defending legal claims, investigations, or enforcing actions threatened or brought against the Aluminum Beverage Cans Business, or as required by law;

Provided, however, for purposes of this Paragraph, Respondents' employees who provide or are involved in the receipt of support services under this Order to Maintain Assets shall be deemed to be performing obligations under the Decision and Order.

- H. If the receipt, access to, use, or disclosure of Confidential Business Information pertaining to the Aluminum Beverage Cans Business is permitted to Respondents' employees under Paragraph II.F. of the Decision and Order, Respondents shall limit such information (1) only to those Persons who require such

Order to Maintain Assets

information for the purposes permitted under Paragraph II.F. of the Decision and Order, (2) only to the extent such Confidential Business Information is required, and (3) only after such Persons have signed an appropriate agreement in writing to maintain the confidentiality of such information.

- I. Respondents shall enforce the confidentiality terms of this Order to Maintain Assets and the Decision and Order as to any Person other than the Acquirer of the Aluminum Beverage Cans Business and take such action as is necessary to cause each such Person to comply with these terms, including training of Respondents' employees and all other actions that Respondents would take to protect its own trade secrets and proprietary information.
- J. Respondents shall adhere to and abide by the Remedial Agreements (which agreement shall not vary or contradict, or be construed to vary from or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondents under such agreements), which are incorporate by reference into this Order to Maintain Assets and made a part hereof.
- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Aluminum Beverage Cans Business within the Geographic Territory through its full transfer and delivery to the Acquirer, to minimize any risk of loss of competitive potential for the Aluminum Beverage Cans Business within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Aluminum Beverage Cans Business except for ordinary wear and tear.

Order to Maintain Assets

III.**IT IS FURTHER ORDERED** that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements. The Commission hereby appoints ING Financial Markets LLC (“ING”) as the Monitor and approves the Monitor Agreement between ING and Respondents which agreement, *inter alia*, names Philip Comerford, Jr., as ING designated Project Manager.
- B. Not later than one (1) day after the appointment of the Monitor, Respondents shall, pursuant to the Monitor Agreement and to the Orders, confer on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents’ compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- C. The Monitor shall serve until the later of (1) eighteen (18) months after the Divestiture Date or (2) the termination of all Respondents’ obligations under all Remedial Agreements; *provided, however*, the Commission may extend or modify this period as may be necessary to accomplish the purposes of the Orders.
- D. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor Respondents’ compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a

Order to Maintain Assets

manner consistent with the purposes of the Orders and in consultation with the Commission, including, but not limited to:

- a. Assuring that Respondents expeditiously comply with all of their obligations and performs all of their responsibilities as required by this Orders and the Remedial Agreements;
 - b. Monitoring all Remedial Agreements; and
 - c. Assuring that Confidential Business Information is not received or used by Respondents or the Acquirer, except as allowing in the Orders;
2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 3. The Monitor shall serve for such time as is necessary to monitor Respondents' compliance with the provisions of the Orders and the Remedial Agreements;
 4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under the Orders and the Remedial Agreements. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders and the Remedial Agreements;
 5. The Monitor shall serve, without bond or other security, at the expense of Respondents on such

Order to Maintain Assets

reasonable and customary terms and conditions as the Commission may set. The Monitor shall have the authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission;

6. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor. For purposes of this Paragraph III, the term "Monitor" shall include all persons retained by the Monitor pursuant to Paragraph III.D.5 of this Order to Maintain Assets and Paragraph III.D.5 of the Decision and Order;
7. Respondents shall report to the Monitor in accordance with the requirements of the Orders and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by the Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Orders and the Remedial Agreements;
8. Within one (1) month from the date the Monitor is appointed pursuant to this Paragraph, every sixty (60) days thereafter, and otherwise requested by

Order to Maintain Assets

the Commission, the Monitor shall report in writing to the Commission concerning performance by Respondents' of their obligations under the Orders and the Remedial Agreements;

9. Respondents may require the Monitor and each of the Monitors consultants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
 - F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor.
 - G. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of the proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed substitute Monitor, Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor. Not later than ten (10) days after appointment of a substitute Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the substitute Monitor all the rights and powers necessary to permit the substitute Monitor to monitor Respondent's compliance with the terms of the Orders

Order to Maintain Assets

and the Remedial Agreements in a manner consistent with the purposes of the Orders.

- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders and the Remedial Agreements.

IV.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition Date, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Respondents shall submit to the Commission and, if appointed, the Monitor, a verified written report setting forth in detail the manner and form in which it intends to comply, are complying, and have complied with this Order:
1. Within thirty (30) days after the date this Order to Maintain Assets becomes final;
 2. Every thirty (30) days thereafter until Respondents have fully divested, licensed, transferred and/or granted the Aluminum Beverage Cans Business to an Acquirer; and
 3. Every three (3) months thereafter so long as Respondents have a continuing obligation under this Order and/or the Remedial Agreements to render services to the Acquirer or otherwise to comply with this Order;

Provided, however, that, after the proposed Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at

Order to Maintain Assets

the same time as the reports required to be submitted by Respondents pursuant to the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondents;
- B. Any proposed acquisition, merger, or consolidation of Respondents; or
- C. Any other change in the Respondents, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

VI.

IT IS FURTHER ORDERED that for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents, with respect to any matter contained in this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents related to compliance with the Consent Agreement and/or this Order, which copying services shall be provided by Respondents at the request of the authorized representative of the Commission and at the expense of Respondents; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from them, to interview

Order to Maintain Assets

officers, directors, or employees of Respondents, who may have counsel present.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the later of:

- A. The day after the divestiture of the Aluminum Beverage Cans Business, as required by and described in the proposed Decision and Order, has been completed and the Monitor, in consultation with the Commission staff and the Acquirer, notified the Commission that all assignments, conveyances, deliveries, grants, license, transactions, transfers and other transitions related to such divestiture are complete;
- B. The day the proposed Decision and Order becomes final; or
- C. The Commission otherwise directs that this Order to Maintain Assets be terminated;

Provided, however, if the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of the Commission Rule 2.34, 16 C.F.R. § 2.34, this Order to Maintain Assets shall terminate no later than three (3) days after such action by the Commission.

By the Commission.

Decision and Order

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Ball Corporation (“Ball”) of the voting securities of Respondent Rexam PLC (“Rexam”), collectively “Respondents,” and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Ball Corporation, is a corporation organized, existing, and doing business under, and by

Decision and Order

virtue of, the laws of the State of Indiana with its executive offices and principal place of business at 10 Longs Peak Drive, Bloomfield, CO 80021.

2. Respondent Rexam PLC, is a public limited company organized, existing, and doing business under, and by virtue of, the laws of England and Wales with its principal executive offices located at 4 Millbank, London SW1P 3XR, United Kingdom, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Corporate Secretary, Rexam Beverage Can Company, 4201 Congress Street, Suite 340, Charlotte, NC 28209.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS HEREBY ORDERED that, as used in this Order, the following definitions, and all other definitions used in the Order to Maintain Assets, shall apply:

- A. “Ball” means Ball Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates in each case controlled by Ball Corporation, including, but not limited to, Ball UK Acquisition Ltd., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Ball includes Rexam, after the Acquisition Date.
- B. “Rexam” means Rexam PLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries,

Decision and Order

partnerships, divisions, groups, and affiliates in each case controlled by Rexam PLC, including, but not limited to, Rexam Beverage Can Company (“RBCC”), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Commission” means the Federal Trade Commission.
- D. “Acquirer” means:
 - 1. Ardagh; or
 - 2. a Person approved by the Commission to acquire the Aluminum Beverage Cans Business pursuant to this Decision and Order.
- E. “Acquisition” means the proposed acquisition by Respondent Ball of all the voting securities of Respondent Rexam as described in the Recommended Cash and Share Offer for Rexam PLC by Ball UK Acquisition Limited, A Wholly-Owned Subsidiary of Ball Corporation, dated February 19, 2015, between Ball Corporation, Ball UK Acquisition Ltd., and Rexam PLC, and any amendments, exhibits, or schedules attached thereto.
- F. “Acquisition Date” means the date the Acquisition is consummated.
- G. “Aluminum Beverage Cans Business” means all of RBCC’s assets, including Tangible Personal Property and intangible assets, businesses and goodwill, related to the research, development, manufacture, distribution, marketing or sale of Aluminum Beverage Cans Products including, but not limited to:
 - 1. The Aluminum Beverage Cans Manufacturing Facilities;
 - 2. The Aluminum Beverage Cans Corporate Facility;

Decision and Order

3. The Aluminum Beverage Cans Technical and Engineering Facility;
4. The Aluminum Beverage Cans Contracts;
5. An upfront, paid up, perpetual and royalty-free, license to all Intellectual Property relating to the research, development, manufacture, distribution, marketing or sale of Aluminum Beverage Cans Products; *provided, however*, this license shall include rights to all of Respondent Rexam's Intellectual Property related to the Aluminum Beverage Cans Products worldwide.
6. All inventories relating to Aluminum Beverage Cans Products, affiliated with an Aluminum Beverage Cans Manufacturing Facility, wherever located;
7. All consents, licenses, certificates, registrations, or permits issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement relating to the research, development, manufacture, distribution, marketing or sale of Aluminum Beverage Cans Products, and all pending applications therefor or renewals thereof;
8. All Business Records relating to the research, development, manufacture, distribution, marketing or sale of Aluminum Beverage Cans Products; *provided, however*, that where documents or other materials included in the Business Records to be divested contain information: (a) that relates both to the Aluminum Beverage Cans Business to be divested and to the Retained Business or other products or businesses and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Aluminum Beverage Cans Business to be divested; or (b) for which the relevant party has a legal obligation to retain the

Decision and Order

original copies, the relevant party shall be required to provide only copies or relevant excerpts of the documents and materials containing this information, then Respondents may keep such records and provide copies with appropriate redactions to the Acquirer. In instances where such copies are provided to the Acquirer, the relevant party shall provide the Acquirer access to original documents under circumstances where copies of the documents are insufficient for evidentiary or regulatory purposes.

Provided, however, assets contained in Schedules 1.2(c), 1.2(m), 1.2(n)(i), 1.2(n)(ii), and 1.2(v) of the Divestiture Agreement shall be excluded.

- H. “Aluminum Beverage Cans Contracts” means all agreements and contracts with customers (including, but not limited to, contracts, purchasing agreements, and rebate agreements with customers who will be served from both the Aluminum Beverage Cans Manufacturing Facilities and facilities retained by Respondent Ball, and agreements, contracts, and understandings for transportation, storage, and other services), suppliers, vendors, representatives, agents, licensees and licensors; and all leases, mortgages, notes, bonds, and other binding commitments, whether written or oral, and all rights thereunder and related thereto related to the Aluminum Beverage Cans Business from the Aluminum Beverage Cans Manufacturing Facilities;
- I. “Aluminum Beverage Cans Corporate Facility” means the facility located at 8770 W. Bryn Mawr Avenue, Chicago, IL 60631, including, but not limited to, information technology systems, all physical assets and equipment related to the research, development, manufacture, sale, and distribution of products from the Aluminum Beverage Cans Manufacturing Facilities; *provided, however,* that parts, inventory,

Decision and Order

designs, or other assets held for use exclusively by or for the Retained Business may be excluded.

- J. “Aluminum Beverage Cans Designated Employee” means any person employed by RBCC (1) at the Aluminum Beverage Cans Manufacturing Facilities; (2) working at or out of the Aluminum Beverage Cans Corporate Facility; (3) at the Aluminum Beverage Cans Technical and Engineering Facility; (4) who has spent over twenty-five percent (25%) of his or her time, from January 2015 to December 2015, working for or on behalf of the Aluminum Beverage Cans Business, wherever located; or (5) identified by agreement between Respondent Rexam and an Acquirer and made a part of a Divestiture Agreement including, but not limited to, the Aluminum Beverage Cans Divestiture Employees.
- K. “Aluminum Beverage Cans Divestiture Employees” are certain employees working at or out of the Aluminum Beverage Cans Corporate Facility and the Aluminum Beverage Cans Technical and Engineering Facility, and are identified in Non-Public Confidential Appendix C attached to this Order.
- L. “Aluminum Beverage Cans Manufacturing Facilities” means all real property interests (including fee simple interests and real property leasehold interests), including all easements, appurtenances, licenses, and permits, together with all buildings and other structures, facilities, and improvements located thereon, owned, leased, or otherwise held by RBCC, and all Tangible Personal Property, therein, at the Bishopville Facility, Chicago Facility, Fairfield Facility, Fremont Facility, Olive Branch Facility, Valparaiso Facility, Whitehouse Facility, and Winston-Salem Facility. *Provided, however,* that parts, inventory, designs, or other assets held for use exclusively by or for the Retained Business may be excluded.

Decision and Order

- M. “Aluminum Beverage Cans Products” means the Standard Aluminum Beverage Cans and Specialty Aluminum Beverage Cans:
1. manufactured by RBCC at the Aluminum Beverage Cans Manufacturing Facilities; or
 2. designed, researched and developed, but not yet commercialized, by RBCC, anywhere in the world, and that are intended to be manufactured at the Aluminum Beverage Cans Manufacturing Facilities.
- N. “Aluminum Beverage Cans Technical and Engineering Facility” means the technical and engineering facility located at 2520 Lively Boulevard, Elk Grove, IL 60007, including, but not limited to, all real property interests (including fee simple interests and real property leasehold interests), including all easements, appurtenances, licenses, and permits, together with all buildings and other structures, facilities, and improvements located thereon, owned, leased, or otherwise held by RBCC, and all Tangible Personal Property therein, and parts, inventory, and all other assets relating to the Aluminum Beverage Cans Business. *Provided, however*, that parts, inventory, designs, or other assets held for use exclusively by or for the Retained Business may be excluded.
- O. “Ardagh” means Ardagh Group S.A., a limited liability corporation organized, existing, and doing business under, and by virtue of, the laws of Luxembourg with its office and principal executive offices located at 56, rue Charles Martel, Luxembourg, and its United States address for business operations is 401 E. Jackson Street, Suite 2800, Tampa, FL 33062.
- P. “Arizona” means Arizona Beverages USA LLC, a limited liability corporation, organized, existing, and doing business under, and by virtue of, the laws of the State of New York with its executive offices and

Decision and Order

principal place of business at 60 Crossways Park Drive W, Woodbury, NY 11797.

- Q. “Arizona Contract Manufacturing Agreement” means:
1. The Arizona Contract Manufacturing Agreement entered into between Ardagh Metal Beverage USA Inc. and Rexam Beverage Can Company, dated on the Divestiture Date , and any attachments, amendments, exhibits, and schedules related thereto that have been approved by the Commission. This Arizona Contract Manufacturing Supply Agreement is attached to this Order and contained in Non-Public Appendix D; or
 2. Any agreement between Respondents (or between a Divestiture Trustee appointed pursuant to Paragraph IV. of this Order) and an Acquirer for the purchase of Specialty Aluminum Beverage Cans Products as provided for in Paragraph II.B. of this Order, that receives the prior approval of the Commission, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission.
- R. “Arizona-Rexam Supply Agreement” means that Amended and Restated Can Supply Agreement, dated May 26, 2015, by and between Rexam Beverage Can Company and Arizona Beverages USA LLC.
- S. “Bishopville Facility” means the aluminum beverage cans manufacturing plant located at 609 Cousar Street, Bishopville, SC 29010.
- T. “Business Records” means all originals and all copies of any operating, financial or other information, documents, data, computer files (including files stored on a computer’s hard drive or other storage media), electronic files, books, records, ledgers, papers, instruments, and other materials, whether located,

Decision and Order

stored, or maintained in traditional paper format or by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media, including, without limitation: distributor files and records; customer files and records, customer lists, customer product specifications, customer purchasing histories, customer service and support materials, customer approvals, and other information; credit records and information; correspondence; referral sources; supplier and vendor files and lists; advertising, promotional, and marketing materials, including website content; sales materials; research and development data, files, and reports; technical information; data bases; studies; designs, drawings, specifications and creative materials; production records and reports; service and warranty records; equipment logs; operating guides and manuals; employee and personnel records; education materials; financial and accounting records; and other documents, information, and files of any kind.

- U. “Cap Can®” means RBCC’s Aluminum Beverage Cans Products with a re-sealable cap opening.
- V. “Chicago Facility” means the aluminum beverage cans manufacturing plant located at 1101 West 43rd Street, Chicago, IL 60609.
- W. “Confidential Business Information” means information owned by, or in the possession or control of, RBCC that is not in the public domain and that is directly related to the conduct of the Aluminum Beverage Cans Business. The term “Confidential Business Information” *excludes* the following:
 - 1. information specifically excluded from the Aluminum Beverage Cans Business conveyed to the Acquirer;
 - 2. information that is contained in documents, records, or books of RBCC that is provided to an

Decision and Order

Acquirer that is unrelated to the Aluminum Beverage Cans Business acquired by that Acquirer or that is exclusively related to businesses or products retained by Respondent Rexam;

3. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition law; and
4. information that Respondent Rexam demonstrates to the satisfaction of the Commission, in the Commission's sole discretion:
 - a. Was or becomes generally available to the public other than as a result of disclosure by Respondent Rexam;
 - b. Is necessary to be included in Respondent Rexam's mandatory regulatory filings; *provided, however*, that Respondent Rexam shall make all reasonable efforts to maintain the confidentiality of such information in the regulatory filings;
 - c. Was available, or becomes available, to Respondent Ball on a non-confidential basis, but only if, to the knowledge of Respondent Ball, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information;
 - d. Is information the disclosure of which is consented to by the Acquirer;
 - e. Is necessary to be exchanged in the course of consummating the Acquisition or the transaction under the Divestiture Agreement or any Remedial Agreement;

Decision and Order

- f. Is disclosed in complying with the Order;
 - g. Is information the disclosure of which is necessary to allow Respondents to comply with the requirements and obligations of the laws of the United States and other countries, and decisions of Government Entities; or
 - h. Is disclosed in obtaining legal advice.
- X. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service.
- Y. “Divestiture Agreement” means:
- 1. the Equity and Asset Purchase Agreement by and among Ardagh Group S.A., Ball Corporation, and Rexam PLC, dated April 22, 2016, and all amendments, exhibits, attachments, agreements, and schedules thereto, attached to this Order as Non-public Confidential Appendix A; or
 - 2. any agreement that receives the prior approval of the Commission between Respondents (or between a Divestiture Trustee appointed pursuant to Paragraph IV. of this Order) and an Acquirer to purchase the Aluminum Beverage Cans Business, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission.
- Z. “Divestiture Date” means the date on which Respondent Rexam (or a Divestiture Trustee) closes on the divestiture of the Aluminum Beverage Cans Business as required by Paragraph II (or Paragraph IV) of this Order.
- AA. “Employee Access Period” means one (1) year from the Divestiture Date.

Decision and Order

- BB. “Fairfield Facility” means the aluminum beverage cans manufacturing plant located at 2433 Crocker Circle, Fairfield, CA 94533.
- CC. “Fremont Facility” means the aluminum beverage cans manufacturing plant located at 2145 Cedar Street, Fremont, OH 43420; *PROVIDED, HOWEVER*, assets (including Intellectual Property) exclusively related to the manufacture and production of Cap Can® ends are excluded.
- DD. “Geographic Territory” means the United States.
- EE. “Government Entities” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- FF. “Intellectual Property” means:
1. Patents, and the rights to obtain and file for Patents, trademarks, and copyrights and registrations thereof and to bring suit against a third party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;
 2. product manufacturing technology, including process technology, technology for equipment, inspection technology, and research and development of product or process technology;
 3. Product and manufacturing copyrights;
 4. all plans (including proposed and tentative plans, whether or not adopted or commercialized), research and development, specifications, drawings, and other assets (including the non-exclusive right to use Patents, know-how, and other intellectual property relating to such plans);

Decision and Order

5. product trademarks, trade dress, trade secrets, technology, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, development, and other information, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the products, including, but not limited to, all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with any Government Entity approvals and compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
 6. licenses including, but not limited to, third party software, if transferrable, and sublicenses to software modified by RBCC;
 7. formulations and a description of all ingredients, materials, or components used in the manufacture of products; and
 8. any other intellectual property used in the past by RBCC in the design, manufacture, and sale of products from the Aluminum Beverage Cans Business.
- GG. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the Order to Maintain Assets.
- HH. “Monitor Agreement” means the Monitor Agreement dated February 25, 2016, between ING Financial

Decision and Order

Markets LLC, and Ball Corporation. The Monitor Agreement is attached as Appendix E to this Order.

- II. “Olive Branch Facility” means the aluminum beverage cans manufacturing plant located at 10800 Marina Drive, Olive Branch, MS 38654.
- JJ. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- KK. “Patents” means pending patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Acquisition Date, and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- LL. “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization, or other business entity other than Respondents or Ardagh.
- MM. “Remedial Agreement(s)” means:
 - 1. Any agreement between Respondents and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, and divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final; and/or

Decision and Order

2. Any agreement between Respondents and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order.
- NN. “Retained Business” means the assets and businesses of Respondents other than the Aluminum Beverage Cans Business.
- OO. “Retained Business Firewalled Employees” means Respondents’ employees of the Retained Business who have responsibilities over or are involved in establishing the pricing of Aluminum Beverage Cans Products.
- PP. “Specialty Aluminum Beverage Cans” means specialty aluminum beverage cans of various sizes including, but not limited to: (1) 7.5-ounce slim cans; (2) 8-ounce slim cans; (3) 12-ounce sleek cans; (4) 16-ounce cans; and (5) 24-ounce cans.
- QQ. “Standard Aluminum Beverage Cans” means 12-ounce aluminum beverage cans.
- RR. “Tangible Personal Property” means all machinery, equipment, tools, furniture, office equipment, computer hardware, supplies, materials, vehicles, rolling stock, and other items of tangible personal property (other than inventories) of every kind owned or leased by RBCC, together with any express or implied warranty by the manufacturers or sellers or lessors of any item or component part thereof and all maintenance records and other documents relating thereto.

Decision and Order

- SS. “Transition Services” means any transitional services required by the Acquirer for the operation of the divested business including, but not limited to administrative assistance (including, but not limited to, order processing, shipping, accounting, and information transitioning services), technical assistance, and supply agreements.
- TT. “Transitional Services Agreement(s)” means:
1. The agreements between Respondents and Ardagh for the provision of Transition Services and attached to this Order as Non-Public Confidential Appendix B; or
 2. Any agreement entered into between Respondents and an Acquirer (or the Divestiture Trustee and an Acquirer) for the provision of Transition Services.
- UU. “Valparaiso Facility” means the aluminum beverage cans manufacturing plant located at 4001 Montdale Park Drive, Valparaiso, IN 46383.
- VV. “Whitehouse Facility” means the aluminum beverage cans manufacturing plant located at 10444 Waterville Street, Whitehouse, OH 43571.
- WW. “Winston-Salem Facility” means the aluminum beverage cans manufacturing plant located at 4000 Old Milwaukee Lane, Winston-Salem, NC 27197.

II.**IT IS FURTHER ORDERED** that:

- A. Within ten (10) days of the Acquisition Date, Respondents shall divest the Aluminum Beverage Cans Business to Ardagh, pursuant to and in accordance with the Divestiture Agreement (which shall not limit or contradict, or be construed to vary from or contradict, the terms of this Order), and such

Decision and Order

agreement, if it becomes a Remedial Agreement related to the Aluminum Beverage Cans Business is incorporated by reference into this Order and made a part hereof;

Provided, however, if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Ardagh is not an acceptable Acquirer of the Aluminum Beverage Cans Business then Respondents shall immediately rescind the transaction with Ardagh, in whole or in part, as directed by the Commission, and shall divest, license, and/or transfer the Aluminum Beverage Cans Business within six (6) months from the date this Order is issued, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission;

Provided, further, however, that if Respondents have complied with the terms of this Paragraph before the date on which this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents or appoint the Divestiture Trustee, to effect such modifications to the manner of the divestiture to Ardagh (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. At the Acquirer's option and upon reasonable notice, for a period not to exceed the length of the Arizona-Rexam Supply Agreement, Respondents shall enter an Arizona Contract Manufacturing Agreement and shall purchase a supply of Specialty Aluminum Beverage Cans Products from the Acquirer in order to ensure that Arizona is able to obtain Specialty Aluminum

Decision and Order

Beverage Cans Products on substantially the same terms as the Arizona-Rexam Supply Agreement.

- C. If Respondents (or a Divestiture Trustee) enter into an Arizona Contract Manufacturing Agreement with the Acquirer, Respondents shall:
1. Purchase a supply of Specialty Aluminum Beverage Cans Products from the Acquirer: (i) at the same price set forth in the Arizona-Rexam Supply Agreement; (ii) at substantially the same quality as such Specialty Aluminum Beverage Cans Products are currently manufactured; and (iii) as supplied from the manufacturing locations that are geographically close to Arizona's facilities as specified in the Arizona-Rexam Supply Agreement;
 2. Terminate, on reasonable notice and without cost or penalty to the Acquirer, the Arizona Contract Manufacturing Agreement if: (i) Arizona terminates the Arizona-Rexam Supply Agreement; or (ii) the Acquirer enters into a new agreement with Arizona for the supply of Specialty Aluminum Beverage Cans Products; and
 3. Implement procedures to ensure that Confidential Business Information pertaining to any volumes Respondents purchase from the Acquirer pursuant to the Arizona Contract Manufacturing Agreement shall not be used, disclosed, or shared with any of Respondents' Retained Business Firewalled Employees; *provided, however*, Respondents may use or disclose this Confidential Business Information as necessary to comply with Paragraph II.F.
- D. At the request of the Acquirer, for a period not to exceed eighteen (18) months from the Divestiture Date, Respondents shall provide, at no greater than Direct Cost, Transition Services from knowledgeable

Decision and Order

employees of Respondents to assist the Acquirer in the transfer of the Aluminum Beverage Cans Business from Respondents to the Acquirer in a timely and orderly manner pursuant to the Transitional Services Agreements.

- E. Within ten (10) days of the Divestiture Date, Respondents shall submit to the Acquirer, at Respondents' expense, all Business Records of the Aluminum Beverage Cans Business, in good faith, and in a manner that ensures their completeness and accuracy and that fully preserves their usefulness; *provided, however*, pending complete delivery of all such Business Records of the Aluminum Beverage Cans Business to the Acquirer, Respondents shall provide the Acquirer, and the Interim Monitor with access to all such Business Records of the Aluminum Beverage Cans Business and employees who possess or able to locate such information for the purposes of identifying the books, records, and files directly related to the Aluminum Beverage Cans Business and facilitating the delivery in a manner consistent with this Order.
- F. Respondents shall ensure that employees of the Respondents' Retained Business shall not receive, have access to, use or continue to use, or disclose any Confidential Business Information pertaining to the Aluminum Beverage Cans Business except in the course of:
1. Performing their obligations as permitted under this Order or the Order to Maintain Assets;
 2. Performing their obligations under any Remedial Agreement; or
 3. Complying with financial reporting requirements or environmental, health, and safety policies and standards, ensuring the integrity of the financial and operational controls on the Aluminum

Decision and Order

Beverage Cans Business, obtaining legal advice, defending legal claims, investigations, or enforcing actions threatened or brought against the Aluminum Beverage Cans Business, or as required by law;

Provided, however, for purposes of this Paragraph, Respondents' employees who provide or are involved in the receipt of support services under the Order to Maintain Assets shall be deemed to be performing obligations under this Order.

- G. If the receipt, access to, use, or disclosure of Confidential Business Information pertaining to the Aluminum Beverage Cans Business is permitted to Respondents' employees under Paragraph II.F. of this Order, Respondents shall limit such information (1) only to those Persons who require such information for the purposes permitted under Paragraph II.F., (2) only to the extent such Confidential Business Information is required, and (3) only after such Persons have signed an appropriate agreement in writing to maintain the confidentiality of such information.
- H. Respondents shall enforce the confidentiality terms of this Order as to any Person other than the Acquirer of the Aluminum Beverage Cans Business and take such action as is necessary to cause each such Person to comply with these terms, including training of Respondents' employees and all other actions that Respondents would take to protect its own trade secrets and proprietary information.
- I. From the date Respondents execute the Divestiture Agreement until the Employee Access Period terminates, Respondents shall provide a proposed Acquirer with the opportunity to recruit and employ any Aluminum Beverage Cans Designated Employee in conformance with the following:

Decision and Order

1. No later than ten (10) days after a request from a proposed Acquirer, or staff of the Commission, Respondents shall provide a proposed Acquirer with the following information for each Aluminum Beverage Cans Designated Employee, as and to the extent permitted by law:
 - a. name, job title or position, date of hire and effective service date;
 - b. a specific description of the employee's responsibilities;
 - c. the base salary or current wages;
 - d. the most recent bonus paid, aggregate annual compensation for RBCC's last fiscal year and current target or guaranteed bonus, if any;
 - e. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
 - f. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly-situated employees; and
 - g. at a proposed Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant Aluminum Beverage Cans Designated Employee(s);
2. No later than ten (10) days after a request from a proposed Acquirer, Respondents shall provide the proposed Acquirer with:
 - a. an opportunity to meet, personally and outside the presence or hearing of any employee or agent of Respondents, with any Aluminum Beverage Cans Designated Employee;

Decision and Order

- b. an opportunity to inspect the personnel files and other documentation relating to any such employee, to the extent permissible under applicable laws; and
 - c. to make offers of employment to any Aluminum Beverage Cans Designated Employee;
 3. Respondents shall (i) not interfere, directly or indirectly, with the hiring or employing by a proposed Acquirer of any Aluminum Beverage Cans Designated Employee, (ii) not offer any incentive to any Aluminum Beverage Cans Designated Employee to decline employment with a proposed Acquirer, (iii) not make any counteroffer to any Aluminum Beverage Cans Designated Employee who receives a written offer of employment from a proposed Acquirer, and (iv) remove any impediments within the control of Respondents that may deter any Aluminum Beverage Cans Designated Employee from accepting employment with a proposed Acquirer, including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts with Respondents that would affect the ability of such employee to be employed by a proposed Acquirer;

Provided, however, that nothing in this Order shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee.

- J. Respondents shall provide reasonable financial incentives to the Aluminum Beverage Cans Divestiture Employees as needed to facilitate the employment of such employees by the Acquirer; *PROVIDED, HOWEVER,* (i) if the proposed Acquirer has made a written offer of employment to an Aluminum Beverage Can Divestiture Employee, and (ii) such

Decision and Order

employee has declined employment with the proposed Acquirer, then Respondents, in consultation with the Monitor (if one is appointed), shall make available a substitute employee with substantially the same skills and job function to the Acquirer for employment.

- K. For a period of two (2) years after the Divestiture Date, Respondents shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Person employed by an Acquirer of the Aluminum Beverage Cans Business, to terminate his or her employment relationship with an Acquirer;

Provided, however, Respondents may: (1) advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, so long as these actions are not targeted specifically at any Aluminum Beverage Cans Designated Employees; and (2) hire employees of the Aluminum Beverage Cans Business who apply for employment with Respondents, so long as such individuals were not solicited by Respondents in violation of this paragraph;

Provided, further, however, that this Paragraph shall not prohibit Respondents from making offers of employment to or employing any employee of the Aluminum Beverage Cans Business if an Acquirer has notified Respondents in writing that an Acquirer does not intend to make an offer of employment to that employee, or where such an offer has been made and the employee has declined the offer, or where the individual's employment has been terminated by an Acquirer.

- L. Until Respondents (or the Divestiture Trustee) complete the divestiture and other obligations to transfer the Aluminum Beverage Cans Business as required by this Order, Respondents shall take actions as are necessary to:

Decision and Order

1. Maintain the full economic viability and marketability of the Aluminum Beverage Cans Business;
 2. Minimize any risk of loss of competitive potential for the Aluminum Beverage Cans Business;
 3. Prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Aluminum Beverage Cans Business; and
 4. Not sell, transfer, encumber, or otherwise impair the Aluminum Beverage Cans Business (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Aluminum Beverage Cans Business.
- M. The purpose of this Paragraph II is to ensure the continued use of the assets in the same businesses in which such assets were engaged at the time of the announcement of the Acquisition by Respondents, minimize the loss of competitive potential for the Aluminum Beverage Cans Business, minimize the risk of disclosure or unauthorized use of Confidential Business Information related to the Aluminum Beverage Cans Business; to prevent the destruction, removal, wasting, deterioration, or impairment of the Aluminum Beverage Cans Business, except for ordinary wear and tear; and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.**IT IS FURTHER ORDERED** that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Monitor") to assure that the

Decision and Order

Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements. The Commission hereby appoints ING Financial Markets LLC (“ING”) as the Monitor and approves the Monitor Agreement between ING and Respondents which agreement, *inter alia*, names Philip Comerford, Jr., as ING designated Project Manager.

- B. Not later than one (1) day after the appointment of the Monitor, Respondents shall, pursuant to the Monitor Agreement and to this Order, confer on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents’ compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- C. The Monitor shall serve until the later of (1) eighteen (18) months after the Divestiture Date or (2) the termination of all Respondents’ obligations under all Remedial Agreements; *provided, however*, the Commission may extend or modify this period as may be necessary to accomplish the purposes of this Order and the Order the Maintain Assets.
- D. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor Respondents’ compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission, including, but not limited to:

Decision and Order

- a. Assuring that Respondents expeditiously comply with all of their obligations and performs all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements;
 - b. Monitoring any Transition Services Agreements; and
 - c. Assuring that Confidential Business Information is not received or used by Respondents or the Acquirer, except as allowing in this Order and in the Order to Maintain Assets;
2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 3. The Monitor shall serve for such time as is necessary to monitor Respondents' compliance with the provisions of this Order, the Order to Maintain Assets, and the Remedial Agreements;
 4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under this Order, the Order to Maintain Assets, and the Remedial Agreements. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order, the Order to Maintain Assets, and the Remedial Agreements;
 5. The Monitor shall serve, without bond or other security, at the expense of Respondents on such

Decision and Order

reasonable and customary terms and conditions as the Commission may set. The Monitor shall have the authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission;

6. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor. For purposes of this Paragraph III, the term "Monitor" shall include all persons retained by the Monitor pursuant to Paragraph III.D.5 of this Order.;
7. Respondents shall report to the Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by the Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under this Order, the Order to Maintain Assets, and the Remedial Agreements;
8. Within one (1) month from the date the Monitor is appointed pursuant to this Paragraph, every sixty (60) days thereafter, and otherwise requested by

Decision and Order

the Commission, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under this Order, the Order to Maintain Assets, and the Remedial Agreements;

9. Respondents may require the Monitor and each of the Monitors consultants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
 - F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor.
 - G. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of the proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed substitute Monitor, Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor. Not later than ten (10) days after appointment of a substitute Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the substitute Monitor all the rights and powers necessary to permit the substitute Monitor to monitor

Decision and Order

Respondent's compliance with the terms of this Order, the Order to Maintain Assets, and the Remedial Agreements in a manner consistent with the purposes of this Order.

- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order, the Order to Maintain Assets, and the Remedial Agreements.

IV.**IT IS FURTHER ORDERED** that:

- A. If Respondents have not divested, absolutely and in good faith and with the Commission's prior approval, the Aluminum Beverage Cans Business and otherwise fully complied with the obligations as required by Paragraph II of this Order, the Commission may appoint a Divestiture Trustee to divest the Aluminum Beverage Cans Business in a manner that satisfies the requirements of this Order. The Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order.
- B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal

Decision and Order

Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

- C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- D. Within ten (10) days after appointment of a Divestiture Trustee, Respondents shall execute an agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture or transfer required by the Order.
- E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the relevant assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and to enter into Transitional Services agreements;

Decision and Order

2. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or in the case of a court-appointed Divestiture Trustee, by the court; *provided, however,* that the Commission may extend the divestiture period only two (2) times;
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph IV in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court;
4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no

Decision and Order

minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided, further, however*, that Respondents shall select such entity within five (5) days of receiving notification of the Commission's approval;

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order;

Decision and Order

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee. For purposes of this Paragraph IV.E.6., the term "Divestiture Trustee" shall include all persons retained by the Divestiture Trustee pursuant to Paragraph IV.E.5. of this Order;
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order;
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every thirty (30) days concerning the Divestiture Trustee's efforts to accomplish the divestiture;
9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission; and
10. The Commission may require, among other things, the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in

Decision and Order

connection with the performance of the Divestiture Trustee's duties.

- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph IV.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

V.**IT IS FURTHER ORDERED** that:

- A. The Remedial Agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of an Acquirer or to reduce any obligations of the Respondents under such agreement.
- B. The Remedial Agreements shall be incorporated by reference into this Order and made a part hereof.
- C. Respondents shall comply with all provisions of the Remedial Agreements, and any breach by Respondents of any term of such agreement shall constitute a violation of this Order. If any term of the Remedial Agreements varies from the terms of this Order ("Order Term"), then to the extent that Respondents cannot fully comply with both terms, the Order Term shall determine Respondents' obligations under this Order. Any failure by the Respondents to comply with any term of such Divestiture Agreement shall constitute a failure to comply with this Order.

Decision and Order

- D. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VI.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition Date, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Respondents shall submit to the Commission and, if appointed, the Monitor, a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order:
1. Within thirty (30) days after the date this Order becomes final;
 2. Every thirty (30) days thereafter until Respondents have fully divested, licensed, transferred and/or granted the Aluminum Beverage Cans Business to an Acquirer; and
 3. Every three (3) months thereafter so long as Respondents have a continuing obligation under this Order and/or the Remedial Agreements to render services to the Acquirer or otherwise to comply with this Order.

Decision and Order

- C. At such other times as the Commission may request, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it has complied and is complying with this Order and any Remedial Agreement.

VII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondents;
- B. Any proposed acquisition, merger, or consolidation of Respondents; or
- C. Any other change in the Respondents, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents, with respect to any matter contained in this Order, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondents related to compliance with the Consent Agreement and/or this Order, which copying services shall be provided by Respondents at the request of the authorized representative of the Commission and at the expense of Respondents; and

Decision and Order

- B. Upon five (5) days' notice to Respondents and without restraint or interference from them, to interview officers, directors, or employees of Respondents, who may have counsel present.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on August 15, 2026.

By the Commission.

NON-PUBLIC APPENDIX A**DIVESTITURE AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

NON-PUBLIC APPENDIX B**TRANSITION SERVICES AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Decision and Order

NON-PUBLIC APPENDIX C

**ALUMINUM BEVERAGE CANS DIVESTITURE
EMPLOYEES**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

NON-PUBLIC APPENDIX D

**ARIZONA CONTRACT MANUFACTURING
AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Decision and Order

PUBLIC APPENDIX E**MONITOR AGREEMENT**

This Monitor Agreement (this "Agreement") entered into this ~~26~~²⁵ day of February, 2016 by and among ING Financial Markets LLC ("ING" or the "Monitor"), Ball Corporation ("Ball") and Rexam PLC ("Rexam" and together with Ball, the "Respondents"), (ING, Ball and/or Rexam collectively, the "Parties") provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission") has accepted or will shortly accept for public comment an Agreement Containing Consent Order, including a proposed Decision and Order and a proposed Order to Hold Separate and Maintain Assets ("Hold Separate Order" and collectively, the "Orders"), which, among other things, requires the divestiture of certain plants and other assets, as defined in the Orders, and contemplates the appointment of a Monitor to monitor Respondents' compliance with its obligations under the Orders;

WHEREAS, the Commission plans to appoint ING as Monitor pursuant to the Orders, and ING has consented to such appointment;

WHEREAS, the Orders will further provide that Respondents shall execute an agreement, subject to the prior approval of the Commission, that confers all the rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the terms of the Orders; and

WHEREAS, the Parties to this Agreement intend to be legally bound, subject only to the Commission's approval of this Agreement.

NOW, THEREFORE, the Parties agree as follows:

All capitalized terms used in this Agreement and not specifically defined herein shall have the respective definitions given to them in the Orders.

ARTICLE I

1.1 Monitor's Responsibilities. The Monitor shall be responsible for monitoring Respondents' compliance with its obligations as set forth in the Orders and the Divestiture Agreements, as defined in the Orders ("Monitor's Responsibilities").

1.2 Access to Relevant Information and Facilities. Subject to any legally recognized privilege, the Monitor shall have full and complete access to the personnel, facilities, books, and records of Respondents related to Respondents' obligations under the Orders and the Divestiture Agreements, as the Monitor may reasonably request. Respondents shall cooperate with any reasonable request of the Monitor. The Monitor shall give Respondents reasonable notice of any request for such access or such information and shall attempt to schedule any access or requests for information in such a manner as will not unreasonably interfere with Respondents' operations. At the request of the Monitor, Respondents shall promptly arrange meetings and discussions, including tours of relevant facilities, at reasonable times and locations

Decision and Order

between the Monitor and employees of Respondents who have knowledge relevant to the proper discharge of the Monitor's responsibilities under the Orders.

1.3 Compliance Reports. Respondents shall report to the Monitor in accordance with the requirements of the Orders.

1.4 Monitor's Obligations. The Monitor shall:

- a. carry out the Monitor's Responsibilities, including submission of periodic reports, and such additional written reports as may be requested by the Commission staff, to the Commission staff regarding Respondents' compliance with the Orders;
- b. maintain the confidentiality of all confidential information, including Confidential Business Information, and any other non-public confidential information provided to the Monitor by Respondents, the Acquirers of the Divested Businesses, any supplier or customer of Respondents, or the Commission, and shall use such confidential information only for the purpose of discharging the Monitor's obligations pursuant to this Agreement and not for any other purpose, including, without limitation, any other business, scientific, technological, or personal purpose. The Monitor may disclose confidential information only to:
 - i. persons employed by ING Groep N.V. or an affiliate of ING Groep N.V. or who are working with the Monitor under this Agreement;
 - ii. persons working with the Monitor under this Agreement (and only to the extent such persons have executed a confidentiality agreement consistent with the provisions of this Agreement); and
 - iii. persons employed at the Commission, the European Commission or the Brazilian Administrative Council of Economic Defense (*CADE*) working on this matter.
- c. request confidential treatment by the Commission, the European Commission, and CADE of any confidential information turned over to these entities;
- d. maintain a record and inform the Commission of all persons (other than the persons referenced in 1.4 (b)(i) and 1.4 (b)(iii) above) to whom confidential information related to this Monitor Agreement has been disclosed;
- e. require any consultants, accountants, attorneys, and any other representatives or assistants retained by the Monitor to assist in carrying out the Monitor's Responsibilities to execute a confidentiality agreement that requires such third parties to treat confidential information with the same standards of care and obligations of confidentiality to which the Monitor must adhere under this Agreement;

Decision and Order

- f. maintain the confidentiality, for a period of three (3) years after the termination of this Agreement, of all other aspects of the performance of the Monitor's Responsibilities and not disclose any confidential information, including Confidential Business Information, relating thereto;
- g. not be involved in any way in the management, production, supply and trading, sales, marketing, and financial operations of any products of Respondents that compete with the products sold by the plants and other assets, as defined in and to be divested pursuant to the Orders, except to the extent permitted by the Orders, and
- h. upon termination of the Monitor's duties under this Agreement, consult with the Commission's staff regarding disposition of any written and electronic materials (including materials that Respondents provided to the Monitor) in the possession or control of the Monitor that relate to the Monitor's duties, and the Monitor shall dispose of such materials, which may include sending such materials to the Commission's staff, as directed by the staff. In response to a request by Respondents to return or destroy materials that Respondents provided to the Monitor, the Monitor shall inform the Commission's staff of such request and, if the Commission's staff do not object, shall comply with the Respondents' request. Notwithstanding the foregoing, the Monitor shall not be required to return or destroy confidential information contained in an archived computer back-up system for its disaster recovery and/or security purposes, and it may retain a copy of confidential information, subject to the terms of this Agreement, in accordance with its internal record retention procedures for legal or regulatory purposes. Nothing herein shall abrogate the Monitor's duty of confidentiality, which includes an obligation not to disclose any non-public information obtained while acting as a Monitor for three (3) years after termination of this Agreement.

For the purpose of this Agreement, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt from a source other than the Monitor, the Respondents, or any director, officer, employee, agent, consultant or affiliate of the Monitor, Respondents, when such source was not known to recipient after due inquiry to be restricted from making such disclosure to such recipient.

In the event that confidential information must be disclosed by the Monitor or any person referenced in 1.4(b)(i) herein under applicable law or pursuant to legal process, such party shall, to the extent not otherwise prohibited, give written notice to the Respondents that such disclosure is required so that the Respondents may, at Respondents' sole expense, seek an appropriate protective order or waive compliance with the terms hereof or both. If, absent

Decision and Order

the entry of a protective order or the receipt of a waiver of this Monitor Agreement, the Monitor or any person referenced in 1.4(b)(i) herein is compelled by law or legal process to disclose any confidential information, such party (x) may disclose such information solely to the extent required by law; (y) shall not disclose such information until such time as it is required by law; and (z) shall exercise commercially reasonable efforts to obtain reliable assurances that confidential treatment will be accorded to any confidential information so disclosed. Notwithstanding the foregoing, the Monitor or any person referenced in 1.4(b)(i) herein may disclose confidential information to any regulatory or self-regulatory agency having jurisdiction over such party in the course of routine reviews or audits when such disclosure is required by law, which confidential information may be disclosed with notice to Respondents.

1.5 Monitor Payment. Ball will pay the Monitor the hourly fee specified in the attached confidential fee schedule (“Hourly Fee”) for all reasonable time spent in performance of the Monitor’s duties under this Agreement. In addition, Ball will pay: (a) out-of-pocket expenses reasonably incurred by the Monitor in the performance of the Monitor’s duties; and (b) fees and disbursements reasonably incurred by such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor’s duties and responsibilities hereunder; however, all such fees and disbursements shall be pre-approved by Ball, which shall not withhold approval unreasonably. The Monitor shall provide Ball with an invoice on a monthly basis that includes details and an explanation of all matters for which Monitor submits an invoice and Ball shall pay such invoices according to Ball’s standard payment terms of 15/31 second month prox terms. Any consultants, accountants, attorneys, and other representatives and assistants retained by the Monitor shall invoice their services to the Monitor who will review and approve such invoices and submit to Ball for payment. At its own expense, Ball may retain an independent auditor to verify such invoices. The Monitor and Ball shall submit any disputes about invoices to the Commission for assistance in resolving such disputes.

1.6 Monitor’s Indemnification. Ball agrees to indemnify the Monitor, ING Groep N.V. and all affiliates of ING Groep N.V. and their directors and employees (the “Indemnified Parties”) and Ball shall hold the Indemnified Parties harmless (regardless of any action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor’s duties and obligations hereunder, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from gross negligence, willful misconduct, or bad faith by the Indemnified Parties. The Monitor’s maximum liability to Respondents relating to services rendered pursuant to this Monitor Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the total sum of the fees paid to the Monitor by Ball, except to the extent resulting from the gross negligence, willful misconduct or bad faith by the Indemnified Parties, in which case the liability is not so limited.

Decision and Order

1.7 Disputes. In the event of a disagreement or dispute between Respondents and the Monitor concerning Respondents' obligations under one or both of the Orders, and, in the event that such disagreement or dispute cannot be resolved by the Parties, any Party may seek the assistance of the individual in charge of the Commission's Compliance Division.

1.9 Conflicts of Interest. If the Monitor becomes aware during the term of this Agreement that it has or may have a conflict of interest that may affect or could have the appearance of affecting performance by the Monitor of any of the Monitor's Responsibilities, the Monitor shall immediately inform Ball and the Commission of any such conflict.

ARTICLE II

2.1 Termination. This Agreement shall terminate upon the earlier of: (a) the expiration or termination of the Orders; (b) the expiration or termination of the last to expire of the Divestiture Agreements; (c) Respondents' receipt of written notice from the Commission that the Commission has determined that ING has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve as Monitor; and (d) with at least thirty (30) days advance notice to be provided by the Monitor to Respondents and to the Commission, upon resignation of the Monitor. If this Agreement is terminated for any reason, the confidentiality obligations set forth in Section 1.3 above will remain in force.

2.2 Governing Law. This Agreement and the rights and obligations of the Parties hereunder shall in all respects be governed by the substantive laws of the state of New York, including all matters of construction, validity and performance. The Orders shall govern this Agreement and any provisions herein which conflict or are inconsistent with them may be declared null and void by the Commission and any provision not in conflict shall survive and remain a part of this Agreement.

2.3 Disclosure of Information. Nothing in this Agreement shall require Respondents to disclose any material information that is subject to a legally recognized privilege or that Respondents are prohibited from disclosing by reason of law or an agreement with a third party.

2.4 Assignment. This Agreement may not be assigned or otherwise transferred by Respondents or the Monitor without the consent of Respondents and the Monitor and the approval of the Commission. Any such assignment or transfer shall be consistent with the terms of the Orders.

2.5 Modification. No amendment, modification, termination, or waiver of any provision of this Agreement shall be effective unless made in writing, signed by all Parties, and approved by the Commission. Any such amendment, modification, termination, or waiver shall be consistent with the terms of the Orders.

2.6 Entire Agreement. This Agreement, and those portions of the Orders incorporated herein by reference, constitute the entire agreement of the Parties and supersede any and all prior agreements and understandings between the Monitor and Respondents, written or oral, with respect to the subject matter hereof.

Decision and Order

2.7 Duplicate Originals. This Agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document.

2.8 Section Headings. Any heading of a section is for convenience only and is to be assigned no significance whatsoever as to its interpretation and intent.

ARTICLE III

3.1 In the performance of his functions and duties under this Agreement, the Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of its own business affairs.

3.2 It is understood that the Monitor will be serving under this Agreement as an independent contractor and that the relationship of employer and employee shall not exist between the Monitor and Respondents. The Monitor shall not have a fiduciary responsibility to the Respondents, but shall have fiduciary duties to the Commission.

3.3 This Agreement is for the sole benefit of the Parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give, or be construed to give, any other person any legal or equitable rights hereunder.

3.4 In the event that ING wishes to terminate this Agreement, ING shall provide written notice to the Respondents and the Commission. Respondents and ING shall work in good faith with the Commission to identify and propose to the Commission a successor Monitor. ING shall continue to serve as Monitor under the terms of this Agreement until such time as the Commission approves a successor Monitor, and ING's termination of this Agreement shall be effective only upon the approval by the Commission of a successor Monitor.

ARTICLE IV

4.1 If the Orders include a Hold Separate Order, the Monitor should have all of the powers and responsibilities and protections conferred upon the Monitor by the Hold Separate Order, including but not limited to:

- a. monitoring the organization and operations of the Hold Separate Business, as defined in the Hold Separate Order;
- b. monitoring the management of the Hold Separate Business through the Manager, as defined in the Hold Separate Order;
- c. monitoring the independence of the Hold Separate Business;
- d. monitoring Respondents' compliance with its obligations as required by the Hold Separate Order; and
- e. reviewing Replacement Contracts and Allocated Shared Contracts, both as defined in the Hold Separate Order, and determining, in consultation with

Decision and Order

Commission staff, whether these contracts comply with the Hold Separate Order.

4.2 As of the date of this Agreement, Respondents shall transfer to and confer upon the Monitor all rights, powers and authority necessary to permit the Monitor to perform its duties and responsibilities pursuant to and consistent with the purposes of the Hold Separate Order.

4.3 Subject to applicable laws and regulations, the Monitor shall have full and complete access to the personnel, books, records, documents, and facilities of the Hold Separate Business, and to any other relevant information as the Monitor may reasonably request, including but not limited to all documents kept by the Respondents in the ordinary course of business that relate to the Hold Separate Business. Respondents shall develop such financial and other information as the Monitor may reasonably request and shall cooperate with the Monitor. The Monitor shall give Respondents reasonable notice of any request for such access or information. The Monitor shall attempt to schedule any access or requests for information in such a manner as will not unreasonably interfere with Respondents' operations.

[The rest of the page has been intentionally left blank.]

Decision and Order

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first above written.

MONITOR

ING Financial Markets LLC



Phillip Comerford, Jr.
Managing Director

RESPONDENT

Ball Corporation

By:
Title:

RESPONDENT

REXAM

Rexam PLC

By:
Title:

Decision and Order

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first above written.

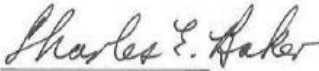
MONITOR

ING Financial Markets LLC

Phillip Comerford, Jr.
Managing Director

RESPONDENT

Ball Corporation


By: CHARLES E. BAKER
Title: VICE PRESIDENT

RESPONDENT

REXAM

Rexam PLC

By:
Title:

Decision and Order

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first above written.

MONITOR

ING Financial Markets LLC

RESPONDENT

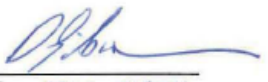
Ball Corporation

Phillip Comerford, Jr.
Managing Director

By:
Title:

RESPONDENT**REXAM**

Rexam PLC



By: DAVID GIBSON
Title: COMPANY SECRETARY

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**I. INTRODUCTION AND BACKGROUND**

Pursuant to an agreement dated February 19, 2015 (the “Acquisition”), Ball Corporation (“Ball”) seeks to acquire Rexam PLC (“Rexam”) in a transaction valued at approximately £5.4 billion, or \$8.4 billion, at the time the Acquisition was announced. In order to preserve competition that would be lessened as a result of the proposed Acquisition, the Federal Trade Commission (“Commission”) has accepted for public comment, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Ball and Rexam. The Commission has also issued a Complaint and Decision & Order, and has assigned a Monitor Trustee to oversee compliance with the Consent Agreement.

The Commission’s Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the markets for standard 12-ounce aluminum beverage cans (“Standard Cans”) and specialty aluminum beverage cans (“Specialty Cans”) in the United States. The Consent Agreement would remedy the alleged violations by restoring the competition that would be lost as a result of the proposed Acquisition.

Under the terms of the proposed Consent Agreement, Ball and Rexam are required to divest seven aluminum can body plants, one aluminum can end plant, and other innovation and support functions in order to preserve competition in the relevant markets in the United States. These manufacturing plants account for the majority of Rexam’s sales in the United States. Ball and Rexam have agreed to divest these and additional assets around the world to Ardagh Group S.A. (“Ardagh”) in a transaction entered into on April 22, 2016 and valued at \$3.42 billion, including assumption of liabilities.

Analysis to Aid Public Comment

The proposed Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed Consent Agreement and any comments received, and decide whether the Consent Agreement should be withdrawn, modified, or made final.

II. THE PARTIES

Ball, an Indiana corporation headquartered in Broomfield, CO, is the largest manufacturer of aluminum beverage cans in the both the United States and the world. In 2015, Ball had total sales of \$8.0 billion, 74% of which were derived from its worldwide metal beverage container business. Approximately 16% of Ball's revenues come from its worldwide sales of metal food and household containers, and approximately 10% from its U.S. aerospace business. In 2015, Ball had approximately \$2.7 billion in sales of aluminum beverage cans in the United States.

Rexam is the second-largest manufacturer of aluminum beverage cans in North America and the world. Rexam is a United Kingdom company headquartered in London. Rexam manufactures only aluminum beverage containers today, after selling its plastic packaging business in 2011 and its glass manufacturing business in 2005. In 2015, Rexam had total aluminum beverage container sales of about \$5.7 billion, with approximately \$1.75 billion coming from the United States.

Ardagh, headquartered in Luxembourg, is one of the world's largest producers of glass bottles for the beverage industry and metal cans for the food industry. Ardagh does not currently produce aluminum cans for the beverage industry, but it serves many of the same customers as Ball and Rexam through its glass bottle business. In 2015, Ardagh had sales of approximately \$5.9 billion, with approximately \$3.6 billion coming from glass packaging and \$2.3 billion from metal food packaging.

Analysis to Aid Public Comment

III. STANDARD CANS

The first relevant line of commerce in which to analyze the Acquisition is standard 12-ounce aluminum beverage cans (“Standard Cans”). Approximately 3 out of every 4 beverage cans sold in the United States today are Standard Cans, which are found, for instance, in a 12-pack of carbonated soft drinks or beer. Beverage producers purchase Standard Cans because of their superior shelf life, filling efficiency, recyclability, compact storage, and relatively low cost.

Other packaging substrates, such as plastic bottles and glass bottles, do not serve as competitive constraints to Standard Cans. Beverage producers sell their products in different types of containers in order to meet consumer demand, and could not substitute other container types for Standard Cans without risking a loss in sales. Beverage producers have also invested substantial sums of money in specialized filling lines that are designed to fill either aluminum cans, plastic bottles, or glass bottles, and cannot switch from one container type to another. As a result, beverage producers negotiate for Standard Cans independently from plastic bottles and glass bottles, and do not shift volumes between Standard Cans and other packaging substrates in response to fluctuations in their relative prices.

The relevant geographic markets in which to analyze competition for Standard Cans are regional. Beverage producers incur significant freight costs from shipping empty cans to their filling plants. For this reason, manufacturers of Standard Cans have built a network of plants throughout the United States to meet regional customer demand and minimize shipping costs. Although aluminum can manufacturers often ship Standard Cans several hundred miles and win bids when they are not the closest supplier, it is not common or cost-effective for Standard Cans to ship cross-country. As a result, the Complaint identifies three regional markets in the United States in which substantial competition exists between Ball and Rexam for the sale of Standard Cans: (1) the South/Southeast; (2) the Midwest; and (3) the West Coast, consisting primarily of California.

Analysis to Aid Public Comment

The Commission often calculates the Herfindahl-Hirschman Index (“HHI”) to assess market concentration. Under the Federal Trade Commission and Department of Justice Horizontal Merger Guidelines, markets with an HHI above 2,500 are generally classified as “highly concentrated,” and acquisitions “resulting in highly concentrated markets that involve an increase in the HHI of more than 200 points will be presumed to be likely to enhance market power.”¹ Absent the proposed remedy, the Acquisition would increase HHIs for Standard Cans by 1,712 points to 4,874 in the South/Southeast; by 2,201 points to 5,050 in the Midwest; and by 1,673 points to 4,680 on the West Coast. As a result, there is a presumption that the proposed merger of Ball and Rexam would substantially lessen competition in each of the regional markets for Standard Cans.

IV. SPECIALTY CANS

The second relevant line of commerce in which to analyze the Acquisition is an assortment of specialty aluminum beverage cans (“Specialty Cans”), which come in a variety of dimensions that differ from Standard Cans. Specialty Cans include 7.5-ounce and 8-ounce slim cans, which are narrower and shorter than Standard Cans; 12-ounce sleek cans, which are narrower and taller than standard 12-ounce cans; 16-ounce cans, which have the same diameter as Standard Cans but are taller; 24-ounce cans, which are wider and taller than Standard Cans; and other aluminum cans in non-standard shapes and sizes. Specialty Can sales have been growing as beverage producers seek to package their products in new shapes and sizes to reach different consumers and consumption occasions.

Beverage producers package in different types of Specialty Cans for different reasons. For example, carbonated soft drink producers package some of their products in 7.5-ounce slim cans specifically to reach consumers who want a smaller portion in an attractive, sub-100 calorie package. Popular with producers of flavored malt beverages are 8-ounce slim cans. Energy drink producers package in 16-ounce and other “sleek” cans in order to differentiate their products and convey a premium image in ways

¹ [2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines § 5.3.](#)

Analysis to Aid Public Comment

that cannot be achieved by using Standard Cans. Some tea and energy drink producers further differentiate their products and convey value by packaging in large 24-ounce cans.

Although one type of Specialty Can is not typically a substitute for another, it is appropriate to group or cluster the different Specialty Cans together for the purposes of market definition analysis because each of the products in the assortment is offered under similar competitive conditions. As such, grouping the many different types of Specialty Cans into a single cluster enables a more efficient evaluation of competitive effects.

Beverage producers would not substitute Standard Cans, glass bottles, plastic bottles, or other container types for Specialty Cans in sufficient quantities to defeat a hypothetical, small but significant and non-transitory increase in the price of Specialty Cans. Beverage producers package in specific shapes and sizes of Specialty Cans to maximize sales and attract certain customers who would not purchase their products in a different package type. Moreover, beverage producers have made substantial investments in infrastructure that are used to fill Specialty Cans and that cannot be used to fill PET bottles or glass bottles.

The relevant geographic market in which to analyze Specialty Cans is the United States. A national market is appropriate because each Specialty Can type is produced at only a small number of locations nationwide, and Specialty Cans are shipped over much longer distances than Standard Cans, often over 1,000 miles. Specialty Cans of particular shapes and sizes are produced at only a few locations in the United States because their volumes are only a small fraction of the volume of Standard Cans, and it is not cost-effective to spread such small volumes across a large number of plants.

Ball and Rexam are the two largest suppliers of Specialty Cans in the United States with shares of approximately 56% and 21%, respectively, across all Specialty Can sizes. Absent the proposed remedy, the Acquisition would increase HHIs for Specialty Cans by 2,284 points to 6,267 in the United States. As a result, there is a presumption that the proposed merger of Ball and

Analysis to Aid Public Comment

Rexam would substantially lessen competition in the national market for Specialty Cans.

V. EFFECTS OF THE ACQUISITION

Absent relief, the Acquisition would likely cause significant competitive harm in the markets for the manufacture and sale of Standard Cans and Specialty Cans to beverage producers. The Acquisition would eliminate substantial direct competition between Ball and Rexam for the sale of Standard Cans and Specialty Cans. In individual contract negotiations with Ball and Rexam, beverage producers have been able to secure better prices and other terms by switching, or threatening to switch, their business from one supplier to the other. In some of these negotiations, no other suppliers besides Ball and Rexam have submitted a bid, and beverage producers have therefore depended on the competition between Ball and Rexam to obtain a contract with favorable terms. The Acquisition would also increase the ease and likelihood of anticompetitive coordination between the only two remaining independent beverage can suppliers, Ball and Crown Holdings, Inc. Thus, the Acquisition would likely result in higher prices and a reduction in quality, selection, service, and innovation.

VI. ENTRY

Entry in the manufacture of Standard Cans and Specialty Cans would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the likely competitive harm from the Acquisition. Considerable entry barriers exist in the manufacture of Standard Cans and Specialty Cans, including, but not limited to, substantial capital costs needed to construct a new aluminum can plant and significant volume requirements necessary to run a plant efficiently. For Standard Cans, a consistent decline in demand has created a further disincentive to entry, which has led to a steady removal of capacity for over 20 years. With respect to Specialty Cans, a new entrant would be at a significant disadvantage if it were to construct new Specialty Can lines compared to incumbent suppliers (led by Ball and Rexam) that can convert Standard Can lines to Specialty Can production at lower cost.

Analysis to Aid Public Comment

The threat of vertical integration by beverage producers is also unlikely to deter or counteract the competitive harm from the Acquisition. A single beverage can plant requires an annual production volume in the billions of cans to run profitably, which would preclude all but the very largest beverage producers from contemplating vertical integration. Moreover, it is difficult for even the largest beverage producers to make a credible threat of vertical integration because their filling plants are spread throughout the United States in a way that they could never fully supply internally. As a result, even a large, vertically integrated beverage producer would have to continue buying at least some beverage cans from existing suppliers, but at a higher price since it would receive a smaller volume discount, which would further disincentivize vertical integration. Coupled with the significant capital costs and technical requirements needed to build a new beverage can plant, vertical integration would not be a credible threat for the vast majority of beverage producers.

VII. THE PROPOSED CONSENT AGREEMENT

The proposed Consent Agreement remedies the competitive concerns raised by the Acquisition by requiring Ball to divest seven beverage can plants and one can end plant in the United States to Ardagh. Divestitures of Rexam's Bishopville, SC and Olive Branch, MS can plants preserve competition for Standard Cans in the South/Southeastern United States. Divestitures of Rexam's Fremont, OH and Chicago, IL can plants preserve competition for Standard Cans in the Midwest. Divestiture of Rexam's Fairfield, CA can plant preserves competition for Standard Cans on the West Coast. Divestitures of Rexam's Winston-Salem, NC, Whitehouse, OH, and Chicago, IL can plants preserve competition in Specialty Cans in the United States. Finally, divestiture of Rexam's Valparaiso, IN can end plant ensures that Ardagh will be able to manufacture lids for all of its Standard Cans and Specialty Cans produced in the United States.

As part of the Consent Agreement, Ball is also divesting Rexam's U.S. headquarters in Chicago, IL and Rexam's U.S. Technical Center in Elk Grove, IL to Ardagh. In addition, Ball has agreed to sell to Ardagh ten beverage can plants and two can end plants in Europe; two beverage can plants in Brazil; and other

Analysis to Aid Public Comment

innovation and support functions in Germany, the United Kingdom, and Switzerland to resolve competitive concerns in Europe. Divestiture of the Ball and Rexam assets to a single, global buyer is important to preserve competition for many multinational customers.

The Consent Agreement requires Ball to transfer all customer contracts currently serviced at the beverage can plants that are being divested to Ardagh. Additionally, in order to fully service the customer contract with Arizona Beverage Co. (“Arizona”) and to ensure the viability of certain divestiture assets, the Consent Agreement requires Ball to purchase a supply of beverage cans sufficient to service Arizona’s requirements for the remaining duration of that agreement or until Ardagh enters into a separate customer agreement with Arizona.

The Consent Agreement also requires Ball to provide support services for up to 18 months, including support for potential line conversions from Standard Cans to Specialty Cans, at Ardagh’s request. In addition, Ball must provide Ardagh with a royalty-free, perpetual license to use patents and technologies necessary to operate the divested can business. Ball and Rexam must also help facilitate the employment of certain key employees by Ardagh.

The Consent Agreement incorporates a proposed Order to Maintain Assets to ensure the continued health and competitiveness of the divested assets. The Consent Agreement also provides that the Commission may appoint a Monitor Trustee to monitor Ball and Rexam’s compliance with their obligations pursuant to the Consent Agreement, and oversee the integration of the Rexam and Ball assets into Ardagh. The Commission has selected ING to serve as Monitor Trustee in this matter until integration of the divested assets is completed. The European Commission has also selected ING to oversee the divestiture, which makes the Monitor Trustee uniquely capable of monitoring the global transition of all assets acquired by Ardagh. The Consent Agreement also provides for appointment of a Divestiture Trustee to effectuate the divestitures if Ball fails to carry out the sale of assets and its related obligations.

Analysis to Aid Public Comment

Through the proposed divestitures, Ardagh will become the third-largest beverage can manufacturer in the United States and the world. Ardagh will own beverage can plants that span a broad geographic footprint, offer a well-balanced product mix, and have flexible manufacturing capabilities. Ardagh is an ideal buyer of the divested assets because it has existing long-standing relationships with key beverage customers through its glass bottle business, and existing experience with metal container manufacturing through its food can business. Furthermore, the fact that Ardagh does not currently produce aluminum beverage cans means that the divestiture will not create competitive issues of its own. Accordingly, Ardagh's acquisition of the divested assets will preserve the competition that would have otherwise been lost through Ball's acquisition of Rexam.

* * *

The sole purpose of this Analysis is to facilitate public comment on the proposed Consent Order. This Analysis does not constitute an official interpretation of the proposed Consent Order, nor does it modify its terms in any way.

Complaint

IN THE MATTER OF

HEIDELBERGCEMENT AG
AND
ITALCEMENTI S.P.A.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4579; File No. 151 0200*
Complaint, June 17, 2016 – Decision, August 15, 2016

This consent order addresses the \$4.2 billion acquisition by HeidelbergCement AG of certain assets of Italcementi S.p.A. The complaint alleges that the proposed transaction, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in certain regional markets in the United States for the manufacture and sale of portland cement. The consent order requires the divestiture of one party's cement operations in each of the relevant markets.

Participants

For the *Commission*: Peter Colwell, Joseph R. Neely, and James E. Southworth.

For the *Respondents*: David Wales, Jones Day LLP; Mark W. Nelson, Cleary Gottlieb Steen & Hamilton LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent HeidelbergCement AG ("Heidelberg"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondent Italcementi S.p.A. ("Italcementi"), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the

Complaint

Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Heidelberg is a corporation incorporated and organized under the laws of Germany, having its registered seat in Heidelberg, registered with the commercial register of the local court of Mannheim under no. HRB 330082, with its registered business address at Berliner Straße 6, 69120 Heidelberg, Germany. Heidelberg's principal U.S. subsidiary, Lehigh Hanson, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its U.S. headquarters and principal place of business located at 300 East John Carpenter Freeway, Irving, TX 75062.

2. Respondent Italcementi is incorporated and organized under the laws of Italy, having its seat in Bergamo, registered with Bergamo Chamber of Commerce under no. 00637110164, with its registered business address at Via Camozzi 124, 24121 Bergamo, Italy. Italcementi's principal U.S. subsidiary, Essroc Cement Corp., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its offices and principal place of business located at 3251 Bath Pike, Nazareth, PA 18064.

3. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

4. Pursuant to a Share Purchase Agreement dated July 28, 2015, Heidelberg proposes to acquire 100% of Italcementi's voting shares in a two-part transaction (the "Acquisition"). First, Heidelberg agreed to acquire approximately 45% of Italcementi voting securities held by Italmobiliare S.p.A. (the "Share

Complaint

Purchase”). The total consideration for the Share Purchase is approximately \$1.9 billion, to be paid in a combination of cash and newly issued Heidelberg voting shares. Second, after the Share Purchase, Heidelberg agreed to initiate a mandatory public cash tender offer for the remaining shares of Italcementi, with an expected purchase price of approximately \$2.3 billion. The total value of the Italcementi shares that Heidelberg will acquire is approximately \$4.2 billion. The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

5. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the manufacture, import, and sale of portland cement, including, but not limited to, blended cement, masonry cement, mortar, and clinker.

6. Portland cement is the essential binding ingredient in concrete. A fine, usually gray powder, portland cement is a chemical combination of calcium, silicon, aluminum, iron, and small amounts of other ingredients. Users mix portland cement with water and aggregates (crushed stone, sand, or gravel) to form concrete, a fundamental building material that is widely used in residential, non-residential, and public infrastructure construction projects.

7. For the purposes of this Complaint, the relevant geographic areas in which to analyze the effects of the Acquisition on the portland cement market are:

- a. Baltimore, MD-Washington, D.C and surrounding areas;
- b. Richmond, VA and surrounding areas;
- c. Virginia Beach-Norfolk-Newport News, VA and surrounding areas;
- d. Syracuse, NY and surrounding areas; and

Complaint

- e. Indianapolis, IN and surrounding areas.

IV. THE STRUCTURE OF THE MARKETS

8. Respondents Heidelberg and Italcementi are significant participants in each of the relevant markets, and each relevant market is already highly concentrated. The Acquisition would further increase concentration levels, resulting in the merged company having enhanced market power as a supplier of portland cement in each relevant market. The Acquisition would remove competition between Respondents, and reduce the number of competitively significant suppliers from three to two in each of the relevant markets.

V. ENTRY CONDITIONS

9. New entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Building a new plant or distribution terminal of sufficient scale requires significant sunk costs and is challenging because of the extensive permitting that is required. Because of the various obstacles that must be overcome, it would take more than two years for a firm to accomplish the steps required to enter and achieve a significant impact in the relevant markets.

VI. EFFECTS OF THE ACQUISITION

10. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by eliminating actual, direct, and substantial competition between Respondents Heidelberg and Italcementi and reducing the number of significant competitors in each relevant market; thereby increasing the likelihood that:

- a. the merged company would unilaterally exercise market power in the relevant markets;

Order to Maintain Assets

- b. the remaining firms in the relevant markets would engage in collusion or coordinated interaction between or among each other; and
- c. consumers would be forced to pay higher prices or accept reduced service.

VII. VIOLATIONS CHARGED

11. The Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

12. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission, on this seventeenth day of June, 2016, issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent HeidelbergCement AG (“Heidelberg”) of Respondent Italcementi S.p.A. (“Italcementi”) (collectively, “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C.

Order to Maintain Assets

§ 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place the Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent Heidelberg is a corporation organized, existing, and doing business under and by virtue the laws of Germany, having its registered seat in Heidelberg, registered with the commercial register of the local court of Mannheim under no. HRB 330082, with its registered business address at Berliner Straße 6, 69120 Heidelberg, Germany. Heidelberg’s principal U.S. subsidiary, Lehigh Hanson, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its U.S. headquarters and principal place of business located at 300 East John Carpenter Freeway, Irving, TX 75062.
2. Respondent Italcementi is a corporation organized, existing, and doing business under and by virtue of the

Order to Maintain Assets

laws of Italy, having its seat in Bergamo, registered with Bergamo Chamber of Commerce under no. 00637110164, with its registered business address at Via Camozzi 124, 24121 Bergamo, Italy. Italcementi's principal U.S. subsidiary, Essroc Cement Corp., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its U.S. headquarters and principal place of business located at 3251 Bath Pike, Nazareth, PA 18064.

3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Respondents, and this proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the definitions used in the Consent Agreement and the Decision and Order shall apply. In addition, the Assets To Be Maintained are defined as the Martinsburg Cement Business, the Optional Terminals, and the Indianapolis Terminal.

II.

- A. Respondents shall maintain the viability, marketability, and competitiveness of the Assets To Be Maintained, and shall not cause the wasting or deterioration of any of them. Respondents shall not cause the Assets To Be Maintained to be operated in a manner inconsistent with applicable laws, nor shall they sell, transfer, encumber, or otherwise impair the viability, marketability, or competitiveness of the Assets To Be Maintained. Respondents shall conduct or cause to be conducted the business of the Assets To Be Maintained in the regular and ordinary course and in accordance with past practice (including regular repair and maintenance efforts) and shall use best efforts to preserve the existing relationships with

Order to Maintain Assets

suppliers, customers, employees, and others having business relations with the Assets To Be Maintained in the ordinary course of business and in accordance with past practice.

- B. Respondents shall operate the Assets To Be Maintained in the ordinary course of business consistent with past practices and Respondents' business, strategic, and capital plans. Respondents shall use best efforts to keep the organization and properties of the Assets To Be Maintained including current business operations, physical facilities, working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with the Assets To Be Maintained, and shall not transfer any employees from any of the Assets To Be Maintained to any of Respondents' assets or businesses that Respondents will not divest. Included in the above obligations, Respondents shall, without limitation:
1. Maintain all operations and products at each of the terminals within the Assets To Be Maintained;
 2. Not transfer inventory from the Assets To Be Maintained, other than in the ordinary course of business consistent with past practices;
 3. Not terminate or modify any lease of any trucks, railcars, barges, or other vessels used to transport or store Cement within or relating to the Assets To Be Maintained, other than in the ordinary course of business consistent with past practices;
 4. Not terminate or modify in any material respect any contract, agreement, policy, or practice relating to the production, transportation, supply, or sale of Cement produced at Respondents' plants or provided from Respondents' terminals that will not be divested pursuant to the Order to or for the Assets To Be Maintained, other than in the

Order to Maintain Assets

ordinary course of business consistent with past practices;

5. Not terminate or modify in any material way any contract, agreement, policy, or practice relating to the production, transportation, supply, or sale of Cement at the Assets To Be Maintained or provided from terminals within the Assets To Be Maintained to or for any of Respondents' plants or terminals that will not be divested pursuant to this Order, other than in the ordinary course of business consistent with past practices;
6. Maintain the books and records of the Assets To Be Maintained consistent with past practices; and,
7. Not change or modify in any material respect the existing pricing, discounts, credit terms, delivery terms and charges, or other terms and conditions applicable to the suppliers and customers of the Assets To Be Maintained, other than changes in the ordinary course of business consistent with past practices.

III.

IT IS HEREBY ORDERED that:

- A. William Hill shall serve as the Monitor pursuant to the agreement executed by the Monitor and Respondents, and attached as Appendix I ("Monitor Agreement") to the Decision and Order. The Monitor is appointed to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s);
- B. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

Order to Maintain Assets

1. The Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and related requirements of this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s), and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the orders and in consultation with the Commission;
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission; and,
 3. The Monitor shall serve until the completion of all divestitures required by the Decision and Order.
- C. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s).
- D. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s).
- E. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have the authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably

Order to Maintain Assets

necessary to carry out the Monitor's duties and responsibilities.

- F. No later than (1) day after the date the Acquisition is consummated, Respondents shall, pursuant to the Monitor Agreement, confer on the Monitor all rights, powers, and authorities necessary to permit the Monitor to monitor Respondents' compliance with the terms of this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s), in a manner consistent with the purposes of the orders.
- G. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor. For purposes of this Paragraph III.G., the term "Monitor" shall include all persons retained by the Monitor pursuant to Paragraph III.F. of this Order to Maintain Assets.
- H. Respondents shall report to the Monitor in accordance with the requirements of this Order to Maintain Assets or the Decision and Order, and as otherwise provided in the Monitor Agreement approved by the Commission. The Monitor shall evaluate the reports submitted by the Respondents with respect to the performance of Respondents' obligations under this Order to Maintain Assets and the Decision and Order. Within thirty (30) days from the date the Monitor receives the first such report, and every sixty (60) days thereafter, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the orders.

Order to Maintain Assets

- I. Respondents may require the Monitor and each of the Monitor's consultants, accountants, and other representatives and assistants to sign a customary confidentiality agreement. Provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commission.

- J. The Commission may require, among other things, the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:
 - 1. The Commission shall select the substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after the notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.

 - 2. Not later than ten (10) days after the appointment of the substitute Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the relevant terms of this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s) in a manner consistent with the purposes of the orders and in consultation with the Commission.

Order to Maintain Assets

IV.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondents;
- B. Any proposed acquisition, merger, or consolidation of Respondents; or
- C. Any other change in the Respondents, including but not limited to assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order to Maintain Assets.

V.

IT IS FURTHER ORDERED that within thirty (30) days after this Order to Maintain Assets is issued, and every thirty (30) days thereafter until this Order to Maintain Assets terminates, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with all provisions of this Order to Maintain Assets. Respondents shall submit at the same time a copy of their reports concerning compliance with this Order to Maintain Assets to the Monitor. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order to Maintain Assets.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

Order to Maintain Assets

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities, and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Respondents relating to compliance with this Order to Maintain Assets, which copying services shall be provided by Respondents at the request of the authorized representative(s) of the Commission and at the expense of Respondents; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate at the earlier of:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or,
- B. With respect to each of the Assets To Be Divested, the day after Respondents' (or a Divestiture Trustee's) completion of the divestiture of Assets To Be Divested, as described in and required by the Decision and Order.

Provided, however, that if the Commission, pursuant to Paragraph II.B. of the Decision and Order, requires the Respondents to rescind any or all of the divestitures contemplated by any Divestiture Agreement, then, upon rescission, the requirements of this Order to Maintain Assets shall again be in effect with respect to the relevant Assets To Be Divested until the day after Respondents' (or a Divestiture Trustee's) completion of the

Decision and Order

divestiture(s) of the relevant Assets To Be Divested, as described in and required by the Decision and Order.

By the Commission.

DECISION AND ORDER
[Redacted Public Record Version]

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent HeidelbergCement_AG (“Heidelberg”) of Respondent Italcementi S.p.A. (“Italcementi”) (collectively, “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and Order to Maintain Assets (“Asset Maintenance

Decision and Order

Order”), and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from an interested person, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Heidelberg is a corporation organized, existing, and doing business under and by virtue the laws of Germany, having its registered seat in Heidelberg, registered with the commercial register of the local court of Mannheim under no. HRB 330082, with its registered business address at Berliner Straße 6, 69120 Heidelberg, Germany. Heidelberg’s principal U.S. subsidiary, Lehigh Hanson, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its U.S. headquarters and principal place of business located at 300 East John Carpenter Freeway, Irving, TX 75062.
2. Respondent Italcementi is a corporation organized, existing, and doing business under and by virtue of the laws of Italy, having its seat in Bergamo, registered with Bergamo Chamber of Commerce under no. 00637110164, with its registered business address at Via Camozzi 124, 24121 Bergamo, Italy. Italcementi’s principal U.S. subsidiary, Essroc Cement Corp., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its U.S. headquarters and principal place of business located at 3251 Bath Pike, Nazareth, PA 18064.
3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Respondents, and this proceeding is in the public interest.

Decision and Order

ORDER**I.**

IT IS HEREBY ORDERED that, as used in this Order, the following definitions shall apply:

DEFINITIONS OF PERSONS

- A. “Acquirer” means, as the context requires, either or both of the Martinsburg Acquirer and the Indianapolis Acquirer.
- B. “Cemex” means Kosmos Cement Company, a general partnership, organized, existing, and doing business under and by virtue of the laws of the State of Kentucky, with its offices and principal place of business located at 1501 Belvedere Road, West Palm Beach, FL 33406.
- C. “Commission” means the Federal Trade Commission.
- D. “Governmental Entity” means any federal, provincial, state, county, local, or other political subdivision of the United States or any other country, or any department or agency thereof, or any state or federal court.
- E. “Heidelberg” means HeidelbergCement AG, its directors, officers, employees, agents, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by HeidelbergCement AG (including, but not limited to, Lehigh Hanson, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- F. “Indianapolis Acquirer” means either Cemex or another Person approved by the Commission to purchase the Indianapolis Terminal Assets.

Decision and Order

- G. “Italcementi” means Italcementi S.p.A., its directors, officers, employees, agents, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Italcementi S.p.A., (including, but not limited to, Essroc Cement Corp), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- H. “Martinsburg Acquirer” means a Person approved by the Commission to acquire the Martinsburg Cement Business Assets.
- I. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Governmental Entity, and any subsidiaries, divisions, groups, or affiliates thereof.
- J. “Respondent” or “Respondents” means Heidelberg and Italcementi, individually and collectively.

GENERAL DEFINITIONS

- K. “Acquisition” means the proposed acquisition of approximately 45 percent of the outstanding voting securities of Italcementi by Heidelberg as described and contemplated by the Share Purchase Agreement dated July 28, 2015, as amended.
- L. “Acquisition Date” means the date the Acquisition is consummated.
- M. “Ashland Terminal” means the Terminal Assets relating to Italcementi’s Ashland Terminal located at 9680 Old Ridge Road, Ashland, VA, that stores, distributes and sells Cement and related products.
- N. “Asset Maintenance Monitor” means the Person approved by the Commission to serve as an Asset

Decision and Order

Maintenance Monitor pursuant to the Asset Maintenance Order issued by the Commission.

- O. “Asset Maintenance Order” means the Order to Maintain Assets issued by the Commission in this matter.
- P. “Assets To Be Divested” means:
1. The Martinsburg Cement Business and, at the option of the Acquirer and subject to the prior approval of the Commission, the Columbus Terminal and the Middlebranch Terminal; and,
 2. The Indianapolis Terminal.
- Q. “Baltimore Terminal” means the Terminal Assets relating to Italcementi’s Baltimore Terminal located at 5700 Chemical Road, Baltimore, MD, that stores, distributes and sells Cement and related products.
- R. “Bessemer Terminal” means:
1. The Terminal Assets relating to Italcementi’s Bessemer terminal located at Second Street, PO Box 779, Bessemer, PA, that stores, distributes and sells Cement and related products; and,
 2. An agreement approved by the Commission between Respondents and the Martinsburg Acquirer requiring Respondents to use or maintain any real property adjacent to the real property upon which the Bessemer terminal is located and any rights or easements retained by Respondents in or relating to the real property upon which the Bessemer terminal is located in a reasonable manner that does not interfere materially with the operation of the Bessemer Terminal by the Martinsburg Acquirer.

Decision and Order

- S. “Books and Records” means any and all original, copies, drafts, and final versions of all books, records, files, customer files, customer lists, customer purchasing histories, vendor files, vendor lists, advertising and marketing materials, sales materials, technical information, architectural drawings and blueprints of any kind, databases, financial information, reports, regulatory materials, or documents, information, and files of any kind, regardless of whether the document, information, or files are stored or maintained in traditional paper format, by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media
- T. “Chesapeake Terminal” means the Terminal Assets relating to Italcementi’s Chesapeake terminal located at 100 Pratt Street, Chesapeake, VA, that stores, distributes and sells Cement and related products.
- U. “Cement” means the product that is the result of the combination of calcium (normally from limestone), silicon, aluminum, iron, and other raw materials, and that is produced by quarrying, crushing and grinding the raw materials, burning them in kilns at high temperatures, and then finely grinding the resulting pellets (“clinker”) with gypsum into an extremely fine powder. The term “Cement” includes, but is not limited to, Portland cement, masonry and mortar cement, and the clinker that is ground to produce Cement.
- V. “Cemex Agreement” means the agreement between Essroc Cement Corp. and Kosmos Cement Company dated May 5, 2016 attached as Confidential Appendix I to this Order.
- W. “Columbus Terminal” means the Terminal Assets relating to Italcementi’s Columbus terminal located at 1550 Williams Road, Columbus, OH, that stores, distributes and sells Cement and related products.

Decision and Order

- X. “Direct Costs” means cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide services under this Order or the Asset Maintenance Order. “Direct Cost” to an Acquirer for its use of any of Respondents’ employees’ labor shall not exceed the then-current average wage rate for such employee, including benefits.
- Y. “Divestiture Agreement” means any agreement between Respondents and an Acquirer (or a Divestiture Trustee appointed pursuant to Paragraph V. of this Order and an Acquirer) and all amendments, exhibits, attachments, agreements, and schedules thereto, related to any of the Assets To Be Divested that has been approved by the Commission to accomplish the requirements of this Order. The term “Divestiture Agreement” includes, as appropriate, the Indianapolis Terminal Divestiture Agreement and the Martinsburg Business Divestiture Agreement.
- Z. “Divestiture Date” means the date any of the respective divestitures required by this Order are consummated.
- AA. “Divestiture Employees” means:
1. All employees of Respondents who perform duties at the locations of any one or more of the Assets to be Divested (including, but not limited to, the Solvay Terminal Assets) ; and,
 2. All employees of Respondents wherever located who perform duties at any location that are reasonably necessary for the operation in a manner that achieves the purposes of this Order of the Assets to be Divested (including, but not limited to, the Solvay Terminal Assets).

Decision and Order

- BB. “Divestiture Trustee” means any person or entity appointed by the Commission pursuant to Paragraph V. of this Order to act as a trustee in this matter.
- CC. “Essroc/EPA Consent Decree” means the consent decree in United States of America, et al, v. Essroc Cement Corp., Civil Action No. 11-1650, filed in the United States District Court for the Western District of Pennsylvania.
- DD. “Frederick Terminal” means the Terminal Assets relating to Italcementi’s terminal located at 4120 Buckeystown Pike, Frederick, MD that stores, distributes and sells Cement and related products.
- EE. “Grinding” means the process of grinding clinker or granulated blast furnace slag into the powder that is or is an ingredient used in making cement.
- FF. “Indianapolis Terminal” means the Terminal Assets relating to Italcementi’s terminal located at 1051 South Emerson Avenue, Indianapolis, IN, that stores, distributes and sells Cement and related products.
- GG. “Indianapolis Terminal Divestiture Agreement” means:
1. The Cemex Agreement; or,
 2. Any other contracts and agreements that receive the approval of the Commission to divest the Indianapolis Terminal to an Acquirer approved by the Commission as required by this Order.
- HH. “Intellectual Property” means all intellectual property owned or licensed (as licensor or licensee) by Respondents in which Respondents have a proprietary interest, and all associated rights thereto, including all of the following in any jurisdiction throughout the world: (i) all Patents; (ii) all trade secrets, Know-How, and confidential or proprietary information (including

Decision and Order

ideas, research and development, formulas, compositions, manufacturing and production processes and techniques, technical data and information, blue prints, designs, drawings, specifications, protocols, quality control information, customer and supplier lists, pricing and cost information, business and marketing plans and proposals, and all other data, technology, and plans); (iii) all computer software (including source code, executable code, data, databases and related documentation); and (iv) all rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing.

- II. “Know-How” means know-how, trade secrets, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, development, and other similar information.

- JJ. “Leetsdale Terminal” means the Terminal Assets relating to Italcementi’s Leetsdale terminal located at 500 W. Park Road, Leetsdale, PA, that stores, distributes and sells Cement and related products.

- KK. “Martinsburg Business Divestiture Agreement” means any contracts and agreements that receive the approval of the Commission to divest the Martinsburg Cement Business to an Acquirer approved by the Commission as required by this Order.

- LL. “Martinsburg Cement Business” means the
 - 1. Martinsburg Cement Plant;
 - 2. Ashland Terminal;
 - 3. Baltimore Terminal;
 - 4. Bessemer Terminal;
 - 5. Chesapeake Terminal;

Decision and Order

6. Frederick Terminal;
7. Leetsdale Terminal;
8. Newport News Terminal, and,
9. Solvay Terminal.

Provided, however, the Martinsburg Cement Business does not include:

1. Books and Records that contain only information that relates solely to assets properly retained by Respondents under this Order;
2. Books and Records:
 - a. That contain information that relates both to Assets To Be Divested and to assets properly retained by Respondents under this Order; and,
 - b. From which Respondents, using best efforts, have redacted information about the dates, products, quantity of products, prices, credit terms, and other commercial information about transactions with customers at any of the Assets To Be Divested;
3. A copy of those portions of Primary Books and Records and a copy of Redacted Books and Records divested to an Acquirer that:
 - a. Respondents are required to keep or maintain for legal, regulatory, tax, or bona fide document retention purposes; and,
 - b. Respondents keep or maintain at a location and under conditions of access that allow only Respondents' agents and employees who perform legal or accounting services for Respondents to access;

Decision and Order

4. Contracts with common carriers to use any vehicles, railcars, barges, or other transportation vessels, other than contracts for such vehicles, railcars, barges, or other transportation vessels in number, type, quantity, and quality as are reasonably necessary for an Acquirer to operate the Assets To Be Divested in a manner to achieve the purposes of this Order; and,
 5. Other Cement plants, or other sources of Cement or related products, in addition to the Martinsburg Cement Plant; and,
 6. Other Cement terminals in addition to the Terminals To Be Divested and the Optional Terminals.
- MM. “Martinsburg Cement Plant” means Italcementi’s Plant Assets relating to Italcementi’s Cement plant located at 1826 S. Queen Street, Martinsburg, WV, that produces, stores, distributes and sells Cement and related products.
- NN. “Material Confidential Information” means any material non-public information relating to the Assets To Be Divested either prior to or after the applicable Divestiture Date, including, but not limited to, business and strategic plans, customer or supplier lists, customer or supplier contract terms, information about sales to customers or purchases from suppliers, manufacturing volumes or costs, price lists, marketing methods, or Know-How, and:
1. Obtained by Respondents prior to the Divestiture Date; or,
 2. Obtained by Respondents after the Divestiture Date, in the course of performing Respondents’ obligations under any Remedial Agreement(s) or the Asset Maintenance Order;

Decision and Order

Provided, however, that Material Confidential Information shall not include:

1. Information that is in the public domain when received by Respondents;
 2. Information that is not in the public domain when received by Respondents and thereafter becomes public through no act or failure to act by Respondents;
 3. Information that Respondents develop or obtain independently, without violating any applicable law or this Order, and without breaching any confidentiality obligation with respect to the information; and,
 4. Information that becomes known to Respondents from a third party not in breach of applicable law or a confidentiality obligation with respect to the information.
- OO. “Middlebranch Terminal” means the Terminal Assets relating to Italcementi’s Middlebranch terminal located at 8282 Middlebranch Ave. NE, Middlebranch, OH, that stores, distributes and sells Cement and related products. The Middlebranch Terminal includes all assets located at the Middlebranch terminal relating to Grinding that takes place at the Middlebranch terminal, including, but not limited to:
1. Real property, whether owned or leased, and including any storage areas, quarries, pits, or other natural resource rights (together, in each case, with all easements, rights of way, buildings, improvements, and appurtenances);
 2. All personal property, equipment, machinery and tools, furniture and fixtures;

Decision and Order

3. Such vehicles, railcars, barges, or other transportation vessels in number, type, quantity, and quality (wherever located) as are reasonably necessary for an Acquirer to operate the Assets To Be Divested in a manner to achieve the purposes of this Order;
4. Storage facilities at the Middlebranch terminal for any products produced by Grinding or sold at the plant, or shipped to any terminal, in bagged, bulk, or other form;
5. Assets related to or used for receiving raw materials used in or related to Grinding or shipping products produced by Grinding;
6. Inventory, supplies, and raw materials;
7. Primary Books and Records and Redacted Books and Records, in each case wherever located;
8. Contracts;
9. Customer and vendor lists; and,
10. Licenses, government approvals, registrations, permits, and applications (to the extent transferable);

Provided, that, the Middlebranch Terminal does not include Terminal Assets relating to Grinding at other than the Terminals To Be Divested and the Columbus Terminal.

Provided, further, that, Contracts do not include contracts for granulated blast furnace slag not exclusively used by the Middlebranch Terminal Assets.

Decision and Order

- PP. “Monitor” means any Person appointed by the Commission pursuant to Paragraph IV. of this Order to act as a monitor in this matter.
- QQ. “Newport News Terminal” means the Terminal Assets relating to Italcementi’s terminal located at 1900 Harbor Access Road, Newport News, VA that stores, distributes and sells Cement and related products.
- RR. “Optional Terminals” means the Columbus Terminal and the Middlebranch Terminal.
- SS. “Plant Assets” means all of Respondents’ rights, title, and interest in and to all assets, tangible and intangible, located or used at the Martinsburg Cement Plant relating to, used in, or reserved for use in, its Cement plant operations, including but not limited to, all:
1. Real property, whether owned or leased, and including any quarries, pits, or other natural resource rights (together, in each case, with all easements, rights of way, buildings, improvements, and appurtenances);
 2. Personal property, equipment, machinery and tools, furniture and fixtures;
 3. Such vehicles, railcars, barges, or other transportation vessels in number, type, quantity, and quality (wherever located) as are reasonably necessary for an Acquirer to operate the Assets To Be Divested in a manner to achieve the purposes of this Order;
 4. Storage facilities for any Cement produced or sold at the plant, or shipped to any terminal, in bagged, bulk, or other form;
 5. Terminal Assets located at the Cement plant used to ship from the plant, or sell or deliver at the

Decision and Order

plant, any Cement (whether produced at the plant or some other location);

6. Inventory, supplies, and raw materials;
7. Primary Books and Records and Redacted Books and Records, in each case wherever located;
8. Contracts;
9. Customer and vendor lists;
10. Intellectual Property used in or necessary for the operation of any Cement plant required to be divested by this Order;
11. Licenses, government approvals, registrations, permits, and applications (to the extent transferable);
12. Telephone and fax numbers; and,
13. Goodwill.

Provided, however, that Plant Assets do not include those assets consisting of or pertaining to any of the Respondents' trademarks, trade dress, service marks, or trade names, except with respect to any purchased inventory or as may be provided in any Remedial Agreement(s).

Provided further that, Plant Assets do not include any terminals other than the Terminals To Be Divested and the Optional Terminals.

- TT. "Primary Books and Records" means Books and Records containing information relating solely to the Plant Assets, Terminal Assets, or other assets divested under this Order.

Decision and Order

- UU. “Proposed Acquirer” means any proposed acquirer of any of the Assets To Be Divested submitted to the Commission for its approval under this Order. “Proposed Acquirer” includes Cemex.
- VV. “Redacted Books and Records” means Books and Records:
1. That prior to a Divestiture Date contained information relating both to:
 - a. The Plant Assets, Terminal Assets, or other assets divested under this Order; and,
 - b. Assets retained by Respondents because the Order does not require their divestiture; and,
 2. From which Respondents have removed or redacted information relating solely to assets retained by Respondents before divesting the Books and Records to an Acquirer.
- WW. “Remedial Agreement(s)” means:
1. Any Divestiture Agreement; and,
 2. Any other agreement between a Respondent and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer), including but not limited to any Transition Services Agreement and any Cement supply, throughput, storage or transportation agreement, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Assets To Be Divested, that have been approved by the Commission to accomplish the requirements of this Order.
- XX. “Solvay Terminal” means the Terminal Assets relating to Heidelberg’s terminal located at 1515 Willis

Decision and Order

Avenue, Solvay, NY, that stores, distributes and sells Cement and related products.

- YY. “Terminal Assets” means all of Respondents’ rights, title, and interest in and to all assets, tangible and intangible, located at the Terminals To Be Divested relating to, used in, and/or reserved for use in, its Cement terminal operations, including but not limited to, all:
1. Real property, whether owned or leased (together, in each case, with all easements, rights of way, buildings, improvements, and appurtenances);
 2. Personal property, equipment, machinery and tools, furniture and fixtures;
 3. Such vehicles, railcars, barges, or other transportation vessels in number, type, quantity, and quality (wherever located) as are reasonably necessary for an Acquirer to operate the Assets To Be Divested in a manner to achieve the purposes of this Order;
 4. Storage facilities for any Cement shipped to or sold at the terminal in bagged, bulk, or other form;
 5. Inventory, supplies, and raw materials;
 6. Books and Records (wherever located);
 7. Contracts;
 8. Customer and vendor lists;
 9. Intellectual Property used in or necessary for the operation of any of the Terminals To Be Divested;
 10. Licenses, government approvals, registrations, permits, and applications (to the extent transferable);

Decision and Order

11. Telephone and fax numbers; and,
12. Goodwill.

Provided, however, that Terminal Assets do not include those assets consisting of or pertaining to any of the Respondents' trademarks, trade dress, service marks, or trade names, except with respect to any purchased inventory or as may be provided in any Remedial Agreement(s).

Provided further that, Terminal Assets do not include:

1. Books and Records that contain only information that relates solely to assets properly retained by Respondents under this Order;
2. Books and Records:
 - a. That contain information that relates both to Assets To Be Divested and to assets properly retained by Respondents under this Order; and,
 - b. From which Respondents, using best efforts, have redacted information about the dates, products, quantity of products, prices, credit terms, and other commercial information about transactions with customers at any of the Assets To Be Divested;
3. A copy of those portions of Primary Books and Records and a copy of Redacted Books and Records divested to an Acquirer that:
 - a. Respondents are required to keep or maintain for legal, regulatory, tax, or bona fide document retention purposes; and,
 - b. Respondents keep or maintain at a location and under conditions of access that allow only Respondents' agents and employees who

Decision and Order

perform legal or accounting services for Respondents to access;

4. Contracts with common carriers to use any vehicles, railcars, barges, or other transportation vessels, other than contracts for such vehicles, railcars, barges, or other transportation vessels in number, type, quantity, and quality as are reasonably necessary for an Acquirer to operate the Assets To Be Divested in a manner to achieve the purposes of this Order; and,
5. Cement plants other than the Martinsburg Cement Plant and terminals other than the Terminals To Be Divested and the Optional Terminals.

ZZ. “Terminals To Be Divested” means the Ashland Terminal, Baltimore Terminal, Bessemer Terminal, Chesapeake Terminal, Frederick Terminal, Indianapolis Terminal, Leetsdale Terminal, Newport News Terminal, and Solvay Terminal.

AAA. “Transition Services Agreement” means an agreement that receives the prior approval of the Commission between one or both Respondents and an Acquirer of any of the assets divested under this Order to provide, at the option of the Acquirer and at no more than the Direct Costs of the Respondents, any services (or training for the Acquirer to provide services for itself) reasonably necessary to transfer the divested assets to the Acquirer in a manner consistent with the purposes of this Order, and may include, but are not limited to, payroll, employee benefits, accounting, IT systems, supply, distribution, warehousing, terminal or throughput services, access to Know-How, use of trademarks or trade names, or other logistical and administrative support.

Decision and Order

II.**IT IS FURTHER ORDERED** that:

- A. Respondents shall divest the Assets To Be Divested, absolutely and in good faith, as follows:
1. Within ten (10) days of the Acquisition Date, the Indianapolis Terminal shall be divested, absolutely and at no minimum price, to:
 - a. Cemex pursuant to and in accordance with the Indianapolis Terminal Divestiture Agreement; or,
 - b. A Person who receives the prior approval of the Commission and in accordance with an Indianapolis Terminal Divestiture Agreement that receives the prior approval of the Commission;

Provided further that, if prior to the date this Order becomes final, Respondents have divested the Indianapolis Terminal pursuant to Paragraph II.A.1. and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:

- i. Any Indianapolis Acquirer identified in Paragraph II.A.1. is not an acceptable Acquirer, then Respondents shall, within five days of notification by the Commission, rescind such transaction with that Indianapolis Acquirer, and shall divest such assets, absolutely and in good faith, at no minimum price, to another Acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission, within 90 days of the date the Commission

Decision and Order

notifies Respondents that such Indianapolis Acquirer is not an acceptable Acquirer; or,

- ii. The manner in which any divestiture identified in Paragraph II.A.1. was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee pursuant to Paragraph V.A. of this Order, to effect such modifications to the manner of divesting those assets to such Acquirer (including, but not limited to, entering into additional agreements or arrangements, or modifying the relevant Divestiture Agreement) as may be necessary to satisfy the requirements of this Order.

and,

2. Within one hundred and twenty (120) days of the Acquisition Date, the Martinsburg Cement Business shall be divested, absolutely and at no minimum price, to an Acquirer that receives the prior approval of the Commission, and in a manner that receives the prior approval of the Commission.

Provided that, at the option of the Acquirer and subject to the prior approval of the Commission, Respondents shall divest the Columbus Terminal and the Middlebranch Terminal to the Acquirer of the Martinsburg Cement Business.

- B. All Remedial Agreement(s) approved by the Commission:
 1. Shall be deemed incorporated by reference into this Order, and any failure by Respondents to comply with the terms of any such Remedial Agreement(s) shall constitute a violation of this Order; and

Decision and Order

2. Shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of any Acquirer or to reduce any obligation of Respondents under such agreement. If any term of any Remedial Agreement(s) varies from the terms of this Order (“Order Term”), then to the extent that Respondents cannot fully comply with both terms, the Order Term shall determine Respondents’ obligations under this Order.
- C. At the option of each Acquirer, and subject to the prior approval of the Commission, Respondents shall enter into a Transition Services Agreement for a term extending up to two years following the relevant Divestiture Date, which agreement may be terminated at any time by the Acquirer without penalty upon commercially reasonable notice to Respondents.
- D. Prior to each applicable Divestiture Date:
1. Respondents shall secure, at their sole expense, consents from any Person that are necessary to effect the complete transfer of the Assets To Be Divested to each Acquirer (including, but not limited to, any approvals of use or ownership of any of the Assets To Be Divested relating to the Essroc/EPA Consent Decree), and for each Acquirer to operate the Assets To Be Divested in a manner consistent with the purposes of this Order;

Provided, however, that Respondents shall not be required to secure the consent of any Governmental Entity relating to any permit, license, or right that Respondents have no legal right to divest or transfer to the Acquirer; and,
 2. Respondents shall use best efforts to assist each Acquirer to obtain from any Governmental Entity the transfer from Respondents or issuance to the

Decision and Order

Acquirer of any permit, license, or right that Respondents have no legal right to divest or transfer to the Acquirer.

- E. Pending divestiture of any of the Assets To Be Divested, Respondents shall:
1. Take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the Assets To Be Divested, to minimize any risk of loss of competitive potential for the Assets To Be Divested, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Assets To Be Divested, except for ordinary wear and tear; and,
 2. Not sell, transfer, encumber, or otherwise impair the Assets To Be Divested (other than in the manner prescribed in this Decision and Order and in the Asset Maintenance Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Assets To Be Divested.
- F. With respect to each of the divestitures of Assets to be Divested required by this Order:
1. Respondents shall provide reasonable opportunity in advance of the Divestiture Date for the Proposed Acquirer to:
 - a. Meet personally, and outside of the presence or hearing of any employee or agent of Respondents, with any or all of the Divestiture Employees pursuant to the applicable Divestiture Agreement; and
 - b. Make offers of employment to any or all of the Divestiture Employees pursuant to the applicable Divestiture Agreement;

Decision and Order

2. Respondents shall: (i) not directly or indirectly interfere with the hiring by the Acquirer of Divestiture Employees; (ii) not directly or indirectly attempt to persuade any one or more of the Divestiture Employees to decline any offer of employment from any Acquirer, or offer any incentive to any Divestiture Employee to decline employment with any Acquirer; (iii) remove any impediments within the control of Respondents that may deter those Divestiture Employees from accepting employment with such Acquirer (including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by such Acquirer); (iv) not make any counteroffer to any Divestiture Employee who has an outstanding offer of employment, or who has accepted an offer of employment, from an Acquirer; and (v) continue to extend to any Divestiture Employee, prior to the applicable Divestiture Date, all Divestiture Employee benefits offered in the ordinary course of business, including regularly scheduled or merit raises and bonuses, and regularly scheduled vesting of all pension benefits;

3. Respondents shall not, directly or indirectly, for a period of two (2) years from the applicable Divestiture Date, solicit, negotiate, hire, or enter into any arrangement for the services of any Divestiture Employee who has accepted an offer of employment with, or who is employed by, an Acquirer.

Provided, however, a violation of this provision will not occur if:

- a. The Divestiture Employee's employment has been terminated by the Acquirer;

Decision and Order

- b. Respondents advertise for employees in newspapers, trade publications, or other media not targeted specifically at any one or more of the Divestiture Employees of the Acquirer(s); or,
 - c. Respondents hire a Divestiture Employee who has applied for employment with Respondents, provided that such application was not, directly or indirectly, solicited or induced by Respondents in violation of this Order.
- G. The purpose of the divestitures is to ensure the continuation of the Assets To Be Divested as ongoing, viable facilities engaged in the Cement business and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.**IT IS FURTHER ORDERED** that:

- A. Respondents shall not:
- 1. Provide, disclose, or otherwise make available any Material Confidential Information to any Person except as required or permitted by this Order, the Asset Maintenance Order, or any Remedial Agreement(s); or
 - 2. Use any Material Confidential Information for any reason or purpose other than as required or permitted by this Order, the Asset Maintenance Order, or any of the Remedial Agreement(s), and shall limit access to Material Confidential Information to only those employees necessary for Respondents to fulfill their obligations under the Order, the Asset Maintenance Order, or the Remedial Agreement(s).

Decision and Order

- B. Respondents shall devise and implement measures to protect against the storage, distribution, and use of Material Confidential Information that is not permitted by this Order, the Asset Maintenance Order, or the Remedial Agreement(s). These measures shall include, but not be limited to, restrictions placed on access by persons to information available or stored on any of Respondents' computers or computer networks.
- C. Notwithstanding anything else in paragraph III of this Order and subject to the Asset Maintenance Order, Respondents may use and disclose Material Confidential Information:
1. In the ordinary course of business in the operation of Respondents' retained businesses and assets if:
 - a. The Material Confidential Information relates both to the Assets To Be Divested and to Respondents' retained businesses or assets;
 - b. The Divestiture Agreement permits Respondents to retain Material Confidential Information that also relates to Respondents' retained businesses or assets; and
 - c. Respondents protect against the disclosure or use of such Material Confidential Information in the same way Respondents protect against the disclosure or use of Respondents' other confidential information;
 2. For the purpose of performing Respondents' obligations under this Order, the Asset Maintenance Order, or the Remedial Agreement(s);
 3. To ensure compliance with legal and regulatory requirements including, but not limited to:

Decision and Order

- a. Retaining a copy of Material Confidential Information for the sole purpose of complying with any applicable law, regulations, and other legal obligations; and,
 - b. Requirements of the rules and regulations of the Securities and Exchange Commission and of any stock, the performance of necessary audits and the maintenance of effective internal controls and procedures for required disclosures of financial information;
4. To provide accounting, information technology, and credit-underwriting services;
 5. To provide legal services associated with actual or potential litigation and transactions;
 6. To monitor and ensure compliance with financial, tax reporting, governmental environmental, health, and safety requirements; or
 7. As otherwise provided by this Order and the Asset Maintenance Order.

IV.**IT IS FURTHER ORDERED** that:

- A. The Commission appoints William Hill as Monitor, and approves the agreement between the Monitor and Respondents, attached as Appendix II (“Monitor Agreement”). The Monitor is appointed to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Remedial Agreement(s).
- B. The Monitor’s duties and responsibilities shall include the following, among other responsibilities that may be required:

Decision and Order

1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
2. The Monitor shall serve until such time as Respondents have complied fully with all of their obligations under the Remedial Agreement(s);
3. The Monitor shall have the power and authority to monitor Respondents' compliance with this Order and the Remedial Agreement(s);
4. The Monitor shall have power and authority to review and audit, at the Respondents' sole cost and expense, the books and records of Respondents to determine whether Respondents have complied fully with their obligations under the Order and the Remedial Agreement(s);
5. The Monitor shall exercise such power and authority and carry out his or her duties and responsibilities in a manner consistent with the purposes of this Order and in consultation with the Commission and its staff;
6. The Monitor shall review all reports submitted to the Commission by Respondents under this Order and, within thirty (30) days from the date the Monitor receives a report, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order and the Remedial Agreement(s); and,
7. The Monitor shall provide written reports to the Commission every thirty (30) days, or upon a schedule determined by Commission staff, that provides the Commission with timely information to determine if Respondents have complied and are complying with their obligations under this Order and the Remedial Agreement(s). In addition, the Monitor shall provide such additional written

Decision and Order

reports as Commission staff may request that reasonably are related to determining if Respondents have complied and are complying with their obligations under this Order and the Remedial Agreement(s). The Monitor shall not provide to Respondents, and Respondents shall not be entitled to receive, copies of these reports.

- C. Respondents shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including, but not limited to, the following:
1. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order and the Remedial Agreement(s);
 2. Subject to any demonstrated legally recognized privilege, Respondents shall provide the Monitor full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under this Order and the Remedial Agreement(s);
 3. Within one (1) calendar day of submitting a report required by this Order, Respondents shall deliver a copy of such report to the Monitor;
 4. Except as otherwise set forth in this Order, the Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions to which the Monitor and Respondents agree and that the Commission approves;

Decision and Order

5. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor; and,
7. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement.

Provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commission or its staff, or require the Monitor to report to Respondents the substance of communications to or from the Commission, its staff, or an Acquirer.

- D. Respondents shall comply with all terms of the Monitor Agreement, and any breach by Respondents of any term of the Monitor Agreement shall constitute a violation of this Order. Notwithstanding any paragraph, section, or other provision of the Monitor Agreement, any modification of the Monitor Agreement, without the prior approval of the Commission, shall constitute a failure to comply with this Order.

Decision and Order

- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed substitute Monitor, Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor. Not later than ten (10) days after the appointment of the Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the relevant requirements of this Order and the Remedial Agreement(s) in a manner consistent with the purpose of this Order. If a substitute Monitor is appointed, Respondents shall consent to the terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor as set forth in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.
- H. A Monitor appointed pursuant to this Order may be, but need not be, the same person appointed as the

Decision and Order

Divestiture Trustee pursuant to Paragraph V. of this Order and as Asset Maintenance Monitor appointed pursuant to the Asset Maintenance Order.

V.**IT IS FURTHER ORDERED** that:

- A. If Respondents have not divested all of the Assets To Be Divested in the time and manner required by Paragraph II of this Order, the Commission may appoint a Divestiture Trustee to divest the remaining Assets To Be Divested, and to enter into Transition Services Agreements VI. and other Remedial Agreement(s), and perform Respondents' other obligations, in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to divest the required assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including one or more court-appointed Divestiture Trustees, pursuant to Section 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission may select a Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, and stated in writing their reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by

Decision and Order

the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

1. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement for any divestitures required by Paragraph II. of this Order that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effectuate the divestitures required by, and satisfy the additional obligations imposed by, this Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.
2. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - a. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to effectuate the divestitures required by, and satisfy the additional obligations imposed by, this Order.
 - b. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture required by this Order, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan to satisfy the divestiture obligations of this Order, or believes that such obligation can be achieved within a reasonable time, the period may be extended by the

Decision and Order

Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; *provided, however*, that the Commission may extend the period only two (2) times.

- c. Subject to any demonstrated legally recognized privilege, any Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as any Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede any Divestiture Trustee's accomplishment of the divestiture. Any delays caused by Respondents shall extend the time under this Paragraph for a time period equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
- d. Any Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner that receives the prior approval of the Commission and to an Acquirer that receives the prior approval of the Commission as required by this Order; *provided, however*, if any Divestiture Trustee receives bona fide offers for any asset to be divested from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity,

Decision and Order

the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such entity within five (5) days after receiving notification of the Commission's approval.

- e. Any Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. Any Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. Any Divestiture Trustee shall account for all monies derived from the divestitures and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of any Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
- f. Respondents shall indemnify any Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all

Decision and Order

reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, malfeasance, willful or wanton acts, or bad faith by the Divestiture Trustee.

- g. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
 - h. The Divestiture Trustee shall report in writing to Respondents and to the Commission every thirty (30) days concerning the Divestiture Trustee's efforts to accomplish the divestitures.
 - i. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
 - j. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- C. If the Commission determines that the Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture

Decision and Order

Trustee in the same manner as provided in this Paragraph.

- D. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of any Divestiture Trustee, issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures required by this Order.
- E. The Divestiture Trustee appointed pursuant to this Paragraph may be, but need not be, the same person as the Monitor appointed under this Order and as Asset Maintenance Monitor appointed pursuant to the Asset Maintenance Order.

VI.**IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the date this Order is issued, and every thirty (30) days thereafter until the completion of the last divestiture required by this Order, Respondents shall submit to the Commission (and a complete copy to the Monitor appointed under this Order, and the Asset Maintenance Monitor appointed under the Asset Maintenance Order) a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. For the period covered by this report, the report shall include, but not be limited to, among other things that are required from time to time, a full description of the efforts being made to comply with Paragraph II. of this Order, including a description of all substantive contacts or negotiations for the divestitures and the identity and contact information of all parties contacted. Respondents shall include in the reports copies of all material written communications to and from such parties, all internal memoranda reviewing or evaluating possible acquirers or divestiture proposals,

Decision and Order

and all reports and recommendations concerning completing the obligations.

- B. On the first anniversary of the date this Order is issued, and thereafter on each subsequent anniversary until Respondents have satisfied in full all of their obligations under Paragraph II. of this Order and all of the Remedial Agreement(s), Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. For the period covered by each such report, Respondents shall state the name and contact information for each Person that maintains or claims (regardless of whether Respondents agree or disagree with such Person, and regardless whether a judicial or arbitration action has been threatened or commenced) that one or more Respondents have failed to comply fully with the Order (including any Remedial Agreement(s) made a part thereof), briefly describe the Person's claim, and provide copies of any written communications between Respondents and the Person concerning the claim.

VII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondents;
- B. Any proposed acquisition, merger or consolidation of Respondents; or
- C. Any other change in the Respondents, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

Decision and Order

VIII.

IT IS FURTHER ORDERED that for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondents made to either Respondent's principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Respondents related to compliance with this Order, which copying services shall be provided by Respondents at the request of the authorized representative(s) of the Commission and at the expense of the Respondents; and
- B. To interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on August 15, 2026.

By the Commission.

Analysis to Aid Public Comment

APPENDIX I

Indianapolis Terminal Divestiture Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

APPENDIX II

Monitor Agreement

[Redacted Public Version]

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) designed to remedy the anticompetitive effects resulting from the proposed acquisition of Italcementi S.p.A. (“Italcementi”) by HeidelbergCement AG (“Heidelberg”) (collectively, “Respondents” or “the parties”). Heidelberg and Italcementi compete to sell portland cement in the United States through their respective subsidiaries, Lehigh Hanson, Inc. (“Lehigh”) and Essroc Cement Corp. (“Essroc”). Under the terms of the proposed Consent Agreement, the Respondents are required to divest Italcementi’s cement plant in Martinsburg, West Virginia, along with up to ten cement terminals and all related assets to a buyer approved by the Commission (the “Martinsburg Assets”). In addition to the cement plant, the Martinsburg Assets include the following

Analysis to Aid Public Comment

terminals that Essroc has used to distribute cement manufactured at Martinsburg: Ashland, Virginia; Baltimore, Maryland; Bessemer, Pennsylvania; Chesapeake, Virginia; Frederick, Maryland; Leetsdale, Pennsylvania; and Newport News, Virginia. Two additional Essroc terminals located in Columbus and Middlebranch, Ohio are required to be divested at the option of the buyer and subject to the prior approval of the Commission. In addition to these nine terminals that historically serve Essroc's Martinsburg cement plant, Respondents are required to divest to the buyer of the Martinsburg Assets Lehigh's cement terminal in Solway, New York. Finally, the Consent Agreement requires Essroc to divest its cement terminal in Indianapolis, Indiana to Cemex, Inc. ("Cemex").

The Consent Agreement has been placed on the public record for thirty days to solicit comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the Consent Agreement and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make final the Decision and Order ("Order").

THE TRANSACTION

Pursuant to a Share Purchase Agreement dated July 28, 2015, Heidelberg proposes to acquire 100% of Italcementi's voting shares in a two-step transaction. First, Heidelberg has agreed to acquire approximately 45% of Italcementi voting securities held by Italmobiliare S.p.A. The aggregate consideration for these shares totals approximately \$1.9 billion. Following the closing of the Share Purchase, Heidelberg will launch a mandatory public cash tender offer for the remaining outstanding shares of Italcementi, for an expected purchase price of approximately \$2.3 billion. The total value of Italcementi shares to be acquired is thus approximately \$4.2 billion.

The Commission's Complaint alleges that the proposed transaction, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in certain regional markets in

Analysis to Aid Public Comment

the United States for the manufacture and sale of portland cement. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the proposed acquisition.

THE PARTIES

Headquartered in Germany, Heidelberg is the second-largest global producer of cement, ready-mix concrete, and aggregates. It operates eighty-five cement plants in more than forty countries around the globe. Heidelberg operates as Lehigh in the United States, where it has twelve cement plants, one slag cement grinding facility, two cement-grinding facilities, and thirty-nine cement terminals.

Italcementi is an Italian public corporation that operates in the United States through its subsidiary, Essroc. Worldwide, Italcementi is the fourth-largest producer of cement. Essroc operates six cement plants and twenty-one cement terminals in North America.

THE RELEVANT PRODUCTS AND STRUCTURE OF THE MARKETS

In the United States, both parties manufacture and sell portland cement. Portland cement is an essential ingredient in making concrete, a cheap and versatile building material. Because portland cement has no close substitute and the cost of cement usually represents a relatively small percentage of a project's overall construction costs, few customers are likely to switch to other products in response to a small but significant increase in the price of portland cement.

The primary purchasers of portland cement are ready-mix concrete firms and producers of concrete products. These customers usually pick up portland cement from a cement company's plant or terminal in trucks. Because portland cement is a heavy and relatively cheap commodity, transportation costs limit the distance customers can economically travel to pick up cement. The precise scope of the area that can be served by a particular plant or terminal depends on a number of factors,

Analysis to Aid Public Comment

including the density of the specific region and local transportation costs.

Due to transportation costs, cement markets are local or regional in nature. The relevant geographic markets in which to analyze the effects of the proposed acquisition on portland cement competition are (1) Baltimore-Washington and surrounding areas; (2) Richmond, VA and surrounding areas; (3) Virginia Beach-Norfolk-Newport News and surrounding areas (i.e., Hampton Roads); (4) Syracuse, NY metropolitan and surrounding areas; and (5) Indianapolis and surrounding areas. Each of the relevant markets is highly concentrated, and the merger would reduce the number of competitively significant suppliers from three to two in each of the markets.

ENTRY

Entry into the relevant portland cement markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed transaction. It is costly and time consuming to enter a new geographic market. Constructing a new portland cement plant of sufficient size to be competitive would likely cost over \$300 million and take more than five years to permit, design, and build; even the expansion of an existing facility would likely cost hundreds of millions of dollars and take four or more years to complete. Building competitive cement distribution terminals is also difficult and time consuming. It can take more than two years to acquire a suitable location, obtain the necessary permits, and complete construction of a competitive terminal in the relevant markets. Given the difficulties of entry, it is unlikely that any new entry could be accomplished in a timely manner in the relevant markets to defeat a likely price increase caused by the proposed acquisition.

EFFECTS OF THE ACQUISITION

Unless remedied, the proposed merger would likely result in harm to competition in each of the relevant portland cement markets. Those markets are already highly concentrated. By reducing the number of significant competitors, the merger would

Analysis to Aid Public Comment

result in an effective duopoly in each relevant market. As explained below, the evidence shows that absent the required divestitures, the merger would likely both produce unilateral and coordinated effects in the relevant markets.

For many customers in the relevant markets, the parties are the two most proximate suppliers, and other rival cement suppliers are more distant and thus have higher shipping costs. The merger would likely force these customers to pay higher prices by eliminating their ability to play one party off against the other in individual negotiations to obtain better cement prices. After the acquisition, the merged party could effectively target customers for whom the merged parties are the nearest competitors with price increases. The merged party could also target customers that prefer to buy cement from multiple sources to protect against supply disruptions with price increases because the merger would leave such customers with only two significant suppliers.

The proposed transaction is also likely to enhance the likelihood of coordinated interaction by reducing the number of significant suppliers in relevant markets that are already vulnerable to coordination. The relevant markets are vulnerable because they are highly concentrated; cement is a homogenous product; and sales are small, frequent, and usually not made pursuant to long-term contracts. The markets also exhibit a high degree of transparency: competitors are commonly aware of each other's production capacities, costs, sales volumes, prices, and customers. The evidence indicates that the merging firms already closely monitor competitors' cement pricing and sales, which facilitates coordination.

THE CONSENT AGREEMENT

The proposed Consent Agreement eliminates the competitive concerns raised by Heidelberg's proposed acquisition of Italcementi by requiring the divestiture of one party's cement operations in each of the relevant markets. Italcementi is required to divest a cement plant in Martinsburg, West Virginia, including its quarry and all other related assets, together with up to ten cement distribution terminals in Maryland, Virginia,

Analysis to Aid Public Comment

Pennsylvania, and Ohio, to a Commission-approved buyer or buyers, at no minimum price, within 120 days of closing of the proposed transaction. Furthermore, Heidelberg is required to divest its distribution terminal in Solvay, New York, and all related assets to the Commission-approved buyer of the Martinsburg Assets, in order to remedy the competitive effects of the proposed acquisition in the Syracuse market. Finally, Essroc must divest its cement distribution terminal in Indianapolis and all related assets to Cemex within ten days of the closing of the proposed transaction to remedy the competitive effects of the proposed acquisition in the Indianapolis market.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that any of the identified buyers is not an acceptable acquirer, the proposed Order requires the parties to divest the assets to a Commission-approved acquirer within ninety days of the Commission notifying the parties that the proposed acquirer is not acceptable. If the Commission determines that the manner in which any divestiture was accomplished is not acceptable, the Commission may direct the parties, or appoint a divestiture trustee, to effect such modifications as may be necessary to satisfy the requirements of the Order.

The Consent Agreement also contains an Order to Maintain Assets to protect the viability, marketability, and competitiveness of the divestiture asset packages until the assets are divested to a buyer or buyers approved by the Commission.

To ensure compliance with the proposed Order, the Commission has agreed to appoint an Interim Monitor to ensure that Heidelberg and Italcementi comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to appropriate purchasers.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

**TEVA PHARMACEUTICAL INDUSTRIES LTD.
AND
ALLERGAN PLC**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4589; File No. 151 0196
Complaint, July 26, 2016 – Decision, September 7, 2016*

This consent order addresses the \$40.5 billion acquisition by Teva Pharmaceutical Industries Ltd. of certain assets of Allergan plc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current or future competition in pharmaceutical markets for one or more strengths of ninety-four pharmaceutical products in the United States. The consent order requires the parties (1) to divest rights and assets related to pharmaceutical markets for one or more strengths of seventy-nine pharmaceutical products and (2) provide certain Teva active pharmaceutical ingredient (“API”) customers that market one or more of fifteen pharmaceutical products with the option to enter into long-term API supply contracts.

Participants

For the *Commission*: Marc S. Lanoue, , Steven C. Lavender, Jacqueline K. Mendel, Samantha R. Morelli, Eric Olson, Jasmine Y. Rosner Danielle M. Sims, and David Von Nirschl.

For the *Respondents*: Ian Connor and Mark Kovner, Kirkland & Ellis LLP; Ann Malester and Jeff White, Weil, Gotshal & Manges LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Teva Pharmaceutical Industries Ltd. (“Teva”), a corporation subject to the jurisdiction of the Commission, has made an offer to acquire the voting securities of certain entities and related assets from Allergan plc (“Allergan”), a corporation

Complaint

subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Teva is a corporation organized, existing, and doing business under and by virtue of the laws of Israel with its principal executive offices located at 5 Basel Street, P.O. Box 3190, Petach Tikva 4951033, Israel, and its United States address as follows: General Counsel, Teva Pharmaceutical Industries Ltd., c/o Teva North America, 425 Privet Road, Horsham, Pennsylvania 19044.

2. Respondent Allergan is a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland with its principal executive offices located at Clonsaugh Business and Technology Park, Coolock Dublin, D17 E400, Ireland, and its United States address as follows: Chief Legal Officer, Allergan plc, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

II. THE PROPOSED ACQUISITION

3. On July 26, 2015, Teva proposed to acquire Allergan's generic pharmaceutical business for approximately \$40.5 billion (the "Acquisition").

III. THE RELEVANT PRODUCT MARKETS

4. U.S. Food and Drug Administration ("FDA") marketing approvals for generic pharmaceutical products are based on establishing bioequivalence to already approved drugs. When such bioequivalence is demonstrated by *in vivo* or *in vitro* studies, the FDA designates such generic drugs as "AB-rated" to the branded product, which allows for automatic substitution of the

Complaint

generic equivalent for the branded drug when the drug is dispensed at the pharmacy. Where only one AB-rated generic drug is approved, it competes against the branded drug. Where multiple AB-rated generic drugs are approved, they compete against each other in a “generic” market, which typically does not include the branded product. Generic drugs that are AB-rated to different branded drugs are not substitutable, even if they contain the same active ingredients in the same proportions in the same dosage form. For the purposes of this Complaint, relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following finished dosage form pharmaceutical products:

- a. generic acitretin capsules;
- b. generic alendronate sodium tablets;
- c. generic amphetamine aspartate/amphetamine sulfate/dextroamphetamine saccharate/dextroamphetamine sulfate extended release tablets;
- d. armodafinil tablets;
- e. generic aspirin/dipyridamole extended release capsules;
- f. [REDACTED]
- g. generic benzoyl peroxide/clindamycin phosphate topical gel;
- h. generic budesonide inhalation suspension;
- i. [REDACTED]
- j. generic buprenorphine HCl/naloxone HCl buccal film;

Complaint

- k. generic buspirone hydrochloride tablets;
- l. generic carbidopa/levodopa tablets;
- m. generic clarithromycin extended release tablets;
- n. generic clonidine HCl transdermal film;
- o. generic clozapine tablets;
- p. generic cyclosporine capsules;
- q. generic cyclosporine oral solution;
- r. generic desmopressin acetate tablets;
- s. generic desogestrel/ethinyl estradiol tablets (AB-rated to Cyclessa);
- t. generic desogestrel/ethinyl estradiol and ethinyl estradiol tablets (AB-rated to Mircette);
- u. generic dexamethylphenidate HCl extended release capsules;
- v. generic dextroamphetamine sulfate extended release capsules;
- w. generic diazepam tablets;
- x. generic dienogest/estradiol valerate and estradiol valerate tablets (AB-rated to Natazia);
- y. generic disopyramide phosphate capsules;
- z. generic drospirenone/ethinyl estradiol tablets (AB-rated to Yasmin-28);
- aa. generic epirubicin injection;
- bb. generic estazolam tablets;

Complaint

- cc. generic estradiol tablets;
- dd. generic ethinyl estradiol/ethynodiol diacetate tablets (AB-rated to Demulen 1/35);
- ee. generic ethinyl estradiol/etonogestrel vaginal rings;
- ff. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Alesse-28);
- gg. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Levlite-28);
- hh. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Lo Seasonique);
- ii. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Nordette);
- jj. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Seasonique);
- kk. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Triphasil-28);
- ll. generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Quartette);
- mm. generic ethinyl estradiol/norethindrone tablets (AB-rated to Modicon-28);
- nn. generic ethinyl estradiol/norethindrone tablets (AB-rated to Tri-Norinyl 28-Day);
- oo. generic ethinyl estradiol/norethindrone acetate tablets (AB-rated to Loestrin 21 1/20);
- pp. generic ethinyl estradiol/norethindrone acetate tablets (AB-rated to Loestrin 21 1.5/30);

Complaint

- qq. generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Estrostep FE);
- rr. generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Loestrin FE 1/20);
- ss. generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Loestrin FE 1.5/30);
- tt. generic ethinyl estradiol/norgestrel tablets (AB-rated to Lo/Ovral);
- uu. generic ezetimibe/simvastatin tablets;
- vv. generic fentanyl buccal tablets;
- ww. generic fludarabine injection;
- xx. generic fluocinonide cream;
- yy. generic fluocinonide cream, emulsified base;
- zz. generic flutamide capsules;
- aaa. generic glyburide/metformin HCl tablets;
- bbb. generic griseofulvin microcrystalline liquid suspension;
- ccc. generic hydroxyzine pamoate capsules;
- ddd. generic imiquimod topical cream;
- eee. generic levalbuterol HCl inhalation solution;
- fff. generic metformin HCl/saxagliptin extended release tablets;
- ggg. generic methotrexate injection;
- hhh. generic methylphenidate HCl extended release tablets;

Complaint

- iii. generic methylphenidate HCl extended release capsules;
- jjj. generic metoclopramide HCl tablets;
- kkk. generic minocycline capsules;
- lll. generic mirtazapine oral disintegrating tablets;
- mmm. generic NAB paclitaxel injection;
- nnn. generic nabumetone tablets;
- ooo. generic nitrofurantoin capsules;
- ppp. generic norethindrone tablets (AB-rated to Micronor 28);
- qqq. generic norethindrone tablets (AB-rated to Nor-QD);
- rrr. generic nortriptyline HCl capsules;
- sss. generic phentermine HCl/topiramate extended release capsules;
- ttt. generic propofol injection emulsion;
- uuu. generic propranolol HCl tablets;
- vvv. generic ramelteon tablets;
- www. generic rotigotine transdermal patch;
- xxx. generic tamoxifen citrate tablets;
- yyy. generic tobramycin inhalation solution;
- zzz. generic trimethoprim tablets; and
- aaaa. trimipramine maleate capsules.

Complaint

5. Additional relevant lines of commerce in which to analyze the effects of the Acquisition, for the purposes of this Complaint, are the development, manufacture, distribution, and sale of the following FDA-approved, finished dosage form pharmaceutical products:

- a. betamethasone dipropionate augmented ointment;
- b. betamethasone dipropionate cream;
- c. betamethasone dipropionate lotion;
- d. betamethasone dipropionate ointment;
- e. betamethasone valerate cream;
- f. betamethasone valerate ointment;
- g. clobetasol propionate shampoo;
- h. clobetasol propionate ointment;
- i. desonide cream;
- j. [REDACTED]
- k. [REDACTED]
- l. probenecid tablets;
- m. colchicine/probenecid tablets;
- n. nystatin/triamcinolone acetonide cream; and
- o. nystatin/triamcinolone acetonide ointment.

Complaint

IV. THE RELEVANT GEOGRAPHIC MARKETS

6. With respect to the lines of commerce set forth in Paragraphs 4 and 5, the United States is the relevant geographic market in which to assess the competitive effects of the Acquisition.

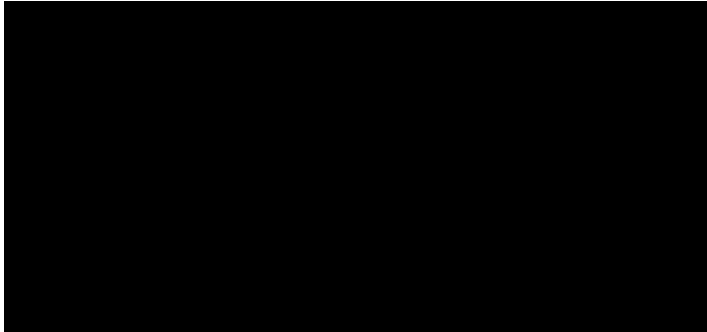
V. THE STRUCTURE OF THE MARKETS

7. The structures of the relevant finished dosage form pharmaceutical product markets set forth in Paragraph 4 are described below:

- a. Acitretin capsules are retinoids used to treat psoriasis. Three firms—Allergan, Teva, and SigmaPharm Laboratories—supply 17.5 mg generic acitretin capsules. Mylan Inc. (“Mylan”) is the only other firm that holds an approved Abbreviated New Drug Application (“ANDA”) for 17.5 mg generic acitretin capsules. The Acquisition would consolidate the 17.5 mg capsule market from four to three suppliers. Five firms supply 10 mg and 25 mg generic acitretin capsules: Allergan, Teva, Mylan, Prasco Laboratories (“Prasco”), and SigmaPharm Laboratories. The Acquisition would reduce the number of suppliers in the 10 mg and 25 mg generic acitretin markets from five to four.
- b. Alendronate sodium tablets are used to treat osteoporosis. Five firms supply 35 mg generic alendronate sodium tablets: Allergan, Teva, Cipla Ltd. (“Cipla”), Sun Pharmaceuticals Industries, Inc. (“Sun”), and Virtus Pharmaceuticals. The Acquisition would reduce the number of suppliers of 35 mg generic alendronate sodium tablets from five to four.
- c. Amphetamine aspartate/amphetamine sulfate/dextro-amphetamine saccharate/dextroamphetamine sulfate extended release tablets are used to treat Attention Deficit Hyperactivity Disorder (“ADHD”). Three firms hold ANDAs for 5 mg, 10 mg, 15 mg, 20 mg, 25

Complaint

mg, and 30 mg strength tablets: Allergan, Teva, and Impax Laboratories, Inc. (“Impax”). Accounting for expected future entry, the Acquisition would reduce the number of suppliers from four to three.

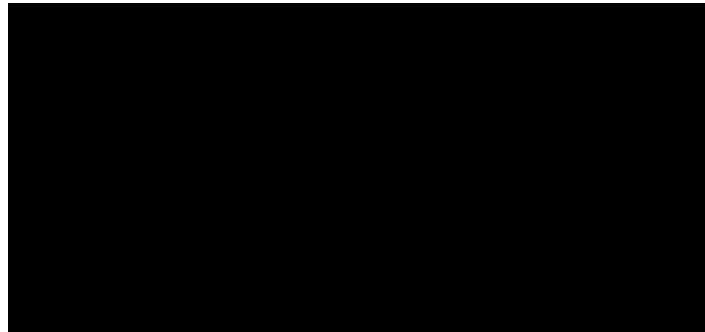
- d. Armodafinil tablets are used to treat excessive sleepiness. Teva owns and markets the branded product, Nuvigil. Allergan recently entered the 200 mg generic armodafinil market as the exclusive first-to-file generic. The Acquisition would reduce the number of suppliers for 200 mg armodafinil tablets from two to one.
- e. Aspirin/dipyridamole extended release capsules are used to prevent strokes in people who have blood flow disorders or a history of blood clots. Teva markets an authorized generic and is the only supplier of generic 25 mg/200 mg aspirin/dipyridamole extended release capsules. Allergan is one of a limited number of suppliers likely to enter the generic 25 mg/200 mg aspirin/dipyridamole extended release capsule market in the near future. The Acquisition would reduce the number of likely future suppliers for generic 25 mg/200 mg aspirin/dipyridamole extended release capsule in the near future.
- f. 
- g. Benzoyl peroxide/clindamycin phosphate topical gel is a combination antiseptic/antibiotic used to treat acne. There are two suppliers of 5%/1% strength benzoyl peroxide/clindamycin phosphate gel, Mylan and Perrigo Company plc (“Perrigo”). Teva participates in

Complaint

the market through a partnership agreement with Perrigo. Allergan is one of a limited number of suppliers likely to enter the generic benzoyl peroxide/clindamycin phosphate topical gel market in the near future. The Acquisition would reduce the number of likely future suppliers for generic benzoyl peroxide/clindamycin phosphate topical gel in the near future.

- h. Budesonide inhalation suspension is a steroid inhalant used for the maintenance treatment of asthma and as prophylactic therapy in children. Only three firms supply 0.25 mg/2 mL and 0.5 mg/2 mL dosage strengths: Allergan, Teva, and Sandoz, Inc. (“Sandoz”). The Acquisition would reduce the number of firms supplying 0.25 mg/2 mL and 0.5 mg/2 mL dosage strengths of generic budesonide inhalation suspensions from three to two. Teva and Sandoz hold approved ANDAs for 1 mg/2 mL generic budesonide inhalant suspension. Allergan is the only supplier entering the 1 mg/2 mL generic budesonide inhalation suspension market in the near future. The acquisition would reduce the number of likely future suppliers of generic budesonide inhalation suspension from three to two in the 1 mg/2 mL strength.

i.



- j. Buprenorphine HCl/naloxone HCl buccal film is used to treat opioid dependence. Teva and Allergan are two of a limited number of suppliers likely to enter the market for generic buprenorphine HCl/naloxone HCl buccal film in the near future. The Acquisition would

Complaint

reduce the number of likely future suppliers for generic buprenorphine HCl/naloxone HCl buccal film.

- k. Bupirone hydrochloride tablets are used to treat anxiety. Four suppliers provide 15 mg generic bupirone hydrochloride tablets: Allergan, Teva, Mylan, and Zydus Pharmaceuticals, Inc. (“Zydus”). Accounting for expected entry in the near future, the Acquisition would reduce the number of likely future suppliers of 15 mg generic bupirone hydrochloride tablets from five to four.
- l. Carbidopa/levodopa tablets are used to treat Parkinson’s disease. Four firms hold approved ANDAs for generic carbidopa/levodopa tablets in the 10 mg/100 mg, 25 mg/100 mg, and 25 mg/250 mg strengths: Allergan, Teva, Mylan, and Sun. The Acquisition would reduce the number of suppliers from four to three.
- m. Clarithromycin extended release tablets are used to treat various bacterial infections. Allergan and Teva are the only firms that supply generic clarithromycin extended release tablets in the 500 mg strength. Accounting for expected entry in the near future, the Acquisition would reduce the number of likely future suppliers of generic clarithromycin 500 mg tablets from three to two.
- n. Clonidine HCl transdermal film is an alpha-agonist hypotensive agent used to treat high blood pressure. Allergan, Teva, and Mylan are the only three firms supplying generic clonidine HCl transdermal film in the 0.1 mg, 0.2 mg, and 0.3 mg per 24-hour strengths. The Acquisition would reduce the number of firms supplying generic clonidine HCl transdermal film from three to two.
- o. Clozapine tablets are used to treat schizophrenia. Four firms supply 25 mg and 100 mg generic clozapine tablets: Allergan, Teva, Mylan, and Sun. Accounting

Complaint

for expected entry, the Acquisition would reduce the number of suppliers for 25 mg and 100 mg generic clozapine tablets from five to four. Teva and Mylan are the only FDA-approved suppliers of 200 mg generic clozapine tablets. Allergan is one of a limited number of suppliers likely to enter the 200 mg generic clozapine tablet market in the near future. The Acquisition would reduce the number of likely future suppliers of generic clozapine tablets in the 200 mg strength market in the near future.

- p. Cyclosporine capsules are used to prevent organ rejection after a transplant. Four firms supply generic cyclosporine oral capsules in the 25 mg and 100 mg strengths: Allergan, Teva, AbbVie, Inc. (“AbbVie”), and Sandoz. The Acquisition would reduce the number of suppliers of generic cyclosporine capsules from four to three in the 25 mg and 100 mg strength markets.
- q. Cyclosporine oral solution is used to prevent organ rejection after a transplant. Only three firms hold ANDAs for 100 mg/mL generic cyclosporine oral solution: Allergan, Teva, and AbbVie. The Acquisition would reduce the number of suppliers of 100 mg/mL generic cyclosporine oral solution from three to two.
- r. Desmopressin acetate tablets are used to treat bedwetting, clotting disorders, and a form of diabetes that causes excessive urination. Three firms supply 0.1 mg generic desmopressin acetate tablets: Allergan, Teva, and Glenmark Pharmaceuticals Ltd. (“Glenmark”). The Acquisition would reduce the number of firms supplying the 0.1 mg strength market from three to two. Four firms supply 0.2 mg generic desmopressin acetate tablets: Allergan, Teva, Glenmark, and Mylan. The Acquisition would reduce the number of suppliers of the 0.2 mg strength tablet from four to three.

Complaint

- s. Desogestrel/ethinyl estradiol tablets (AB-rated to Cyclessa) are oral contraceptives used to prevent pregnancy. Allergan and Teva are the only firms that have approved ANDAs. Allergan sells its product as a branded generic under the name Caziant. The Acquisition would create a monopoly in the market for generic desogestrel/ethinyl estradiol tablets.
- t. Desogestrel/ethinyl estradiol and ethinyl estradiol tablets (AB-rated to Mircette) are oral contraceptives used to prevent pregnancy. There are three competitively significant generic suppliers: Teva, Allergan, and Glenmark. Other firms approved to market the product have negligible sales and market presence. Allergan sells its product as a branded generic under the name Azurette. The Acquisition would reduce the number of competitively significant suppliers from three to two.
- u. Dexmethylphenidate HCl extended release capsules are used to treat ADHD. Four firms—Allergan, Teva, Sandoz, and Mylan—market 5 mg, 10 mg, and 20 mg strength generic dexmethylphenidate HCl extended release capsules. The Acquisition would reduce the number of suppliers of 5 mg, 10 mg, and 20 mg strength generic dexmethylphenidate HCl extended release capsules from four to three. Teva and Allergan are two of a limited number of suppliers likely to enter the market for 25 mg and 35 mg strength generic dexmethylphenidate HCl extended release capsules in the near future. The Acquisition would reduce the number of likely future suppliers for 25 mg and 35 mg strength generic dexmethylphenidate HCl extended release capsules.
- v. Dextroamphetamine sulfate extended release capsules are used to treat ADHD. Four companies supply generic dextroamphetamine sulfate extended release capsules: Allergan, Teva, Mallinckrodt, LLC, and Impax. The Acquisition would reduce the number of suppliers from four to three.

Complaint

- w. Diazepam tablets are used to treat anxiety. Four firms hold ANDAs for 2 mg, 5 mg, and 10 mg generic diazepam tablets: Allergan, Teva, Endo International plc (“Endo”), and Mylan. The Acquisition would reduce the number of suppliers from four to three.
- x. Dienogest/estradiol valerate and estradiol valerate tablets (AB-rated to Natazia) are oral contraceptives used to prevent pregnancy. Teva and Allergan are two of a limited number of suppliers likely to enter the market for generic dienogest/estradiol valerate and estradiol valerate tablets in the near future. The Acquisition would reduce the number of likely future suppliers.
- y. Disopyramide phosphate capsules are used to treat abnormal heart rhythms. Allergan and Teva are the only two firms that hold ANDAs for 100 mg and 150 mg generic disopyramide phosphate capsules. Accounting for expected generic entry, the Acquisition would reduce the number of likely future suppliers from three to two.
- z. Drospirenone/ethinyl estradiol tablets (AB-rated to Yasmin-28) are oral contraceptives used to prevent pregnancy. There are five competitively significant suppliers of Drospirenone/ethinyl estradiol tablets: Allergan, Teva, Lupin Ltd. (“Lupin”), Sandoz, and Glenmark. Other firms approved to market the product have negligible sales and market presence. Allergan sells its product as a branded generic under the name Zarah. The Acquisition would reduce the number of competitively significant competitors from five to four.
- aa. Epirubicin injection is an anthracycline drug used in chemotherapy for the treatment of breast cancer. There are four suppliers of generic epirubicin injection in the 50 mg/25mL and 200 mg/100mL size vials: Allergan, Teva, Cipla and Hospira, Inc. (“Hospira”), the generic injectable division of Pfizer Inc. The

Complaint

Acquisition would reduce the number of suppliers from four to three.

- bb. Estazolam tablets are used for the short-term treatment of sleep disorders. Teva and Allergan are the only two suppliers for 1 mg and 2 mg generic estazolam tablets. The Acquisition would create a monopoly in the market for generic estazolam tablets.
- cc. Estradiol tablets are used to treat symptoms caused by menopause or removal of the ovaries. Three firms sell 0.5 mg, 1 mg, and 2 mg generic estradiol tablets: Allergan, Teva, and Mylan. The Acquisition would reduce the number of suppliers from three to two.
- dd. Ethinyl estradiol/ethynodiol diacetate tablets (AB-rated to Demulen 1/35) are oral contraceptives used to prevent pregnancy. Teva and Allergan are the only generic suppliers. Allergan sells its product as a branded generic under the name Zovia. The Acquisition would create a monopoly in the market for generic ethinyl estradiol/ethynodiol diacetate tablets.
- ee. Ethinyl estradiol/etonogestrel vaginal rings are contraceptives used to prevent pregnancy. Teva and Allergan are two of a limited number of suppliers likely to enter the market in the near future. The Acquisition would reduce the number of likely future suppliers for generic ethinyl estradiol/etonogestrel vaginal rings.
- ff. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Alesse-28) are oral contraceptives used to prevent pregnancy. Five firms supply generic Alesse-28: Allergan, Teva, Endo, Lupin, and Sandoz. Allergan sells its product as a branded generic under the name Lutera. The Acquisition would reduce the number of suppliers from five to four.
- gg. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Levlite-28) are oral contraceptives used to prevent

Complaint

pregnancy. Three firms have ANDAs approved for generic Levlite-28: Allergan, Teva, and Mylan. Allergan sells its product as a branded generic under the name Sronyx. The Acquisition would reduce the number of suppliers from three to two.

- hh. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Lo Seasonique) are oral contraceptives used to prevent pregnancy. Teva owns the branded product and markets an authorized generic. Allergan and Lupin market generic products, which compete directly with Teva's authorized generic. Allergan sells its product as a branded generic under the name Amethia Lo. Accounting for expected entry, the Acquisition would reduce the number of suppliers from four to three.
- ii. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Nordette) are oral contraceptives used to prevent pregnancy. There are five competitively significant suppliers of generic Nordette: Allergan, Teva, Sandoz, Glenmark, and Mylan. Allergan sells its product as a branded generic under the name Levora. The Acquisition would reduce the number of suppliers from five to four.
- jj. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Seasonique) are oral contraceptives used to prevent pregnancy. Teva owns the branded product and markets an authorized generic. Four additional firms supply generic Seasonique: Allergan, Glenmark, Lupin, and Mylan. Allergan sells its product as a branded generic under the name Amethia. The Acquisition would reduce the number of suppliers from five to four.
- kk. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Triphasil-28) are oral contraceptives used to prevent pregnancy. Three firms supply generic Triphasil-28: Allergan, Teva, and Endo. Allergan sells its product as a branded generic under the name Trivora. The

Complaint

Acquisition would reduce the number of suppliers from three to two.

- ll. Ethinyl estradiol/levonorgestrel tablets (AB-rated to Quartette) are oral contraceptives used to prevent pregnancy. Teva and Allergan are two of a limited number of suppliers likely to enter the market for generic Quartette in the near future. The Acquisition would reduce the number of likely future suppliers for generic Quartette.
- mm. Ethinyl estradiol/norethindrone tablets (AB-rated to Modicon-28) are oral contraceptives used to prevent pregnancy. Allergan, Teva, and Mylan market generic Modicon-28. Allergan sells its product as a branded generic under the name Necon. The Acquisition would reduce the number of suppliers from three to two.
- nn. Ethinyl estradiol/norethindrone tablets (AB-rated to Tri-Norinyl 28-Day) are oral contraceptives used to prevent pregnancy. Allergan markets branded Tri-Norinyl 28-Day and an authorized generic, which Allergan sells under the name Leena, and Teva markets the only generic version. The Acquisition would reduce the number of suppliers from two to one.
- oo. Ethinyl estradiol/norethindrone acetate tablets (AB-rated to Loestrin 21 1/20) are oral contraceptives used to prevent pregnancy. There are four suppliers of generic Loestrin 21 1/20: Allergan, Teva, Mylan, and Endo. Allergan sells its product as a branded generic under the name Microgestin 1/20. The Acquisition would reduce the number of suppliers from four to three.
- pp. Ethinyl estradiol/norethindrone acetate tablets (AB-rated to Loestrin 21 1.5/30) are oral contraceptives used to prevent pregnancy. Four firms market generic Loestrin 21 1.5/30: Allergan, Teva, Mylan, and Endo. Allergan sells its product as a branded generic under

Complaint

the name Microgestin 1.5/30. The Acquisition would reduce the number of suppliers from four to three.

- qq. Ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Estrostep FE) are oral contraceptives used to prevent pregnancy. Teva and Allergan, which markets branded Estrostep FE and an authorized generic, are the only suppliers of generic Estrostep FE. Allergan sells its product as a branded generic under the name Tilia Fe. Thus, the Acquisition would create a monopoly in the generic Estrostep FE market.
- rr. Ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Loestrin FE 1/20) are oral contraceptives used to prevent pregnancy. Five firms supply generic Loestrin FE 1/20: Allergan, Teva, Endo, Mylan, and Lupin. Allergan sells its product as a branded generic under the name Microgestin Fe 1/20. The Acquisition would reduce the number of suppliers from five to four.
- ss. Ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Loestrin FE 1.5/30) are oral contraceptives used to prevent pregnancy. Five firms supply generic Loestrin FE 1.5/30: Allergan, Teva, Endo, Lupin, and Mylan. Allergan sells its product as a branded generic under the name Microgestin Fe 1.5/30. The Acquisition would reduce the number of suppliers from five to four.
- tt. Ethinyl estradiol/norgestrel tablets (AB-rated to Lo/Ovral) are an oral contraceptive drug used to prevent pregnancy. Allergan and Teva are the only current suppliers of generic ethinyl estradiol/norgestrel tablets. Allergan sells its product as a branded generic under the name Low-Ogestrel. Accounting for future entry, the Acquisition would reduce the number of current and likely future suppliers from three to two.

Complaint

- uu. Ezetimibe/simvastatin tablets are used to treat high cholesterol. Teva and Allergan are among a limited number of likely future suppliers of generic ezetimibe/simvastatin tablets in the 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, and 10 mg/80 mg strengths. The Acquisition would reduce the number of likely future suppliers for generic ezetimibe/simvastatin tablets.
- vv. Fentanyl buccal tablets are used to treat severe pain. Teva markets the branded product, Fentora, and plans to launch an authorized generic product. Allergan is one of a limited number of future generic fentanyl buccal tablet suppliers. The Acquisition would reduce the number of likely future suppliers for generic fentanyl buccal tablets.
- ww. Fludarabine injection is a chemotherapy drug used to treat chronic lymphocytic leukemia. There are only three independent suppliers of 50 mg lyophilized vials: Allergan, Teva, and Hospira. The Acquisition would reduce the number of independent suppliers from three to two.
- xx. Fluocinonide cream is a steroid used as an anti-inflammatory for the treatment of skin disorders. Three firms market 0.05% generic fluocinonide cream: Teva, Allergan, and Sun, owner of the branded product, which sells an authorized generic. The Acquisition would reduce the number of suppliers from three to two.
- yy. Fluocinonide cream, emulsified base is a steroid used as an anti-inflammatory for the treatment of skin disorders. Only two firms market 0.05% generic fluocinonide emulsified base cream: Teva and Taro, which sells an authorized generic. Allergan is the only supplier likely to enter the market in the near future. The acquisition would reduce the number of likely future suppliers of 0.05% generic fluocinonide emulsified base cream from three to two.

Complaint

- zz. Flutamide capsules are used in hormone-based chemotherapy for the treatment of prostate cancer. Three firms supply 125 mg generic flutamide capsules: Allergan, Teva, and Endo. The Acquisition would reduce the number of suppliers from three to two.
- aaa. Glyburide/metformin HCl tablets are used to treat high blood sugar levels caused by type-2 diabetes. There are four independent suppliers of 1.25/250 mg, 2.5/500 mg, and 5/500 mg generic glyburide/metformin HCl tablets: Allergan, Teva, Aurobindo Pharma Ltd. (“Aurobindo”), and Heritage Pharmaceuticals Inc. (“Heritage”). The Acquisition would reduce the number of suppliers from four to three.
- bbb. Griseofulvin microcrystalline liquid suspension is used to treat fungal infections of the skin, hair, and nails. Allergan, Teva, and Endo supply 125 mg/5mL generic griseofulvin microcrystalline liquid suspension. The proposed Acquisition would reduce the number of suppliers from three to two.
- ccc. Hydroxyzine pamoate capsules are used as a sedative to treat itching, anxiety, and tension caused by allergies. The FDA has approved only four firms to sell 25 mg and 50 mg generic hydroxyzine pamoate capsules: Allergan, Teva, Sandoz, and Heritage. The Acquisition would reduce the number of suppliers from four to three.
- ddd. Imiquimod topical cream is used to treat actinic keratosis. Teva and Allergan are two of a limited number of suppliers likely to enter the market for 3.75% strength generic imiquimod topical cream in the near future. The Acquisition would reduce the number of likely future suppliers for 3.75% strength generic imiquimod topical cream in the near future.
- eee. Levalbuterol HCl inhalation solution is used to prevent or relieve wheezing, shortness of breath, coughing, and chest tightness caused by lung disease such as asthma

Complaint

and COPD. The markets for 0.0103%, 0.0210%, and 0.042% generic levalbuterol HCl solution have four suppliers: Allergan, Teva, Mylan, and Prasco, which distributes an authorized generic. The Acquisition would reduce the number of suppliers from four to three.

fff. Metformin HCl/saxagliptin extended release tablets are used to treat type-2 diabetes. Teva and Allergan are two of a limited number of suppliers likely to enter the market for generic metformin HCl/saxagliptin extended release tablets in the near future. The Acquisition would reduce the number of likely future suppliers for Metformin HCl/saxagliptin extended release tablets in the near future.

ggg. Methotrexate injection is used to treat cancer and severe diseases caused by an overactive immune system. There are four suppliers of 25 mg/mL generic methotrexate injection in the 2mL size vial: Teva, Accord, Hospira, and Mylan. There are four suppliers of 25 mg/mL generic methotrexate in the 10mL size vial: Teva, Accord, Fresenius Kabi, and Mylan. Allergan is the only supplier likely to enter the market in the near future. The acquisition would reduce the number of future suppliers from five to four.

hhh. Methylphenidate HCl extended release tablets are used to treat ADHD. Allergan markets the authorized generic. Teva is one of a limited number of likely future generic suppliers. The Acquisition would reduce the number of likely future suppliers in the near future.

iii. Methylphenidate HCl extended release capsules are used to treat ADHD. Teva and Allergan are two of a limited number of suppliers likely to enter the market for the 10 mg strength in the near future. The Acquisition would reduce the number of likely future suppliers for 10 mg strength. Allergan and Teva are the only firms approved to sell 20 mg, 30 mg, and 40

Complaint

mg generic methylphenidate HCl extended release capsules. Sandoz markets an authorized generic. Allergan and Sandoz supply these markets, and Teva plans to re-launch the product. The acquisition would reduce the number of likely future suppliers of the 20 mg, 30 mg, and 40 mg dosage strengths from three to two.

- jjj. Metoclopramide HCl tablets are used short-term to treat heartburn caused by gastroesophageal reflux. Allergan and Teva are the only independent suppliers of 5 mg strength generic metoclopramide HCl tablets. The Acquisition would create a monopoly in the 5 mg strength market. There are three independent suppliers of 10 mg strength generic metoclopramide HCl tablets: Allergan, Teva, and Endo. The Acquisition would reduce the number of suppliers from three to two in the 10 mg strength market.
- kkk. Minocycline capsules are used to treat a broad spectrum of bacterial infections. Allergan, Teva, Aurobindo, and Sun supply the market with 50 mg, 75 mg, and 100 mg generic minocycline capsules. The Acquisition would reduce the number of suppliers from four to three.
- lll. Mirtazapine oral disintegrating tablets are used to treat major depressive disorder. Allergan, Teva, and Aurobindo hold approved ANDAs for 15 mg, 30 mg, and 45 mg generic mirtazapine oral disintegrating tablets. The Acquisition would reduce the number of suppliers from three to two.
- mmm. NAB paclitaxel injection is a cytotoxic chemotherapy drug used to treat various types of metastatic cancer. Teva and Allergan are two of a limited number of suppliers likely to enter the market for generic NAB paclitaxel injection in the near future. The Acquisition would reduce the number of likely future suppliers for generic NAB paclitaxel injection in the near future.

Complaint

- nnn. Nabumetone tablets are used to reduce pain, swelling, and joint stiffness from arthritis. There are only three suppliers of 500 mg and 750 mg generic nabumetone tablets: Allergan, Teva, and Sandoz. The Acquisition would reduce the number of suppliers from three to two.
- ooo. Nitrofurantoin capsules are used to treat and prevent urinary tract infections. Allergan, Teva, and Mylan hold ANDAs for 50 mg and 100 mg generic nitrofurantoin capsules. Alvogen Group, Inc. sells authorized generic versions of 50 mg and 100 mg nitrofurantoin capsules. The Acquisition would reduce the number of suppliers from four to three.
- ppp. Norethindrone tablets (AB-rated to Micronor 28) are oral contraceptives used to prevent pregnancy. Five firms supply generic Micronor 28: Teva, Glenmark, Lupin, Mylan, and Allergan. Teva sells its product as a branded generic under the name Errin. The Acquisition would reduce the number of suppliers from five to four.
- qqq. Norethindrone tablets (AB-rated to Nor-QD) are oral contraceptives used to prevent pregnancy. Allergan owns and markets the branded product and an authorized generic. Four additional firms supply generic Nor-QD: Teva, Glenmark, Mylan, and Lupin. Teva sells its product as a branded generic under the name Camilla. The Acquisition would reduce the number of generic suppliers from five to four.
- rrr. Nortriptyline HCl capsules are used for the relief of symptoms of depression. Only three firms supply 10 mg, 25 mg, 50 mg, and 75 mg generic nortriptyline HCl capsules: Allergan, Teva, and Taro. The Acquisition would reduce the number of suppliers from three to two.
- sss. Phentermine HCl/topiramate extended release capsules are appetite suppressants used for weight loss. Teva

Complaint

and Allergan are two of a limited number of suppliers likely to enter the market in the near future. The Acquisition would reduce the number of likely future suppliers for generic phentermine HCl/topiramate extended release capsules in the near future.

- ttt. Propofol injection emulsion is a general anesthetic used to induce relaxation and sleepiness before and during surgery and other medical procedures. Allergan, Teva, and Hospira hold approved ANDAs for 10 mg/mL strength generic propofol emulsion injection. Fresenius Kabi owns the branded product, which competes with the generic products. The Acquisition would reduce the number of suppliers from four to three.
- uuu. Propranolol HCl tablets are indicated for the treatment of hypertension. There are four competitively significant firms supplying 10 mg, 20 mg, 40 mg, and 80 mg generic propranolol tablets: Allergan, Teva, Endo, and Mylan. Other firms approved to market the product have negligible sales and market presence. The Acquisition would reduce the number of competitively significant suppliers from four to three.
- vvv. Ramelteon tablets are sedatives used to treat insomnia. Teva and Allergan are two of a limited number of suppliers likely to enter the market for generic ramelteon tablets in the near future. The Acquisition would reduce the number of likely future suppliers for generic ramelteon tablets in the near future.
- www. Rotigotine transdermal patches are used to treat Parkinson's disease. Teva and Allergan are two of a limited number of suppliers likely to enter the generic rotigotine transdermal patch market in the near future. The Acquisition would reduce the number of likely future suppliers of generic rotigotine transdermal patches in the near future.

Complaint

- xxx. Tamoxifen citrate tablets are used to treat breast cancer and to prevent breast cancer in women at high risk of developing it. There are only three firms supplying 10 mg and 20 mg generic tamoxifen citrate tablets: Allergan, Teva, and Mylan. The Acquisition would reduce the number of suppliers from three to two.
- yyy. Tobramycin inhalation solution is an antibiotic used to treat lung infections caused by cystic fibrosis. Three firms have approved ANDAs for 300 mg/5mL tobramycin: Teva, Akorn, Inc., and Amneal Pharmaceuticals (“Amneal”). Sandoz markets an authorized generic. Allergan is the only firm likely to enter in the near future. The Acquisition would reduce the number of likely future suppliers from five to four.
- zzz. Trimethoprim tablets are used to treat and prevent urinary tract infections. Three firms hold approved ANDAs for 100 mg generic trimethoprim tablets: Allergan, Teva, and Novel Laboratories Inc. The Acquisition would reduce the number of suppliers from three to two.
- aaaa. Trimipramine maleate capsules are used to treat symptoms of depression. Teva owns the branded product. Allergan is the only supplier of generic trimethoprim tablets. Thus, the Acquisition would create a monopoly in the market for trimipramine maleate capsules.

8. The structures of the relevant product markets set forth in Paragraph 5 are described below:

- a. Betamethasone dipropionate augmented ointment is a very high potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone dipropionate API to manufacturers of FDA-approved betamethasone dipropionate augmented ointment. While other API suppliers are capable of manufacturing betamethasone dipropionate

Complaint

API, most of Teva's betamethasone dipropionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.

- b. Betamethasone dipropionate cream is a medium potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone dipropionate API to manufacturers of FDA-approved betamethasone dipropionate cream. While other API suppliers are capable of manufacturing betamethasone dipropionate API, most of Teva's betamethasone dipropionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- c. Betamethasone dipropionate lotion is a medium potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone dipropionate API to manufacturers of FDA-approved betamethasone dipropionate lotion. While other API suppliers are capable of manufacturing betamethasone dipropionate API, most of Teva's betamethasone dipropionate API customers can easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- d. Betamethasone dipropionate ointment is a very high potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone dipropionate API to manufacturers of FDA-approved betamethasone dipropionate ointment. While other API suppliers are capable of manufacturing betamethasone dipropionate API, most of Teva's betamethasone dipropionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.

Complaint

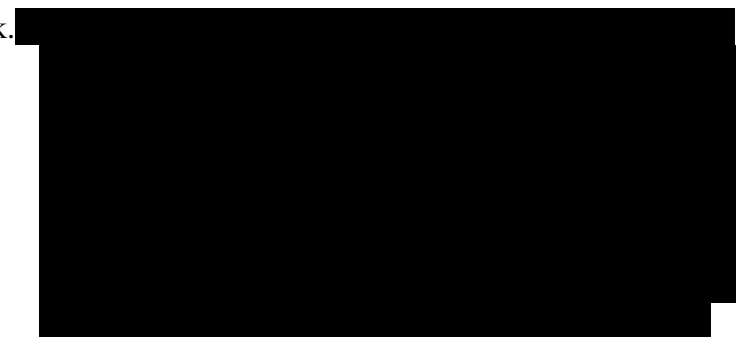
- e. Betamethasone valerate cream is a medium potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone valerate API to manufacturers of FDA-approved betamethasone valerate cream. While other API suppliers are capable of manufacturing betamethasone valerate API, most of Teva's betamethasone valerate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- f. Betamethasone valerate ointment is a medium potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of betamethasone valerate API to manufacturers of FDA-approved betamethasone valerate ointment. While other API suppliers are capable of manufacturing betamethasone valerate API, most of Teva's betamethasone valerate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- g. Clobetasol propionate shampoo is a very high potency corticosteroid indicated for the treatment of scalp psoriasis. Teva is an important supplier of clobetasol propionate API to manufacturers of FDA-approved clobetasol propionate shampoo. While other API suppliers are capable of manufacturing clobetasol propionate API, most of Teva's clobetasol propionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- h. Clobetasol propionate ointment is a very high potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of clobetasol propionate API to manufacturers of FDA-approved clobetasol propionate ointment. While other API suppliers are capable of

Complaint

manufacturing clobetasol propionate API, most of Teva's clobetasol propionate API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.

- i. Desonide cream is a low potency corticosteroid used to treat the swelling, itching, and redness caused by various skin conditions. Teva is an important supplier of desonide API to manufacturers of FDA-approved desonide cream. While other API suppliers are capable of manufacturing desonide API, most of Teva's desonide API customers cannot easily switch to alternative suppliers because a drug manufacturer must use API from a source designated in its ANDA.

j. 

k. 

- l. Probenecid tablets are used in the treatment of chronic gout or gouty arthritis. Teva is an important supplier of probenecid API to manufacturers of FDA-approved

Complaint

probenecid tablets. While other API suppliers are capable of manufacturing probenecid API, most of Teva's probenecid API customers cannot easily switch suppliers because a drug manufacturer must use API from a source designated in its ANDA.

- m. Colchicine/probenecid tablets are used to prevent gout and gouty arthritis in people who have frequent gout attacks. Teva is an important supplier of probenecid API to manufacturers of FDA-approved colchicine/probenecid tablets. While other API suppliers are capable of manufacturing probenecid API, most of Teva's probenecid API customers cannot easily switch suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- n. Nystatin/triamcinolone acetonide cream is used to treat fungal skin infections. Teva is an important supplier of triamcinolone acetonide API to manufacturers of FDA-approved nystatin/triamcinolone acetonide cream. While other API suppliers are capable of manufacturing triamcinolone acetonide API, most of Teva's triamcinolone acetonide API customers cannot easily switch suppliers because a drug manufacturer must use API from a source designated in its ANDA.
- o. Nystatin/triamcinolone acetonide ointment is used to treat fungal skin infections. Teva is an important supplier of triamcinolone API to manufacturers of FDA-approved nystatin/triamcinolone acetonide ointment. While other API suppliers are capable of manufacturing triamcinolone acetonide API, most of Teva's triamcinolone acetonide API customers cannot easily switch suppliers because a drug manufacturer must use API from a source designated in its ANDA.

VI. ENTRY CONDITIONS

9. Entry into the relevant markets listed in Paragraph 4 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the

Complaint

Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would delay entry by at least two years. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

10. Entry into the relevant markets described in Paragraph 5 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would delay entry by at least two years. In addition, it can take up to two years for an API manufacturer to be qualified as a new API supplier on a finished dose form drug manufacturer's ANDA, during which time the drug manufacturer has no alternative to its existing qualified API supplier or suppliers. No other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VII. EFFECTS OF THE ACQUISITION

11. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Teva and Allergan and reducing the number of independent, significant competitors in the markets for (1) generic acitretin capsules; (2) generic alendronate sodium tablets; (3) generic amphetamine aspartate/amphetamine sulfate/dextroamphetamine saccharate/dextroamphetamine sulfate extended release tablets; (4) armodafinil tablets; (5) generic budesonide inhalation suspension; (6) generic buspirone hydrochloride tablets; (7) generic carbidopa/levodopa tablets; (8) generic clarithromycin extended release tablets; (9) generic clonidine HCl

Complaint

transdermal film; (10) generic clozapine tablets; (11) generic cyclosporine capsules; (12) generic cyclosporine oral solution; (13) generic desmopressin acetate tablets; (14) generic desogestrel/ethinyl estradiol tablets (AB-rated to Cyclessa); (15) generic desogestrel/ethinyl estradiol and ethinyl estradiol tablets (AB-rated to Mircette); (16) generic dexmethylphenidate HCl extended release capsules; (17) generic dextroamphetamine sulfate extended release capsules; (18) generic diazepam tablets; (19) generic disopyramide phosphate capsules; (20) generic drospirenone/ethinyl estradiol tablets (AB-rated to Yasmin-28); (21) generic epirubicin injection; (22) generic estazolam tablets; (23) generic estradiol tablets; (24) generic ethinyl estradiol/ethynodiol diacetate tablets (AB-rated to Demulen 1/35); (25) generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Alesse-28); (26) generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Levlite-28); (27) generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Lo Seasonique); (28) generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Nordette); (29) generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Seasonique); (30) generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Triphasil-28); (31) generic ethinyl estradiol/norethindrone tablets (AB-rated to Modicon-28); (32) generic ethinyl estradiol/norethindrone tablets (AB-rated to Tri-Norinyl 28-Day); (33) generic ethinyl estradiol/norethindrone acetate tablets (AB-rated to Loestrin 21 1/20); (34) generic ethinyl estradiol/norethindrone acetate tablets (AB-rated to Loestrin 21 1.5/30); (35) generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Estrostep FE); (36) generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Loestrin FE 1/20); (37) generic ethinyl estradiol/norethindrone acetate/ferrous fumarate tablets (AB-rated to Loestrin FE 1.5/30); (38) generic ethinyl estradiol/norgestrel tablets (AB-rated to Lo/Ovral); (39) generic fludarabine injection; (40)

Complaint

generic fluocinonide cream; (41) generic flutamide capsules; (42) generic glyburide/metformin HCl tablets; (43) generic griseofulvin microcrystalline liquid suspension; (44) generic hydroxyzine pamoate capsules; (45) generic levalbuterol HCl inhalation solution; (46) generic metoclopramide HCl tablets; (47) generic minocycline capsules; (48) generic mirtazapine oral disintegrating tablets; (49) generic nabumetone tablets; (50) generic nitrofurantoin capsules; (51) generic norethindrone tablets (AB-rated to Micronor 28); (52) generic norethindrone tablets (AB-rated to Nor-QD); (53) generic nortriptyline HCl capsules; (54) generic propofol injection emulsion; (55) generic propranolol HCl tablets; (56) generic tamoxifen citrate tablets; (57) generic trimethoprim tablets; and (58) trimipramine maleate capsules, thereby: (a) increasing the likelihood that Teva would be able to unilaterally exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices;

- b. by eliminating future competition between Teva and Allergan and reducing the number of likely future competitors in the markets for (1) generic aspirin/dipyridamole extended release capsules; (2) [REDACTED]; (3) generic benzoyl peroxide/clindamycin phosphate topical gel; (4) generic budesonide inhalation suspension; (5) [REDACTED]; (6) generic buprenorphine HCl/naloxone HCl buccal film; (7) generic clozapine tablets; (8) generic dexmethylphenidate HCl extended release capsules; (9) generic dienogest/estradiol valerate and estradiol valerate tablets (AB-rated to Natazia); (10) generic ethinyl estradiol/etonogestrel vaginal rings; (11) generic ethinyl estradiol/levonorgestrel tablets (AB-rated to Quartette); (12) generic ezetimibe/simvastatin tablets; (13) generic fentanyl buccal tablets; (14)

Complaint

generic fluocinonide cream, emulsified base; (15) generic imiquimod topical cream; (16) generic metformin HCl/saxagliptin extended release tablets; (17) generic methotrexate injection; (18) generic methylphenidate HCl extended release tablets; (19) generic methylphenidate HCl extended release capsules; (20) generic NAB paclitaxel injection; (21) generic phentermine HCl/topiramate extended release capsules; (22) generic ramelteon tablets; (23) generic tobramycin inhalation solution; (24) generic rotigotine transdermal patch, thereby:

(a) increasing the likelihood that the combined entity would forego or delay the launch of these products, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of these products; and

- c. by creating the incentive and ability for Teva, by withholding Teva API products, to foreclose rival suppliers of its newly acquired Allergan finished dose form pharmaceutical products in the markets for (1) betamethasone dipropionate augmented ointment; (2) betamethasone dipropionate cream; (3) betamethasone dipropionate lotion; (4) betamethasone dipropionate ointment; (5) betamethasone valerate cream; (6) betamethasone valerate ointment; (7) clobetasol propionate shampoo; (8) clobetasol propionate ointment; (9) desonide cream; (10) [REDACTED]; (11) [REDACTED]; (12) probenecid tablet; (13) colchicine/probenecid tablet; (14) nystatin/triamcinolone acetonide cream; and (15) nystatin/triamcinolone acetonide ointment, thereby:

(a) increasing the likelihood that Teva would be able to unilaterally exercise market power in these markets; (b) increasing the likelihood and degree of coordinated interaction between or among the remaining

Order to Maintain Assets

competitors; and (c) increasing the likelihood that customers would be forced to pay higher prices.

VIII. VIOLATIONS CHARGED

12. The Acquisition described in Paragraph 3, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-sixth day of July, 2016 issues its Complaint against said Respondent.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Ltd. (“Teva”) of the voting securities of certain entities (defined herein as “Allergan Generic Pharmaceutical Entities”) and related assets from their ultimate parent entity Allergan plc (“Allergan”) (Teva and Allergan hereinafter collectively referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by

Order to Maintain Assets

Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent Teva is a corporation organized, existing, and doing business under and by virtue of the laws of Israel with its principal executive offices located at 5 Basel Street, P.O. Box 3190, Petach Tikva 4951033, Israel, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: General Counsel, Teva Pharmaceutical Industries Ltd., c/o Teva North America, 425 Privet Road, Horsham, Pennsylvania 19044.
2. Respondent Allergan is a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland with its principal executive offices located at Clonshaugh Business and Technology Park, Coolock Dublin, D17 E400, Ireland, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Chief Legal Officer, Allergan plc, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

Order to Maintain Assets

3. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Teva” means: Teva Pharmaceutical Industries Ltd.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Teva Pharmaceutical Industries Ltd. (including, without limitation, TAPI Puerto Rico, Inc., Teva API B.V., Teva API India Limited, Teva API International SA, Teva API Services Mexico, S.de R.L. de C.V.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Teva shall include the Allergan Generic Pharmaceutical Business.
- B. “Allergan” means: Allergan plc; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Allergan plc, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Respondents” means Teva and Allergan, individually and collectively.

Order to Maintain Assets

- E. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order following its issuance and service by the Commission in this matter.
- F. “Divestiture Product Business(es)” means the Business of Respondent (as that Respondent is specified in the definition of each Divestiture Product) within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- G. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- H. “Transition Period” means, for each Divestiture Product that is marketed or sold in the United States before the Closing Date, the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the relevant Acquirer directs the Respondent(s) to cease the marketing, distribution, and sale of such Divestiture Product(s); (ii) the date on which the relevant Acquirer commences the marketing, distribution, and sale of such Divestiture Product(s); or (iii) the date four (4) months after the Closing Date for such Divestiture Product(s).
- I. “Orders” means the Decision and Order and this Order to Maintain Assets.

Order to Maintain Assets

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the related Divestiture Product Businesses.

- B. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:

Order to Maintain Assets

- a. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for such Divestiture Product Business;
- b. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by the Respondents, including, but not limited to, all research, Development, manufacturing, distribution, marketing, and sales expenditures;
- c. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;
- d. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold by Respondents prior to the date the Respondents entered the agreement to effect the Acquisition (as such agreement is identified in the definition of Acquisition), at the related High Volume Accounts;
- e. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and

Order to Maintain Assets

- f. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. Not later than one (1) day after the date this Order to Maintain Assets is issued by the Commission, for each Divestiture Product that has been marketed or sold prior to the Closing Date, Respondents shall provide to the Proposed Acquirer of that Divestiture Product, for each High Volume Account, a list by either SKU or NDC Number containing the current net price per SKU or NDC Number, *i.e.*, the final price per SKU or NDC Number, charged by the relevant Respondent (as that Respondent is identified in the definition of each Divestiture Product) net of all customer-level discounts, rebates, or promotions, for that Divestiture Product, as of five (5) business days or less prior to the date this Order to Maintain Assets is issued.
- E. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondents shall:
- 1. for a period of twelve (12) months from the Closing Date, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter

Order to Maintain Assets

referred to as the “Divestiture Product Core Employee Access Period(s);”

2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer’s or Proposed Acquirer’s written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer’s or Proposed Acquirer’s employees who need such access in connection with the specified and permitted use;
3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including,

Order to Maintain Assets

but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with a Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, a Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit a Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with a Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by a Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and
5. for a period of one (1) year from the Closing Date, not: (i) directly or indirectly solicit or otherwise

Order to Maintain Assets

attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, a Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with that Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that this Paragraph does not require nor shall be construed to require a Respondent to terminate the employment of any employee or to prevent a Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition;

provided further, however, that a Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts a Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from that Respondent.

- F. During the Transition Period, with respect to each Divestiture Product that is marketed or sold in the United States before the Closing Date for that Divestiture Product, Respondents, in consultation with the relevant Acquirer, for the purposes of ensuring an orderly marketing and distribution transition, shall:
1. develop and implement a detailed transition plan to ensure that the commencement of the marketing,

Order to Maintain Assets

distribution, and sale of such Divestiture Products by the Acquirer is not delayed or impaired by the Respondents;

2. designate employees of Respondents knowledgeable about the marketing, distribution, and sale related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer, and the Monitor (if one has been appointed), for the purposes of assisting in the transfer of the Business related to the Divestiture Products to the Acquirer;
3. maintain and manage inventory levels of the Divestiture Products in consideration of the marketing and distribution transition to the Acquirer;
4. continue to market, distribute, and sell the Divestiture Products;
5. allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Acquirer;
6. to the extent known or available to the specified Respondent, provide the Acquirer with a list of the inventory levels (weeks of supply) in the possession of each customer (*i.e.*, retailer, group purchasing organization, wholesaler, or distributor) by stock keeping unit or NDA Number on a regular basis and in a timely manner;

Order to Maintain Assets

7. to the extent known by the specified Respondent, provide the Acquirer with anticipated reorder dates for each customer by stock keeping unit or NDC Number on a regular basis and in a timely manner; and
 8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.
- G. Pending divestiture of the Divestiture Product Assets, Respondents shall:
1. not use, directly or indirectly, any Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
 2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Assets, (ii) other Persons specifically authorized by such Acquirer to receive such information (*e.g.*, employees of the Respondents responsible for the Contract Manufacture or continued Development of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, (iv) the Monitor (if any has been appointed), or (v) Persons necessary to give effect to the Teva Limited License;

Order to Maintain Assets

3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing, sales or Development of the Divestiture Products to the employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products;
 4. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the research and Development of the Development Divestiture Products to any employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products *unless* authorized by the Acquirer of the particular Divestiture Product to do so; and
 5. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- H. Not later than thirty (30) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, each Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or

Order to Maintain Assets

(ii) may have access to such Confidential Business Information.

- I. Each Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Each Respondent shall provide a copy of the notification to the relevant Acquirer. Each Respondent shall maintain complete records of all such notifications at that Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgment program. Each Respondent shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.
- J. Each Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer; to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

Order to Maintain Assets

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Monitor, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondent Teva shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor each Respondent’s compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If a Monitor is appointed, each Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor each Respondent’s compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out

Order to Maintain Assets

the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Monitor shall serve until the divestiture of all Divestiture Product Assets has been completed, and the transfer and delivery of the related Product Manufacturing Technology has been completed, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture that Divestiture Product and able to manufacture the final finished Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Teva; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product;

provided, however, that, with respect to each Divestiture Product, the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books,

Order to Maintain Assets

documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.

- F. The Monitor shall serve, without bond or other security, at the expense of Respondent Teva, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Teva, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Each Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Each Respondent shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the

Order to Maintain Assets

Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by each Respondent of its obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondent Teva has filed its final report pursuant to Paragraph IX.C. of the Decision and Order, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Teva.

- I. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

Order to Maintain Assets

- M. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with the Orders. Each Respondent shall submit at the same time a copy of its report concerning compliance with the Orders to the Monitor, if any Monitor has been appointed. Each Respondent shall include in its reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the relevant Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
- B. a detailed description of the timing for the completion of such obligations.

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission on the same timing as, the reports required to be submitted by Respondents pursuant to Paragraph IX.C. of the Decision and Order.

Order to Maintain Assets

V.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger, or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

Order to Maintain Assets

VII.

IT IS FURTHER ORDERED that Respondent Allergan's obligations under this Order to Maintain Assets shall terminate on the date all of the following have occurred: (i) Respondent Teva has acquired over fifty (50) percent of the voting securities of each of the Allergan Generic Pharmaceutical Entities; (ii) the Closing Dates for the Group A Products, the Group B Products, Group C Products, Group F Products, have occurred; and (iii) Respondent Allergan certifies to the Commission that each of the preceding events have occurred.

VIII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate as to Respondent Teva on the later of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed;
- C. the day after the Product Manufacturing Technology related to each Divestiture Product that is a Contract Manufacture Product or a Pipeline Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to the provision of the Product Manufacturing Technology are complete; or
- D. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

Decision and Order

By the Commission.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Ltd. (“Teva”) of the voting securities of certain entities (defined herein as “Allergan Generic Pharmaceutical Entities”) and related assets from their ultimate parent entity, Respondent Allergan plc (“Allergan”) (Teva and Allergan hereinafter collectively referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted

Decision and Order

the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Teva is a corporation organized, existing, and doing business under and by virtue of the laws of Israel with its principal executive offices located at 5 Basel Street, P.O. Box 3190, Petach Tikva 4951033, Israel, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: General Counsel, Teva Pharmaceutical Industries Ltd., c/o Teva North America, 425 Privet Road, Horsham, Pennsylvania 19044.
2. Respondent Allergan is a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland with its principal executive offices located at Clonsaugh Business and Technology Park, Coolock Dublin, D17 E400, Ireland, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Chief Legal Officer, Allergan plc, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.
3. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

Decision and Order

- A. “Teva” means: Teva Pharmaceutical Industries Ltd.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Teva Pharmaceutical Industries Ltd. (including, without limitation, TAPI Puerto Rico, Inc., Teva API B.V., Teva API India Limited, Teva API International SA, Teva API Services Mexico, S.de R.L. de C.V.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Teva shall include the Allergan Generic Pharmaceutical Business.
- B. “Allergan” means: Allergan plc; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Allergan plc, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Respondents” means Teva and Allergan, individually and collectively.
- E. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer,

Decision and Order

deliver, or otherwise convey pursuant to this Order.

- F. “Acquisition” means Respondent Teva’s acquisition of the Allergan Generic Pharmaceutical Business pursuant to the Acquisition Agreement.
- G. “Acquisition Agreement” means the *Master Purchase Agreement* dated as of July 26, 2015, by and between Allergan plc and Teva Pharmaceutical Industries Ltd., and the *First Amendment to Master Purchase Agreement* dated as of June 9, 2016, that were submitted by Teva to the Commission in this matter. The Acquisition Agreement is contained in Non-Public Appendix I.
- H. “Acquisition Date” means the earlier of the following dates: (i) the date on which Respondent Teva acquires fifty percent (50%) or more of the voting securities of any of the Allergan Generic Pharmaceutical Entities; or (ii) the date on which Respondent Teva acquires any of the assets related to such entities.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- J. “Allergan Generic Pharmaceutical Entities” means the following entities (listed with their respective jurisdiction of incorporation), individually and collectively: Warner Chilcott Company, LLC (Commonwealth of Puerto Rico); Warner Chilcott (Ireland) Limited (Republic of Ireland); Warner Chilcott Australia Pty. Ltd. (Commonwealth of Australia); Warner Chilcott Pharmaceuticals B.V.B.A. (Kingdom of Belgium); Warner Chilcott France SAS

Decision and Order

(French Republic); Warner Chilcott Italy S.r.l (Italian Republic); Actavis Pharma Iberia S.L. (f/k/a Warner Chilcott Iberia S.L.) (Kingdom of Spain); Robin Hood Holdings Ltd. (Republic of Malta); Actavis Holding 2 Sàrl (Grand Duchy of Luxembourg); Actavis S.à.r.l. (Grand Duchy of Luxembourg); Actavis Pharma Holding 4 ehf. (APH4) (Iceland); Forest Laboratories UK Ltd. (United Kingdom of Great Britain and Northern Ireland); Forest Pharma BV (Netherlands); Axcan France (Invest) SAS (French Republic); Forest Tosara Ltd. (Republic of Ireland); and Actavis Holdco US, Inc. (Delaware).

- K. “Allergan Generic Pharmaceutical Business” means:
1. the Allergan Generic Pharmaceutical Entities;
 2. the respective directors, officers, employees, agents, representatives, successors, and assigns of each of the Allergan Generic Pharmaceutical Entities;
 3. the assets acquired or to be acquired by Teva from Allergan pursuant to the Acquisition Agreement and referred to as Transferred Assets in Section 2.1(a) of the Acquisition Agreement; and
 4. the Businesses related to all of the Allergan Generic Pharmaceutical Entities to the extent acquired by Teva.
- L. “API Customer(s)” means any customer who has purchased any of the API Products from Respondent Teva during the period from January 1, 2013 until the Acquisition Date for the purposes of manufacturing any Product that is any of the following: (i) an API Finished Dosage Form Product, (ii) the Therapeutic Equivalent of an API Finished Dosage Form Product, (iii) in Development to become the Therapeutic Equivalent of an API Finished Dosage Form Product.

Decision and Order

- M. “API Product(s)” means, the following active pharmaceutical ingredients, individually and collectively:
1. Betamethasone Dipropionate;
 2. Betamethasone Valerate;
 3. Clobetasol;
 4. Desonide;
 5. Fluocinolone;
 6. Fluorouracil;
 7. Probenecid; and
 8. Triamcinolone.
- N. “API Finished Dosage Form Product(s)” means the following Products or any Product that is the Therapeutic Equivalent of the following Products, individually and collectively:
1. “Betamethasone Dipropionate Product(s)” means the Products manufactured, in Development, marketed, or sold, pursuant to each of the following Applications:
 - a. NDA No. 019137, ANDA No. 070885, and any ANDA that relies on NDA No. 019137 as the Reference Listed Drug. These Products are topically administered creams containing, as an active pharmaceutical ingredient, betamethasone dipropionate, at the following strength: EQ 0.05% Base;
 - b. ANDA No. 070275, ANDA No. 070281, and any ANDA that relies on ANDA No. 070275 as the Reference Listed Drug. These Products

Decision and Order

are topically administered lotions containing, as an active pharmaceutical ingredient, betamethasone dipropionate, at the following strength: EQ 0.05% Base;

- c. NDA No. 019141, ANDA No. 071012, and any ANDA that relies on NDA No. 019141 as the Reference Listed Drug. These Products are topically administered ointments containing, as an active pharmaceutical ingredient, betamethasone dipropionate, at the following strength: EQ 0.05% Base; and
 - d. NDA No. 018741, ANDA No. 074304, and any ANDA that relies on NDA No. 018741 as the Reference Listed Drug. These Products are topically administered ointments (augmented) containing, as an active pharmaceutical ingredient, betamethasone dipropionate, at the following strength: EQ 0.05% Base.
2. “Betamethasone Valerate Product(s)” means the Products manufactured, in Development, marketed, sold pursuant to each of the following Applications:
- a. NDA No. 018865, ANDA No. 070051, and any ANDA that relies on NDA No. 018865 as the Reference Listed Drug. These Products are topically administered ointments containing, as an active pharmaceutical ingredient, betamethasone valerate, at the following strength: EQ 0.1% Base; and
 - b. NDA No. 018861, ANDA No. 070050, and any ANDA that relies on NDA No. 018861 as the Reference Listed Drug. These Products are topically administered creams containing, as an active pharmaceutical ingredient, betamethasone valerate, at the following strength: EQ 0.1% Base.

Decision and Order

3. “Clobetasol Product(s)” means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications:
 - a. NDA No. 021644, ANDA No. 078854 and any ANDA that relies on NDA No. 021644 as the Reference Listed Drug. These Products are topically administered shampoos that contain, as an active pharmaceutical ingredient, clobetasol propionate at the following strength: 0.05%; and
 - b. ANDA No. 074407, and any ANDA that relies on ANDA No. 074407 as the Reference Listed Drug. These Products are topically administered ointments that contain, as an active pharmaceutical ingredient, clobetasol propionate, at the following strength: 0.05%.
4. “Desonide Product(s)” means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications: NDA No. 017010 and any ANDA that relies on NDA No. 017010 as the Reference Listed Drug. These Products are topically administered creams that contain, as an active pharmaceutical ingredient, desonide, at the following strength: 0.05%.
5. “Fluocinolone Product(s)” means the Fluocinolone Products as defined in Non-Public Appendix VI.
6. “Fluorouracil Product(s)” means the Fluorouracil Products as defined in Non-Public Appendix VI.
7. “Probenecid Product(s)” means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications:
 - a. ANDA No. 084211, and any ANDA that relies on ANDA No. 084211 as the Reference Listed

Decision and Order

Drug. These Products are orally administered tablets that contain, as an active pharmaceutical ingredient, probenecid, at the following strengths: 500 mg; and

- b. ANDA No. 084279, and any ANDA that relies on ANDA No. 084279 as the Reference Listed Drug. These Products are orally administered tablets that contain, as active pharmaceutical ingredients, colchicine and probenecid, at the following strengths: 0.5 mg colchicine and 500 mg probenecid.
8. “Triamcinolone Product(s)” means the Products manufactured, in Development, marketed, or sold pursuant to each of the following Applications:
- a. ANDA No. 062364 and any ANDA that relies on ANDA No. 062364 as the Reference Listed Drug. These Products are topically administered creams that contain, as active pharmaceutical ingredients, nystatin and triamcinolone acetonide, at the following strengths: 100,000 units/gm nystatin and 0.1% triamcinolone acetonide; and
 - b. ANDA No. 063305 and any ANDA that relies on ANDA No. 063305 as the Reference Listed Drug. These Products are topically administered ointments that contain, as active pharmaceutical ingredients, nystatin and triamcinolone acetonide, at the following strengths: 100,000 units/gm nystatin and 0.1% triamcinolone acetonide.
- O. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R.

Decision and Order

Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

- P. “Armodafinil Product(s)” means the following: generic versions of the Products manufactured, in Development, marketed, or sold pursuant to the following Application: NDA No. 021875, and any supplements, amendments, or revisions to this NDA that are orally administered tablets containing, as an active pharmaceutical ingredient, armodafinil, at the following strength: 200 mg.
- Q. “Armodafinil Supply Agreement” means the *Armodafinil Supply Agreement* between Cephalon, Inc. and Aurobindo Pharma USA, Inc. dated as of June 9, 2016, and all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement. The Armodafinil Supply Agreement is contained in Non-Public Appendix III. The Armodafinil Supply Agreement that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective is a Remedial Agreement.
- R. “Aurobindo” means Aurobindo Pharma Limited, a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of India with its principal executive offices located at Water Mark Building, Plot No. 11, Survey No. 9,

Decision and Order

Kondapur, Hitech City, Hyderabad – 500 084, Telangana, India. Aurobindo includes its United States subsidiary, Aurobindo Pharma USA, Inc., a Delaware corporation.

- S. “Benzoyl Peroxide/Clindamycin Product Divestiture Agreement” means the *Transfer of Agreement* a.k.a. *Letter Agreement* by and between Perrigo UK Finco Limited Partnership (as successor in interest to Perrigo Netherland BV) and Barr Laboratories, Inc. dated as of June 9, 2016, and all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement. The Benzoyl Peroxide/Clindamycin Product Divestiture Agreement is contained in Non-Public Appendix II.G. The Benzoyl Peroxide/Clindamycin Product Divestiture Agreement that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective is a Remedial Agreement.
- T. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.
- U. “Categorized Assets” means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the Divestiture Product), as such assets and rights are in existence as of the date the specified Respondent signs the Agreement Containing Consent Orders in this matter and to be maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:
1. all rights to all of the Applications related to the specified Divestiture Product;

Decision and Order

2. all rights to all of the Clinical Trials related to the specified Divestiture Product;
3. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
4. all Product Approvals related to the specified Divestiture Product;
5. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
6. all Product Marketing Materials related to the specified Divestiture Product;
7. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
8. all Website(s) related exclusively to the specified Divestiture Product;
9. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
10. for each specified Divestiture Product that has been marketed or sold by the specified Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
 - a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by

Decision and Order

applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;

- b. to prohibit Respondents from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
- c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by a Respondent);
- d. to seek cross-referencing from a customer of the specified Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
- e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and
- f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);

Decision and Order

11. all Product Development Reports related to the specified Divestiture Product;
12. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;
13. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);
14. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date:
 - a. a list of all customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers during the one (1) year period immediately prior to the Closing Date, stated on either an annual, quarterly, or monthly basis, including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
 - b. for each High Volume Account, a list by either SKU or NDC Number containing the following: (i) the net price per SKU or NDC

Decision and Order

Number as of the Closing Date, *i.e.*, the final price per SKU or NDC Number, charged by the specified Respondent net of all customer-level discounts, rebates, or promotions; (ii) the net price per SKU or NDC Number charged by the specified Respondent at the end of each quarter during the one (1) year immediately prior to the Closing Date; (iii) any supply outages by SKU or NDC Number during the one (1) year period immediately prior to the Closing Date the result of which caused the specified Respondent to make a financial payment to the customer or to incur a penalty for a failure to supply; and (iv) to the extent known by the specified Respondent, the status of the Divestiture Product on the customer's respective formulary (*i.e.*, primary, secondary, or backup);

- c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: wholesale acquisition cost; and
 - d. backorders by SKU or NDC Number as of the Closing Date;
15. for each specified Divestiture Product, a list of all suppliers that are listed as a qualified source of the active pharmaceutical ingredient on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product, but only in those instances wherein a Respondent is (i) the holder of the Application for that Retained Product and (ii) the Application is not subject to an exclusive license to a Third Party;
16. a list of each specified Divestiture Product that has had any finished product batch determined to be out-of-specification during the three (3) year

Decision and Order

period immediately preceding the Closing Date, and, for each such Divestiture Product: (i) a detailed description of the deficiencies (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure) with respect to any out-of-specification batch; (ii) the corrective actions taken to remediate the cGMP deficiencies in the Divestiture Product; and (iii) to the extent known by the specified Respondent, the employees (whether current or former) responsible for taking such corrective actions;

17. for each specified Divestiture Product that is a Contract Manufacture Product:
 - a. to the extent known or available to the specified Respondent, a list of the inventory levels (weeks of supply) in the possession of each customer (*i.e.*, retailer, group purchasing organization, wholesaler, or distributor) as of the date prior to and closest to the Closing Date as is available; and
 - b. to the extent known by the specified Respondent, any pending reorder dates for a customer as of the Closing Date;
18. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process, and finished goods related to the specified Divestiture Product;
19. the quantity and delivery terms in all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified

Decision and Order

Divestiture Product not later than five (5) days after the Closing Date;

20. at the option of the Acquirer of the specified Divestiture Product, the right to fill any or all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date; and

21. all of a Respondent's books, records, and files directly related to the foregoing;

provided, however, that "Categorized Assets" shall not include: (i) documents relating to a Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of the specified Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, that Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondents shall

Decision and Order

provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondents provide the Acquirer with the above-described information without requiring a Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- V. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- W. “Cipla” means Cipla Limited, a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of India with its principal executive offices located at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, India 400 013.
- X. “Clinical Plan” means a written clinical plan setting forth the protocol for the conduct of a Clinical Trial, preparation and filing of each Regulatory Package related to such Clinical Trial, and the activities to be conducted by each Person that is a party to conducting such Clinical Trial in support of such Clinical Trial, including the timelines for such Clinical Trial.
- Y. “Clinical Trial(s)” means a controlled study in humans of the safety, efficacy or bioequivalence of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- Z. “Clinical Research Organization Designee(s)” means any Person other than the Respondent that has been designated by an Acquirer to conduct a Clinical Trial related to a Divestiture Product for that Acquirer.

Decision and Order

- AA. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- BB. “Confidential Business Information” means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:
1. information relating to a Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 3. information that is contained in documents, records, or books of a Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
 4. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- CC. “Contract Manufacture” means the following:
1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer (including, without limitation, for the

Decision and Order

purposes of Clinical Trials and/or commercial sales);

2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent of, and in the identical dosage strength, formulation, and presentation as, a Contract Manufacture Product on behalf of an Acquirer; or
3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

DD. “Contract Manufacture Product(s)” means the following Divestiture Products, individually and collectively:

1. Alendronate Products;
2. Carbidopa/Levodopa Products;
3. Clozapine Products;
4. Clozapine II Products;
5. Desmopressin Products;
6. Diazepam Products;
7. Disopyramide Products;
8. Estradiol Products;
9. Ethinyl Estradiol/Etonogestrel Vaginal Ring Products;
10. Ezetimibe/Simvastatin Products;
11. Fentanyl Products;

Decision and Order

12. Glyburide/Metformin Products;
13. Injectable Epirubicin Products;
14. Injectable Fludarabine Products;
15. Injectable Methotrexate Products;
16. Metoclopramide Products;
17. Modified Release Aspirin/Dipyridamole Product(s)
18. Modified Release Clarithromycin Products;
19. Modified Release Dextroamphetamine Products;
20. Modified Release Metformin/Saxagliptin Products;
21. Modified Release Mirtazapine Products;
22. Modified Release Phentermine/Topiramate Products;
23. Nabumetone Products;
24. Nitrofurantoin Products;
25. Nortriptyline Products;
26. OC Desogestrel/Ethinyl Estradiol Azurette Products;
27. OC Desogestrel/Ethinyl Estradiol Caziant Products;
28. OC Drospirenone/Ethinyl Estradiol Zarah Products;
29. OC Estradiol Valerate/Estradiol Valerate/Dienogest Products;

Decision and Order

30. OC Ethinyl Estradiol/Ethinodiol Zovia Products;
31. OC Ethinyl Estradiol/Levonorgestrel Products;
32. OC Ethinyl Estradiol/Levonorgestrel Levora Products;
33. OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Products;
34. OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Products;
35. OC Ethinyl Estradiol/Norethindrone Necon Products;
36. OC Ethinyl Estradiol/Norethindrone Tilia Fe Products;
37. OC Norethindrone Camila Products;
38. OC Norethindrone Errin Products;
39. Propranolol Products;
40. Tamoxifen Products;
41. Trimethoprim Products; and
42. and any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient(s), excipient(s), or packaging materials (including, without limitation, drug vials);

provided, however, that with the consent of the Acquirer of the specified Product, a Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent's agreement to Contract Manufacture.

Decision and Order

- EE. “Development” means all preclinical and clinical drug development activities, including test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- FF. “Development Two Product Divestiture Agreements” means the “Development Two Product Divestiture Agreements” as defined in Non-Public Appendix IV.
- GG. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of a Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.

Decision and Order

HH. “Divestiture Product(s)” means the following, individually and collectively:

1. “Acitretin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 202552, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, acitretin, at the following strengths: 10 mg; 17.5 mg; 22.5 mg; 25 mg.
2. “Alendronate Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 075710, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, alendronate sodium, at the following strengths: EQ 5 mg Base; EQ 10 mg Base; EQ 35 mg Base; EQ 40 mg Base; EQ 70 mg Base.
3. “Benzoyl Peroxide/Clindamycin Product(s)” means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 202440, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered gels and contain, as active pharmaceutical ingredients, benzoyl peroxide and clindamycin phosphate, at the following strength: 5% benzoyl peroxide and EQ 1% Base clindamycin phosphate. The holder of this ANDA is Perrigo.
4. “Budesonide INH Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled

Decision and Order

by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:

- a. ANDA No. 078404, and any supplements, amendments, or revisions to this ANDA. These Products are sterile suspensions administered by inhalation using a nebulizer containing as an active pharmaceutical ingredient, budesonide, at the following strengths: 0.25 mg/2ml; 0.5 mg/2ml; and
 - b. ANDA No. 202558, and any supplements, amendments, or revisions to this ANDA. These Products are sterile suspensions administered by inhalation using a nebulizer containing as an active pharmaceutical ingredient, budesonide, at the following strength: 1.0 mg/2ml.
5. “Buprenorphine/Naloxone Product(s)” the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 022410 (Suboxone) or the Therapeutic Equivalent of Suboxone as the Reference Listed Drug. These Products are films administered either to the buccal area or the sublingual area and contain, as active pharmaceutical ingredients, buprenorphine hydrochloride and naloxone hydrochloride, at the following strengths: EQ 2.0 mg Base buprenorphine hydrochloride and EQ 0.5 mg Base naloxone hydrochloride; EQ 4.0 mg Base buprenorphine hydrochloride and EQ 1.0 mg Base naloxone hydrochloride; EQ 8.0 mg Base buprenorphine hydrochloride and EQ 2 mg Base naloxone hydrochloride; EQ 12.0 mg Base buprenorphine hydrochloride and EQ 3 mg Base naloxone hydrochloride.

Decision and Order

6. “Buspirone Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 074253, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, buspirone hydrochloride, at the following strengths: 5 mg; 10 mg; 15 mg.

7. “Carbidopa/Levodopa Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of the following Applications:
 - a. ANDA No. 073589;
 - b. ANDA No. 073607; and
 - c. ANDA No. 073618;and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as active pharmaceutical ingredients, carbidopa and levodopa, at the following strengths: 10 mg carbidopa and 100 mg levodopa; 25 mg carbidopa and 100 mg levodopa; 25 mg carbidopa and 250 mg levodopa.

8. “Clonidine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Barr) pursuant to the following Application: ANDA No. 079090, and any supplements, amendments, or revisions to this ANDA. These Products are transdermally administered by film (patch) for extended release and contain, as an active pharmaceutical ingredient, clonidine, at the

Decision and Order

following strengths: 0.1 mg/24-hours; 0.2 mg/24-hours; 0.3 mg/24-hours.

9. “Clozapine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Actavis Labs FL Inc.) pursuant to the following Application: ANDA No. 203807, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, clozapine, at the following strengths: 25 mg; 100 mg.
10. “Clozapine II Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan that are orally administered tablets containing, as an active pharmaceutical ingredient, clozapine, at the following strengths: 50 mg; 200 mg.
11. “Cyclosporine LIQ Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 065054, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered solutions containing, as an active pharmaceutical ingredient, cyclosporine, at the following strength: 100 mg/ml.
12. “Cyclosporine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 065044, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical

Decision and Order

ingredient, cyclosporine, at the following strengths: 25 mg; 100 mg.

13. “Desmopressin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 077122, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, desmopressin acetate, at the following strengths: 0.1 mg; 0.2 mg.

14. “Diazepam Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:
 - a. ANDA No. 071134;
 - b. ANDA No. 071135; and
 - c. ANDA No. 071136;and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, diazepam, at the following strengths: 2 mg; 5 mg; 10 mg.

15. “Disopyramide Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:
 - a. ANDA No. 070173; and
 - b. ANDA No. 070174;

Decision and Order

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, disopyramide phosphate, at the following strengths: EQ 100 mg Base; EQ 150 mg Base.

16. “Estazolam Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 074921, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, estazolam, at the following strengths: 1 mg; 2 mg.
17. “Estradiol Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 040114, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, estradiol, at the following strengths: 0.5 mg; 1 mg; 2 mg.
18. “Ethinyl Estradiol/Etonogestrel Vaginal Ring Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 207577, and any supplements, amendments, or revisions to this ANDA. These Products are rings administered to the vaginal area and contain, as an active pharmaceutical ingredients, ethinyl estradiol and etonogestrel, at the following strength: 0.015 mg ethinyl estradiol/ 24-hours and 0.12 mg etonogestrel/24-hours.

Decision and Order

19. “Ezetimibe/Simvastatin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 200909, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ezetimibe and simvastatin, at the following strengths: 10 mg ezetimibe and 10 mg simvastatin; 10 mg ezetimibe and 20 mg simvastatin; 10 mg ezetimibe and 40 mg simvastatin; 10 mg ezetimibe and 80 mg simvastatin.
20. “Fentanyl Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 206329, and any supplements, amendments, or revisions to this ANDA. These Products are sublingually or buccally administered tablets containing, as an active pharmaceutical ingredient, fentanyl citrate, at the following strengths: EQ 0.1 mg Base; EQ 0.2 mg Base; EQ 0.4 mg Base; EQ 0.6 mg Base; EQ 0.8 mg Base.
21. “Fluocinonide Emulsified Product(s)” means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 074204, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered creams containing, as an active pharmaceutical ingredient, fluocinonide (emulsified base), at the following strength: 0.05%. The holder of this ANDA is G & W Laboratories.
22. “Fluocinonide Product(s)” means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 073085, and any

Decision and Order

supplements, amendments, or revisions to this ANDA. These Products are topically administered creams containing, as an active pharmaceutical ingredient, fluocinonide, at the following strength: 0.05%. The holder of this ANDA is G & W Laboratories.

23. “Flutamide Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 075780, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, flutamide, at the following strength: 125 mg.
24. “Glyburide/Metformin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 076345, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, glyburide and metformin hydrochloride, at the following strengths: 1.25 mg glyburide and 250 mg metformin; 2.5 mg glyburide and 500 mg metformin hydrochloride; 5 mg glyburide and 500 mg metformin.
25. “Griseofulvin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Ivax) pursuant to the following Application: ANDA No. 065354, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered liquid suspensions containing, as an active pharmaceutical ingredient, griseofulvin (micro size), at the following strength: 125 mg/5ml.

Decision and Order

26. “Hydroxyzine Pamoate Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 040156, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, hydroxyzine pamoate, at the following strengths: EQ 25 mg HCL; EQ 50 mg HCL.
27. “Imiquimod Product(s)” means the following: the Products manufactured, in Development, marketed, or sold pursuant to the following Application: ANDA No. 206671, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered creams containing, as an active pharmaceutical ingredient, imiquimod, at the following strength: 3.75%. The holder of this ANDA is G & W Laboratories.
28. “Injectable Epirubicin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of the following Applications: ANDA No. 065331, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection (packaged in vials) and contain, as an active pharmaceutical ingredient, epirubicin hydrochloride, at the following strengths: 2 mg/ ml (50 mg/25 ml; 200 mg/100 ml).
29. “Injectable Fludarabine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of the following Applications:

Decision and Order

- a. ANDA No. 076349, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection (packaged in vials) and contain, as an active pharmaceutical ingredient, fludarabine phosphate (lyophilized), at the following strength: 50 mg;
 - b. ANDA No. 076661. These Products are administered by injection (packaged in vials) and contain, as an active pharmaceutical ingredient, fludarabine phosphate (liquid), at the following strength: 50 mg/2ml (25 mg/ml).
30. “Injectable Methotrexate Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 203407, and any supplements, amendments, or revisions to this ANDA. These Products are administered by injection and contain, as an active pharmaceutical ingredient, methotrexate, at the following strength: 50 mg/2 ml; 250 mg/10 ml; 500 mg/20 ml; 1000 mg/40 ml (25 mg/1 ml).
31. “Injectable Paclitaxel Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are administered by intravenous infusion and contain, as an active pharmaceutical ingredient, paclitaxel (lyophilized -for injectable suspension), at the following strength: 100 mg/vial.
32. “Injectable Propofol Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 075102, and any supplements, amendments, or revisions to this ANDA. These

Decision and Order

Products are administered by injection and contain, as an active pharmaceutical ingredient, propofol, at the following strength: 10 mg/ml.

33. “Levalbuterol Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 077756, and any supplements, amendments, or revisions to this ANDA. These Products are solutions administered by inhalation containing, as an active pharmaceutical ingredient, levalbuterol hydrochloride, at the following strengths: EQ 0.021% Base; EQ 0.042% Base; EQ 0.0103% Base.
34. “Metoclopramide Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:
- a. ANDA No. 072750; and
 - b. ANDA No. 071250;
- and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, metoclopramide, at the following strength: EQ 5 mg Base; EQ 10 mg Base.
35. “Minocycline Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 063011, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active

Decision and Order

pharmaceutical ingredient, minocycline hydrochloride, at the following strength: EQ 50 mg Base; EQ 75 mg Base; EQ 100 mg Base.

36. “Modified Release Amphetamine Sulfate Product(s)” means the Products manufactured, in Development, marketed, or sold pursuant to the following Application: NDA No. 021303, and any supplements, amendments, or revisions to this NDA. These Products are orally administered extended release capsules containing, as an active pharmaceutical ingredients, amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate and dextroamphetamine sulfate, at the following strengths: 1.25 mg amphetamine aspartate, 1.25 mg amphetamine sulfate, 1.25 mg dextroamphetamine saccharate, and 1.25 mg dextroamphetamine sulfate; 2.5 mg amphetamine aspartate, 2.5 mg amphetamine sulfate, 2.5 mg dextroamphetamine saccharate, and 2.5 mg dextroamphetamine sulfate; 3.75 mg amphetamine aspartate, 3.75 mg amphetamine sulfate, 3.75 mg dextroamphetamine saccharate, and 3.75 mg dextroamphetamine sulfate; 5 mg amphetamine aspartate, 5 mg amphetamine sulfate, 5 mg dextroamphetamine saccharate, and 5 mg dextroamphetamine sulfate; 6.25 mg amphetamine aspartate, 6.25 mg amphetamine sulfate, 6.25 mg dextroamphetamine saccharate, and 6.25 mg dextroamphetamine sulfate; 7.5 mg amphetamine aspartate, 7.5 mg amphetamine sulfate, 7.5 mg dextroamphetamine saccharate, and 7.5 mg dextroamphetamine sulfate. The holder of this NDA is Shire.
37. “Modified Release Aspirin/Dipyridamole Product(s)” means the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 206964, and any supplements,

Decision and Order

amendments, or revisions to this ANDA. These Products are orally administered extended release capsules containing, as active pharmaceutical ingredients, aspirin and dipyridamole, at the following strength: 25 mg aspirin and 200 mg dipyridamole.

38. “Modified Release Clarithromycin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 065154, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release tablets containing, as an active pharmaceutical ingredient, clarithromycin, at the following strength: 500 mg.
39. “Modified Release Dexmethylphenidate Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 079108, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release capsules containing, as an active pharmaceutical ingredient, dexmethylphenidate hydrochloride, at the following strengths: 5 mg; 10 mg; 15 mg; 20 mg; 30 mg. The Modified Release Dexmethylphenidate Products also include the orally administered extended release capsules containing, as an active pharmaceutical ingredient, dexmethylphenidate hydrochloride, that are in Development at the following strengths: 25 mg; 35 mg.
40. “Modified Release Dextroamphetamine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Barr) pursuant to

Decision and Order

the following Application: ANDA No. 076137, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release capsules containing, as an active pharmaceutical ingredient, dextroamphetamine sulfate, at the following strengths: 5 mg; 10 mg; 15 mg.

41. “Modified Release Metformin/Saxagliptin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 200678 (Kombiglyze XR) or the Therapeutic Equivalent of Kombiglyze XR as the Reference Listed Drug. These Products are orally administered extended release tablets containing, as active pharmaceutical ingredients, metformin hydrochloride and saxagliptin hydrochloride, at the following strengths: 500 mg metformin hydrochloride and EQ 5 mg Base saxagliptin hydrochloride; 1 gm metformin hydrochloride and EQ 5 mg Base saxagliptin; 1 gm metformin hydrochloride and EQ 2.5 mg Base saxagliptin.

42. “Modified Release Methylphenidate CAP Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Applications:

a. ANDA No. 078458,

b. ANDA No. 200886;

and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release capsules containing, as an active pharmaceutical ingredient,

Decision and Order

methylphenidate hydrochloride, and that are the Therapeutic Equivalent of Ritalin LA (NDA No. 021284) at the following strengths: 10 mg; 20 mg; 30 mg; 40mg; 60 mg.

43. “Modified Release Methylphenidate TAB Product(s)” means the following: the Products manufactured, in Development, marketed, sold, that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 021121 (Concerta) or the Therapeutic Equivalent of Concerta as the Reference Listed Drug. These Products are orally administered extended release tablets containing, as an active pharmaceutical ingredient, methylphenidate hydrochloride, at the following strengths: 18 mg; 27 mg; 36 mg; 54 mg.
44. “Modified Release Mirtazapine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 076901, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets (orally disintegrating) containing, as an active pharmaceutical ingredient, mirtazapine, at the following strengths: 15 mg; 30 mg; 45 mg.
45. “Modified Release Phentermine/Topiramate Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 022580 (Qsymia) or the Therapeutic Equivalent of Qsymia as the Reference Listed Drug. These Products are orally administered extended release capsules containing, as active pharmaceutical ingredients, phentermine hydrochloride and topiramate, at the following strengths: EQ 3.75 mg phentermine hydrochloride and 23 mg topiramate; EQ 7.5 mg phentermine

Decision and Order

hydrochloride and 46 mg topiramate; EQ 11.25 mg phentermine hydrochloride and 69 mg topiramate; EQ 15 mg phentermine hydrochloride and 92 mg topiramate.

46. “Nabumetone Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 075189, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, nabumetone, at the following strengths: 500 mg; 750 mg.
47. “Nitrofurantoin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of the following Applications:
- a. ANDA No. 073671;
 - b. ANDA No. 073652;
- and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, nitrofurantoin macrocrystalline, at the following strengths: 50 mg; 100 mg.
48. “Nortriptyline Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to each of the following Applications:
- a. ANDA No. 073553;
 - b. ANDA No. 073554;

Decision and Order

c. ANDA No. 073555; and

d. ANDA No. 073556;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, nortriptyline hydrochloride at the following strengths: EQ 10 mg Base; EQ 25 mg Base; EQ 50 mg Base; and EQ 75 mg Base.

49. “OC Desogestrel/Ethinyl Estradiol Azurette Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 076916, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, desogestrel and ethinyl estradiol, at the following strengths: 0.15 mg desogestrel and 0.02 mg ethinyl estradiol; 0.01 mg ethinyl estradiol.

50. “OC Desogestrel/Ethinyl Estradiol Caziant Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 077182, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, desogestrel and ethinyl estradiol, at the following strengths: 0.1 mg desogestrel and 0.025 mg ethinyl estradiol; 0.125 mg desogestrel and 0.025 mg ethinyl estradiol; 0.15 mg desogestrel and 0.025 mg ethinyl estradiol.

Decision and Order

51. “OC Drospirenone/Ethinyl Estradiol Zarah Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 090081, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, drospirenone and ethinyl estradiol, at the following strength: 3.0 mg drospirenone and 0.03 mg ethinyl estradiol.
52. “OC Estradiol Valerate/Estradiol Valerate/Dienogest Product(s)” means the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 202999, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, estradiol valerate and dienogest, at the following strengths: 3 mg estradiol valerate; 2 mg estradiol valerate and 2 mg dienogest; 2 mg estradiol valerate and 3 mg dienogest; 1 mg estradiol valerate.
53. “OC Ethinyl Estradiol/Ethinodiol Zovia Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 072721, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and ethynodiol diacetate, at the following strength: 0.035 mg ethinyl estradiol and 1 mg ethynodiol diacetate.

Decision and Order

54. “OC Ethinyl Estradiol/Levonorgestrel Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 206201, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and levonorgestrel, at the following strengths: 0.02 mg ethinyl estradiol and 0.15 mg levonorgestrel; 0.025 mg ethinyl estradiol and 0.15 mg levonorgestrel; 0.03 mg ethinyl estradiol and 0.15 mg levonorgestrel; 0.01 mg ethinyl estradiol (with no levonorgestrel).
55. “OC Ethinyl Estradiol/Levonorgestrel Levora Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 073594, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and levonorgestrel, at the following strength: 0.03 mg ethinyl estradiol and 0.15 mg levonorgestrel.
56. “OC Ethinyl Estradiol/Levonorgestrel Sronyx Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 077681, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and levonorgestrel, at the following strength: 0.02 mg ethinyl estradiol and 0.1 mg levonorgestrel.

Decision and Order

57. “OC Ethinyl Estradiol/Levonorgestrel Trivora Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 074538, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and levonorgestrel, at the following strengths: 0.03 mg ethinyl estradiol and 0.05 mg levonorgestrel; 0.04 mg ethinyl estradiol and 0.075 mg levonorgestrel; 0.03 mg ethinyl estradiol and 0.125 mg levonorgestrel.
58. “OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Actavis Labs UT Inc.) pursuant to the following Application: NDA No. 018977, and any supplements, amendments, or revisions to this NDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and norethindrone acetate, at the following strengths: 0.035 mg ethinyl estradiol and 0.5 mg norethindrone; 0.035 mg ethinyl estradiol and 1.0 mg norethindrone. (sold as *Tri-Norinyl* and *Leena*)
59. “OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 075647, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and norethindrone acetate, at the following strength: 0.02 mg ethinyl

Decision and Order

estradiol and 1.0 mg norethindrone acetate. (sold as *Microgestin 1/20*(*Microgestin 21*) and *Microgestin Fe 1/20* (*Microgestin Fe 21*)).

60. “OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: No. 075548, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and norethindrone acetate, at the following strength: 0.03 mg ethinyl estradiol and 1.5 mg norethindrone acetate. (sold as *Microgestin 1.5/30* (*Microgestin*) and *Microgestin Fe 1.5/30* (*Microgestin Fe*)).
61. “OC Ethinyl Estradiol/Norethindrone Necon Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 070686, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and norethindrone, at the following strength: 0.035 mg ethinyl estradiol and 0.5 mg norethindrone.
62. “OC Ethinyl Estradiol/Norethindrone Tilia Fe Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 076629, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical

Decision and Order

ingredients, ethinyl estradiol and norethindrone acetate, at the following strengths: 0.02 mg ethinyl estradiol and 1.0 mg norethindrone acetate; 0.03 mg ethinyl estradiol and 1.0 mg norethindrone acetate; and 0.035 mg ethinyl estradiol and 1.0 mg norethindrone acetate.

63. “OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 075288, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, ethinyl estradiol and norgestrel, at the following strength: 0.03 mg ethinyl estradiol and 0.3 mg norgestrel.
64. “OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 078834, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, levonorgestrel and ethinyl estradiol, at the following strengths: 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol; 0.01 ethinyl estradiol.
65. “OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 200407. These Products are orally administered tablets

Decision and Order

containing, as active pharmaceutical ingredients, levonorgestrel and ethinyl estradiol, at the following strengths: 0.1 mg levonorgestrel; 0.02 mg ethinyl estradiol; 0.01 mg ethinyl estradiol.

66. “OC Levonorgestrel/Ethinyl Estradiol Luteru Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan (Watson Laboratories, Inc.) pursuant to the following Application: ANDA No. 076625, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as active pharmaceutical ingredients, levonorgestrel and ethinyl estradiol, at the following strength: 0.10 mg levonorgestrel and 0.02 mg ethinyl estradiol.
67. “OC Norethindrone Camila Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Barr) pursuant to the following Application: ANDA No. 076177, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, norethindrone, at the following strength: 0.35 mg.
68. “OC Norethindrone Errin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Barr) pursuant to the following Application: ANDA No. 076225, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, norethindrone, at the following strength: 0.35 mg.

Decision and Order

69. “Propranolol Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva (Pliva) pursuant to each of the following Applications:

- a. ANDA No. 071972;
- b. ANDA No. 071973;
- c. ANDA No. 071974;
- d. ANDA No. 071975; and
- e. ANDA No. 071976;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, propranolol hydrochloride, at the following strengths: 10 mg; 20 mg; 40 mg; 60 mg; 80 mg.

70. “Ramelteon Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: ANDA No. 091693, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, ramelteon, at the following strength: 8 mg.

71. “Rotigotine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva that are the subject of an ANDA or to be the subject of an ANDA that relies on NDA No. 021829 (Neupro) or the Therapeutic Equivalent of Neupro as the Reference Listed Drug. These Products are transdermally administered by film (patch) for

Decision and Order

extended release and contain, as an active pharmaceutical ingredient, rotigotine, at the following strengths: 1 mg/24-hours; 2mg/24-hours; 3 mg/24-hours; 4 mg/24-hours; 6 mg/24-hours; 8 mg/24-hours.

72. “Tamoxifen Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to each of the following Applications:

a. ANDA No. 075797; and

b. ANDA No. 074858;

and any supplements, amendments, or revisions to these ANDAs. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, tamoxifen citrate at the following strengths: EQ 10 mg Base; and EQ 20 mg Base.

73. “Tobramycin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Allergan pursuant to the following Application: ANDA No. 207080, and any supplements, amendments, or revisions to this ANDA. These Products are solutions administered by inhalation and contain, as an active pharmaceutical ingredient, tobramycin, at the following strength: 300 mg/5ml.

74. “Trimethoprim Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Teva pursuant to the following Application: NDA No. 018679, and any supplements, amendments, or revisions to this NDA. These Products are orally administered tablets containing, as an active

Decision and Order

pharmaceutical ingredient, trimethoprim, at the following strength: 100 mg.

75. “Trimipramine Product(s)” means the following: the Products manufactured, in Development, marketed, or sold, pursuant to the following Application: ANDA No. 077361, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered capsules containing, as an active pharmaceutical ingredient, trimipramine maleate, at the following strengths: EQ 25 mg Base; EQ 50 mg Base; EQ 100 mg Base. The holder of this ANDA is Mikah Pharma.
 76. “Development Divestiture Product(s)” means each of the Development Divestiture Products as defined in Non-Public Appendix IV.
- II. “Divestiture Product Assets” means the following, individually and collectively:
1. “Acitretin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Acitretin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Acitretin Products.
 2. “Alendronate Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Alendronate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Alendronate Products.
 3. “Benzoyl Peroxide/Clindamycin Product Assets” means all rights, title, and interest in and to all assets related to the Business related to the

Decision and Order

Benzoyl Peroxide/Clindamycin Products to the extent that such rights are owned, controlled, or held by Teva under the *Development, Manufacturing and Commercialization Agreement* between Perrigo Netherlands BV and Barr Laboratories, Inc., dated as of September 7, 2007, and all amendments, exhibits, attachments to the *Development, Manufacturing and Commercialization Agreement* executed prior to the termination of this agreement. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.G.

4. “Budesonide INH Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Budesonide INH Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Budesonide INH Products.
5. “Buprenorphine/Naloxone Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Buprenorphine/Naloxone Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Buprenorphine/Naloxone Products.
6. “Buspirone Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Buspirone Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Buspirone Products.
7. “Carbidopa/Levodopa Product Assets” means all rights, title, and interest in and to all assets related

Decision and Order

to the Business of Teva within the United States of America related to each of the Carbidopa/Levodopa Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Carbidopa/Levodopa Products.

8. “Clonidine Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Clonidine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Clonidine Products. Clonidine Product Assets also includes all manufacturing equipment owned or controlled by Teva that is used in the manufacture of the Clonidine Products that is located in the facility of Corium International, Inc. in Grand Rapids, Michigan (4558 50th Street).
9. “Clozapine Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Clozapine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Clozapine Products.
10. “Clozapine II Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Clozapine II Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Clozapine II Products.
11. “Cyclosporine LIQ Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Cyclosporine LIQ Products, to the extent legally

Decision and Order

transferable, including, without limitation, the Categorized Assets related to the Cyclosporine LIQ Products.

12. “Cyclosporine Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Cyclosporine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Cyclosporine Products.
13. “Desmopressin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Desmopressin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Desmopressin Products.
14. “Diazepam Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Diazepam Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Diazepam Products.
15. “Disopyramide Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Disopyramide Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Disopyramide Products.
16. “Estazolam Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Estazolam Products, to the extent legally transferable, including,

Decision and Order

without limitation, the Categorized Assets related to the Estazolam Products.

17. “Estradiol Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Estradiol Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Estradiol Products.
18. “Ethinyl Estradiol/Etonogestrel Vaginal Ring Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Ethinyl Estradiol/Etonogestrel Vaginal Ring Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ethinyl Estradiol/Etonogestrel Vaginal Ring Products.
19. “Ezetimibe/Simvastatin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Ezetimibe/Simvastatin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ezetimibe/Simvastatin Products
20. “Fentanyl Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Fentanyl Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Fentanyl Products; *provided, however*, “Fentanyl Product Assets” *excludes* Patents that are owned, controlled or held by Teva on or before the Closing Date related to the Retained Product *Fentora*® (NDA No. 021947), and such Patents

Decision and Order

are not included in the Product Licensed Intellectual Property related to the Fentanyl Product(s).

21. “Fluocinonide Emulsified Product Assets” means all rights, title, and interest in and to all assets related to the Business related to the Fluocinonide Emulsified Products to the extent that such rights are owned, controlled, or held by Allergan under the *Amended and Restated Supply Agreement* by and between Actavis Pharma Inc., Actavis Mid Atlantic LLC, and G&W Laboratories, Inc., dated as of December 19, 2014, as amended February 5, 2015. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.B.
22. “Fluocinonide Product Assets” means all rights, title, and interest in and to all assets related to the Business related to the Fluocinonide Products to the extent that such rights are owned, controlled, or held by Allergan under the *Amended and Restated Supply Agreement* by and between Actavis Pharma Inc., Actavis Mid Atlantic LLC, and G&W Laboratories, Inc., dated as of December 19, 2014, as amended February 5, 2015. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.A.
23. “Flutamide Product Assets” means all rights, title and interest in and to all assets related to the Business related to the Flutamide Products to the extent that such rights are owned, controlled, or held by Teva under the *Supply and Distribution Agreement* between Zenith Goldline Pharmaceutical Inc. and Cipla Limited, dated as of May 14, 2001, and all amendments, exhibits, attachments to the *Supply and Distribution Agreement* executed prior to the termination of this agreement. This agreement was submitted to the

Decision and Order

Commission by Respondent Teva and is contained in Non-Public Appendix II.D.

24. “Glyburide/Metformin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Glyburide/Metformin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Glyburide/Metformin Products.
25. “Griseofulvin Product Assets” means all rights, title and interest in and to all assets related to the Business related to the Griseofulvin Products to the extent that such rights are owned, controlled, or held by Teva under the *Development and Supply Agreement* between Ivax Pharmaceutical, Inc. and Cipla Ltd., dated as of January 3, 2004, and all amendments, exhibits, attachments to the *Development and Supply Agreement* executed prior to the termination of this agreement. This agreement was submitted to the Commission by Respondent Teva and is contained in Non-Public Appendix II.D.
26. “Hydroxyzine Pamoate Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Hydroxyzine Pamoate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Hydroxyzine Pamoate Products.
27. “Imiquimod Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Imiquimod Products, to the extent legally transferable,

Decision and Order

including, without limitation, the Categorized Assets related to the Imiquimod Products.

28. “Injectable Epirubicin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Injectable Epirubicin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Epirubicin Products.
29. “Injectable Fludarabine Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Injectable Fludarabine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Fludarabine Products.
30. “Injectable Methotrexate Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Methotrexate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Methotrexate Products.
31. “Injectable Paclitaxel Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Injectable Paclitaxel Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Paclitaxel Products.
32. “Injectable Propofol Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of

Decision and Order

America related to each of the Injectable Propofol Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Injectable Propofol Products.

33. “Levalbuterol Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Levalbuterol Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Levalbuterol Products.
34. “Metoclopramide Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Metoclopramide Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Metoclopramide Products.
35. “Minocycline Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Minocycline Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Minocycline Products.
36. “Modified Release Amphetamine Sulfate Product Assets” means all rights, title and interest in and to all assets related to the Business related to the Amphetamine Sulfate Products to the extent that such rights are owned, controlled, or held by Teva under the *Adderall XR Distribution and Supply Agreement*, by and between Shire LLC and Teva Pharmaceuticals USA, Inc., dated as of November 8, 2013 and all amendments, exhibits, attachments to the *Adderall XR Distribution and Supply Agreement* executed prior to the termination of this agreement by Teva and its re-execution by an

Decision and Order

Acquirer. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.J.

37. “Modified Release Aspirin/Dipyridamole Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Modified Release Aspirin/Dipyridamole Product Assets, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Aspirin/Dipyridamole Products.
38. “Modified Release Clarithromycin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Clarithromycin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Clarithromycin Products.
39. “Modified Release Dexmethylphenidate Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Modified Release Dexmethylphenidate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Dexmethylphenidate Products.
40. “Modified Release Dextroamphetamine Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Dextroamphetamine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Dextroamphetamine Products.

Decision and Order

41. “Modified Release Metformin/Saxagliptin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Metformin/Saxagliptin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Metformin/Saxagliptin Products.
42. “Modified Release Methylphenidate CAP Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Modified Release Methylphenidate CAP Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Methylphenidate CAP Products.
43. “Modified Release Methylphenidate TAB Product Assets” means all rights, title and interest in and to all assets related to the Business related to the Modified Release Methylphenidate TAB Products to the extent that such rights are owned, controlled, or held by Teva pursuant to the *Strategic Alliance Agreement* between Teva Pharmaceuticals Curacao N.V. and Impax Laboratories, Inc. dated as of June 27, 2001, and all amendments, exhibits, attachments to the *Strategic Alliance Agreement* to the extent related to the Methylphenidate TAB Products executed prior to the termination of this agreement as it pertains to the Methylphenidate TAB Products. This agreement was submitted to the Commission by Respondent Teva and is contained in Non-Public Appendix II.B.
44. “Modified Release Mirtazapine Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the

Decision and Order

Modified Release Mirtazapine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Mirtazapine Products.

45. “Modified Release Phentermine/Topiramate Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Modified Release Phentermine/Topiramate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Modified Release Phentermine/Topiramate Products.
46. “Nabumetone Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Nabumetone Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Nabumetone Products.
47. “Nitrofurantoin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Nitrofurantoin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Nitrofurantoin Products.
48. “Nortriptyline Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Nortriptyline Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Nortriptyline Products.
49. “OC Desogestrel/Ethinyl Estradiol Azurette Product Assets” means all rights, title, and interest

Decision and Order

in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Desogestrel/Ethinyl Estradiol Azurette Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Desogestrel/Ethinyl Estradiol Azurette Products which include all rights to the *Azurette*® Product Trademark.

50. “OC Desogestrel/Ethinyl Estradiol Caziant Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Desogestrel/Ethinyl Estradiol Caziant Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Desogestrel/Ethinyl Estradiol Caziant Products, which include all rights to the *Caziant*® Product Trademark.
51. “OC Drospirenone/Ethinyl Estradiol Zarah Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Drospirenone/Ethinyl Estradiol Zarah Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Drospirenone/Ethinyl Estradiol Zarah Products which include all rights to the *Zarah*® Product Trademark.
52. “OC Estradiol Valerate/Estradiol Valerate/Dienogest Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the OC Estradiol Valerate/Estradiol Valerate/Dienogest Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the

Decision and Order

OC Estradiol Valerate/Estradiol
Valerate/Dienogest Products.

53. “OC Ethinyl Estradiol/Ethinodiol Zovia Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Ethinodiol Zovia Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Ethinodiol Zovia Products which include all rights to the *Zovia*® Product Trademark.
54. “OC Ethinyl Estradiol/Levonorgestrel Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Products; ; *provided, however, “OC Ethinyl Estradiol/Levonorgestrel Product Assets” excludes Patents that are owned, controlled or held by Teva on or before the Closing Date related to the Retained Product *Quartette*® (NDA No. 204061), and such Patents are not included in the Product Licensed Intellectual Property related to the OC Ethinyl Estradiol/Levonorgestrel Product(s).*
55. “OC Ethinyl Estradiol/Levonorgestrel Levora Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Levora Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Levora

Decision and Order

Products which include all rights to the *Levora*® Product Trademark.

56. “OC Ethinyl Estradiol/Levonorgestrel Sronyx Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Sronyx Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Sronyx Products which include all rights to the *Sronyx*® Product Trademark.
57. “OC Ethinyl Estradiol/Levonorgestrel Trivora Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Levonorgestrel Trivora Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Levonorgestrel Trivora Products which include all rights to the *Trivora*® Product Trademark.
58. “OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Products which include all rights to the *Tri-Norinyl*® and *Leena*® Product Trademarks.
59. “OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Product Assets” means all rights, title, and

Decision and Order

interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Products which include all rights to the *Microgestin*® Product Trademark.

60. “OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Products.
61. “OC Ethinyl Estradiol/Norethindrone Necon Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norethindrone Necon Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norethindrone Necon Products which include all rights to the *Necon*® Product Trademark.
62. “OC Ethinyl Estradiol/Norethindrone Tilia Fe Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norethindrone Tilia Fe Products, to the

Decision and Order

extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norethindrone Tilia Fe Products which include all rights to the *Tilia*® Product Trademark.

63. “OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Products which include all rights to the *Low-Ogestrel*® Product Trademark.
64. “OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Products which include all rights to the *Amethia*® Product Trademark.
65. “OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC

Decision and Order

Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol
Amethia Lo Products.

66. “OC Levonorgestrel/Ethinyl Estradiol Lutera Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the OC Levonorgestrel/Ethinyl Estradiol Lutera Product, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Levonorgestrel/Ethinyl Estradiol Lutera Products which include all rights to the *Lutera*® Product Trademark.
67. “OC Norethindrone Camila Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to OC Norethindrone Camila Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Norethindrone Camila Products which include all rights to the *Camila*® Product Trademark.
68. “OC Norethindrone Errin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to OC Norethindrone Errin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the OC Norethindrone Errin Products which include all rights to the *Errin*® Product Trademark.
69. “Propranolol Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Propranolol Products, to the extent legally transferable,

Decision and Order

including, without limitation, the Categorized Assets related to the Propranolol Products.

70. “Ramelteon Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Ramelteon Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ramelteon Products.
71. “Rotigotine Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Rotigotine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Rotigotine Products.
72. “Tamoxifen Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Tamoxifen Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Tamoxifen Products.
73. “Tobramycin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Allergan within the United States of America related to each of the Tobramycin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Tobramycin Products.
74. “Trimethoprim Product Assets” means all rights, title, and interest in and to all assets related to the Business of Teva within the United States of America related to each of the Trimethoprim Products, to the extent legally transferable,

Decision and Order

including, without limitation, the Categorized Assets related to the Trimethoprim Products.

75. “Trimipramine Product Assets” means all rights, title and interest in and to all assets related to the Business related to the Trimipramine Products to the extent such rights are owned, controlled, or held by Allergan pursuant to the *Supply and Distribution Agreement* by and between Actavis, Inc. and Mikah Pharma, LLC, dated as of November 21, 2011, and all amendments, exhibits, attachments to the *Supply and Distribution Agreement* executed prior to the termination of this agreement. This agreement was submitted by Respondents to the Commission and is contained in Non-Public Appendix II.I.
76. “Development Divestiture Product Assets” means each of the Development Divestiture Product Assets as defined in Non-Public Appendix IV.
- JJ. “Divestiture Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Contract Manufacture Product.
- KK. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, held, or controlled by a Respondent:
1. to research and Develop the specified Divestiture Product(s) for marketing, distribution, or sale within the United States of America;
 2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the United States of America;

Decision and Order

3. to import or export the specified Divestiture Product(s) to or from the United States of America to the extent related to the marketing, distribution, or sale of the specified Divestiture Products in the United States of America; and
4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale within, or import into the United States of America;

provided, however, that for any Product Licensed Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by a Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

- LL. “Divestiture Product Releasee(s)” means the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
 2. any Person controlled by or under common control with that Acquirer;
 3. Clinical Trial Research Organization Designee(s); and
 4. any Manufacturing Designee(s), licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- MM. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph VI of this Order.

Decision and Order

- NN. “Domain Name” means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- OO. “Drug Master File(s)” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- PP. “Dr. Reddy’s” means Dr. Reddy’s Laboratories S.A., a corporation organized, existing, and doing business under and by virtue of the laws of the Swiss Confederation with its principal executive offices located at Elisabethenanlage 11, 4051 Basel, Switzerland.
- QQ. “G & W Laboratories” means G & W Laboratories, a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey with its principal executive offices located at 111 Coolidge Street, South Plainfield, New Jersey 07080-3895.
- RR. “Good Clinical Practices” means then-current standards, practices and promulgated or endorsed by (i) International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use; (ii) the FDA; and (iii) any applicable Laws for the country(ies) within which a Clinical Trial is being conducted.
- SS. “Government Entity” means any Federal, state, local, or non-U.S. government; any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.

Decision and Order

- TT. “Group A Product(s)” means the following Divestiture Products, individually and collectively:
1. Carbidopa/Levodopa Products;
 2. Clonidine Products;
 3. Clozapine Products;
 4. Clozapine II Products;
 5. Cyclosporine Products;
 6. Cyclosporine LIQ Products;
 7. Diazepam Products;
 8. Disopyramide Products;
 9. Estazolam Products;
 10. Estradiol Products;
 11. Fentanyl Products;
 12. Fluocinonide Products;
 13. Modified Release Clarithromycin Products;
 14. Modified Release Dextroamphetamine Products;
 15. Modified Release Methylphenidate CAP Products;
 16. Nortriptyline Products;
 17. OC Desogestrel/Ethinyl Estradiol Azurette Products;
 18. OC Desogestrel/Ethinyl Estradiol Caziant Products;

Decision and Order

19. OC Drospirenone/Ethinyl Estradiol Zarah Products;
20. OC Estradiol Valerate/Estradiol Valerate/Dienogest Products;
21. OC Ethinyl Estradiol/Ethinodiol Zovia Products;
22. OC Ethinyl Estradiol/Levonorgestrel Products;
23. OC Ethinyl Estradiol/Levonorgestrel Levora Products;
24. OC Ethinyl Estradiol/Levonorgestrel Sronyx Products;
25. OC Ethinyl Estradiol/Levonorgestrel Trivora Products;
26. OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Products;
27. OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Products;
28. OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Products
29. OC Ethinyl Estradiol/Norethindrone Necon Products;
30. OC Ethinyl Estradiol/Norethindrone Tilia Fe Products;
31. OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Products;
32. OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Products;

Decision and Order

33. OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Products;
 34. OC Levonorgestrel/Ethinyl Estradiol Lutera Products;
 35. OC Norethindrone Camila Products;
 36. OC Norethindrone Errin Products;
 37. Tamoxifen Products; and
 38. Trimethoprim Products.
- UU. “Group A Product Assets” means the following Divestiture Product Assets, individually and collectively:
1. Carbidopa/Levodopa Product Assets;
 2. Clonidine Product Assets;
 3. Clozapine Product Assets;
 4. Clozapine II Product Assets;
 5. Cyclosporine Product Assets;
 6. Cyclosporine LIQ Product Assets;
 7. Diazepam Product Assets;
 8. Disopyramide Product Assets;
 9. Estazolam Product Assets;
 10. Estradiol Product Assets;
 11. Fentanyl Product Assets;
 12. Fluocinonide Product Assets;

Decision and Order

13. Modified Release Clarithromycin Product Assets;
14. Modified Release Dextroamphetamine Product Assets;
15. Modified Release Methylphenidate CAP Product Assets;
16. Nortriptyline Product Assets;
17. OC Desogestrel/Ethinyl Estradiol Azurette Product Assets;
18. OC Desogestrel/Ethinyl Estradiol Caziant Product Assets;
19. OC Drospirenone/Ethinyl Estradiol Zarah Product Assets;
20. OC Estradiol Valerate/Estradiol Valerate/Dienogest Product Assets;
21. OC Ethinyl Estradiol/Ethinodiol Zovia Product Assets;
22. OC Ethinyl Estradiol/Levonorgestrel Product Assets;
23. OC Ethinyl Estradiol/Levonorgestrel Levora Product Assets;
24. OC Ethinyl Estradiol/Levonorgestrel Sronyx Product Assets;
25. OC Ethinyl Estradiol/Levonorgestrel Trivora Product Assets;
26. OC Ethinyl Estradiol/Norethindrone Tri-Norinyl Product Assets;

Decision and Order

27. OC Ethinyl Estradiol/Norethindrone Microgestin 1/20 Product Assets;
 28. OC Ethinyl Estradiol/Norethindrone Microgestin 1.5/30 Product Assets;
 29. OC Ethinyl Estradiol/Norethindrone Necon Product Assets;
 30. OC Ethinyl Estradiol/Norethindrone Tilia Fe Product Assets;
 31. OC Ethinyl Estradiol/Norgestrel Low-Ogestrel Product Assets;
 32. OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Product Assets;
 33. OC Levonorgestrel/Ethinyl Estradiol/Ethinyl Estradiol Amethia Lo Product Assets;
 34. OC Levonorgestrel/Ethinyl Estradiol Lutera Product Assets;
 35. OC Norethindrone Camila Product Assets;
 36. OC Norethindrone Errin Product Assets;
 37. Tamoxifen Product Assets; and
 38. Trimethoprim Product Assets.
- VV. “Group A Product Divestiture Agreements” means the following:
1. *Asset Purchase Agreement* between Teva Pharmaceutical Industries Ltd., Mayne Pharma LLC, and Mayne Pharma Inc., dated as of June 27, 2016;

Decision and Order

2. *Supply Agreement* between Teva Pharmaceutical Industries Ltd. and Mayne Pharma Inc., attached to the preceding *Asset Purchase Agreement*;
3. *Asset Purchase Agreement* among Actavis Elizabeth LLC, Actavis Holdco US, Inc., Actavis Laboratories FL, Inc., Actavis Laboratories UT, Inc., Actavis Mid Atlantic LLC, Actavis Pharma, Inc., Actavis South Atlantic LLC, Andrx LLC, Warner Chilcott Company, LLC, Watson Laboratories, Inc., Mayne Pharma LLC and Mayne Pharma Inc., dated as of June 27, 2016;
4. *Supply Agreement* among Actavis Elizabeth LLC, Actavis Holdco US, Inc., Actavis Laboratories FL, Inc., Actavis Laboratories UT, Inc., Actavis Mid Atlantic LLC, Actavis Pharma, Inc., Actavis South Atlantic LLC, Andrx LLC, Warner Chilcott Company, LLC, Watson Laboratories, Inc., and Mayne Pharma Inc., attached to the preceding *Asset Purchase Agreement*; and
5. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group A Product Divestiture Agreements are contained in Non-Public Appendix II.A. The Group A Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

WW. "Group B Product(s)" means the following Divestiture Products, individually and collectively:

1. Acitretin Products;
2. Alendronate Products;

Decision and Order

3. Budesonide INH Products;
 4. Buspirone Products;
 5. Desmopressin Products;
 6. Development One Products;
 7. Fluocinonide Emulsified Products;
 8. Glyburide/Metformin Products;
 9. Hydroxine Pamoate Products;
 10. Injectable Epirubicin Products;
 11. Levalbuterol Products;
 12. Metoclopramide Products;
 13. Modified Release Aspirin/Dipyridamole Products;
 14. Modified Release Dexmethylphenidate Products;
 15. Modified Release Methylphenidate TAB Products;
 16. Modified Release Mirtazapine Products;
 17. Nabumetone Products;
 18. Nitrofurantoin Products; and
 19. Propranolol Products.
- XX. “Group B Product Assets” means the following Divestiture Product Assets, individually and collectively:
1. Acitretin Product Assets;
 2. Alendronate Product Assets;

Decision and Order

3. Budesonide INH Product Assets;
4. Buspirone Product Assets;
5. Desmopressin Product Assets;
6. Development One Product Assets;
7. Fluocinonide Emulsified Product Assets;
8. Glyburide/Metformin Product Assets;
9. Hydroxine Pamoate Product Assets;
10. Injectable Epirubicin Product Assets;
11. Levalbuterol Product Assets;
12. Metoclopramide Product Assets;
13. Modified Release Aspirin/Dipyridamole Product Assets;
14. Modified Release Dexmethylphenidate Product Assets;
15. Modified Release Methylphenidate TAB Product Assets;
16. Modified Release Mirtazapine Product Assets;
17. Nabumetone Product Assets;
18. Nitrofurantoin Product Assets; and
19. Propranolol Product Assets.

Decision and Order

YY. “Group B Product Divestiture Agreements” means the following:

1. *Asset Purchase Agreement* between Teva Pharmaceutical Industries Ltd. and Impax Laboratories, Inc. dated as of June 20, 2016;
2. *Supply Agreement* between Teva Pharmaceutical Industries Ltd. and Impax Laboratories, Inc., attached to the preceding *Asset Purchase Agreement*;
3. *Asset Purchase Agreement* among Actavis Elizabeth LLC, Actavis Group PTC EHF, Actavis Holdco US, Inc., Actavis LLC, Actavis Mid Atlantic LLC, Actavis Pharma, Inc., Actavis South Atlantic LLC, Andrx LLC, Breath Ltd., The Rugby Group, Inc., Watson Laboratories, Inc. and Impax Laboratories, Inc., dated as of June 20, 2016;
4. *Supply Agreement* among Actavis Elizabeth LLC, Actavis Group PTC EHF, Actavis Holdco US, Inc., Actavis LLC, Actavis Mid Atlantic LLC, Actavis Pharma, Inc., Actavis South Atlantic LLC, Andrx LLC, Breath Ltd., The Rugby Group, Inc., Watson Laboratories, Inc. and Impax Laboratories, Inc., attached to the preceding *Asset Purchase Agreement*;
5. *Termination of Agreements (Methylphenidate HCL ER)* by and between Impax Laboratories, Inc. and Teva Pharmaceuticals USA, Inc., dated as of June 20, 2016; and
6. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group B Product Divestiture Agreements are contained in Non-Public Appendix II.B. The Group B Product Divestiture Agreements that have been

Decision and Order

approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

ZZ. "Group C Product(s)" means the following Divestiture Products, individually and collectively:

1. Injectable Fludarabine Products;
2. Injectable Methotrexate Products; and
3. Injectable Propofol Products.

AAA. "Group C Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Injectable Fludarabine Product Assets;
2. Injectable Methotrexate Product Assets; and
3. Injectable Propofol Product Assets.

BBB. "Group C Product Divestiture Agreements" means the following:

1. *Asset Purchase Agreement* between Teva Pharmaceutical Industries, Ltd. and Sagent Pharmaceuticals, Inc. dated as of June 15, 2016;
2. *Supply Agreement* between Teva Pharmaceutical Industries, Ltd. and Sagent Pharmaceuticals, Inc., attached to the preceding *Asset Purchase Agreement*;
3. *Asset Purchase Agreement* among Actavis Group PTC EHF, Actavis LLC and Sagent Pharmaceuticals, Inc., dated as of June 15, 2016;

Decision and Order

4. *Supply Agreement* among Actavis Group PTC EHF, Actavis LLC and Sagent Pharmaceuticals, Inc. attached to the preceding *Asset Purchase Agreement*; and
5. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group C Product Divestiture Agreements are contained in Non-Public Appendix II.C. The Group C Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

CCC. "Group D Product(s)" means the following Divestiture Products, individually and collectively:

1. Flutamide Products;
2. Griseofulvin Products; and
3. Injectable Paclitaxel Products.

DDD. "Group D Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Flutamide Product Assets;
2. Griseofulvin Product Assets; and
3. Injectable Paclitaxel Product Assets.

EEE. "Group D Product Divestiture Agreements" means the following:

1. *Buy-Back of Asset* by and between Pharmachemie B.V. and Cipla Limited, dated as of June 9, 2016,

Decision and Order

that makes reference to the *Development, License, Manufacture and Commercial Supply Agreement* by and between Pharmachemie B.V. and Cipla Limited dated as of October 1, 2014.

2. *Sale of ANDA Documentation and Termination of related Agreements (Griseofulvin OS Microcrystalline and Flutamine Capsules)* between Teva Pharmaceuticals USA, Inc., Ivax Pharmaceuticals NV, LLC, and Cipla Limited, dated as of June 15, 2016; and
3. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group D Product Divestiture Agreements are contained in Non-Public Appendix II.D. The Group D Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

FFF. "Group E Product(s)" means the following Divestiture Products, individually and collectively:

1. Minocycline Products; and
2. Rotigotine Products.

GGG. "Group E Product Assets" means the following Divestiture Product Assets, individually and collectively:

1. Minocycline Product Assets; and
2. Rotigotine Product Assets.

Decision and Order

HHH. “Group E Product Divestiture Agreements” means the following:

1. *Asset Purchase Agreement* between Teva Pharmaceutical Industries Ltd. and Zydus Worldwide DMCC dated as of June 16, 2016;
2. *Supply Agreement* between Teva Pharmaceutical Industries Ltd. and Zydus Worldwide DMCC, attached to the preceding *Asset Purchase Agreement*; and
3. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group E Product Divestiture Agreements are contained in Non-Public Appendix II.E. The Group E Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective are Remedial Agreements.

III. “Group F Product(s)” means the following Divestiture Products, individually and collectively:

1. Buprenorphine/Naloxone Products;
2. Ethinyl Estradiol/Etonogestrel Vaginal Ring Products;
3. Ezetimbe/Simvastin Products;
4. Imiquimod Products;
5. Modified Release Metformin/Saxagliptin Products;
6. Modified Release Phentermine/Topiramate Products;

Decision and Order

7. Ramelteon Products; and

8. Tobramycin Products.

JJJ. “Group F Product Assets” means the following Divestiture Product Assets, individually and collectively:

1. Buprenorphine/Naloxone Product Assets;
2. Ethinyl Estradiol/Etonogestrel Vaginal Ring Product Assets;
3. Ezetimbe/Simvastin Product Assets;
4. Imiquimod Product Assets;
5. Modified Release Metformin/Saxagliptin Product Assets;
6. Modified Release Phentermine/Topiramate Product Assets;
7. Ramelteon Product Assets; and
8. Tobramycin Product Assets.

KKK. “Group F Product Divestiture Agreements” means the following:

1. *Asset Purchase Agreement* between Teva Pharmaceutical Industries Ltd. and Dr. Reddy’s Laboratories S.A., dated as of June 10, 2016;
2. *Supply Agreement* between Teva Pharmaceutical Industries Ltd. and Dr. Reddy’s Laboratories S.A., attached to the preceding *Asset Purchase Agreement*;

Decision and Order

3. *Asset Purchase Agreement* between Watson Laboratories, Inc. and Dr. Reddy's Laboratories S.A., dated as of June 10, 2016; and
4. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group F Product Divestiture Agreements are contained in Non-Public Appendix II.F. The Group F Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

LLL. "High Volume Account(s)" means any retailer, wholesaler, or distributor whose annual or projected annual purchase amounts, in units or in dollars, of a Divestiture Product in the United States of America from a Respondent, was or was forecasted (prior to the contemplation of the Acquisition and subsequent divestiture) to be among the top twenty (20) highest such purchase amounts of that Respondent's total sales of that Divestiture Product to U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; (iv) for forecasts of purchases of the Divestiture Product, the quarter immediately following the Closing Date.

MMM. "Impax" means Impax Laboratories, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 30831 Huntwood Avenue, Hayward, California 94544.

Decision and Order

- NNN. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- OOO. “Manufacturing Designee” means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- PPP. “Mayne” means Mayne Pharma Group Limited, a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Australia with its principal executive offices located at 1538 Main North Road, Salisbury South, SA 5106, Australia. “Mayne” includes Mayne Pharma Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of North Carolina with its principal executive offices located at 1240 Sugg Parkway, Greenville, North Carolina 27834 and Mayne Pharma, LLC, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 1240 Sugg Parkway, Greenville, NC 27834.
- QQQ. “Mikah Pharma” means Mikah Pharma, LLC, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 20 Kilmer Drive, Hillsborough, New Jersey 08844.
- RRR. “Modified Release Amphetamine Sulfate Product Divestiture Agreements” means the following:
1. *Asset Purchase Agreement* by and between Teva Pharmaceuticals USA, Inc. and Prasco, LLC and dated as of June 16, 2016; and
 2. *Termination of Distribution and Supply Agreement* by Teva Pharmaceuticals USA, Inc., accepted and agreed to by Shire LLC, dated as of June 16, 2016,

Decision and Order

that makes reference to the *Adderall XR Distribution and Supply Agreement*, by and between Shire LLC and Teva Pharmaceuticals USA, Inc., dated as of November 8, 2013, (and which is necessary to effect the divestiture to Prasco, LLC).

The Modified Release Amphetamine Sulfate Product Divestiture Agreements are contained in Non-Public Appendix II.J. The Modified Release Amphetamine Sulfate Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

- SSS. "Monitor" means any monitor appointed pursuant to Paragraph V of this Order or Paragraph III of the related Order to Maintain Assets.
- TTT. "NDC Number(s)" means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- UUU. "Orders" means this Decision and Order and the related Order to Maintain Assets.
- VVV. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.
- WWW. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- XXX. "Patent(s)" means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or

Decision and Order

before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

YYY. “Perrigo” means Perrigo Company plc, a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland with its principal executive offices located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland. Perrigo includes Perrigo Israel Pharmaceuticals Limited.

ZZZ. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups, or affiliates thereof.

AAAA. “Pipeline External Manufacture Products” means, the following Divestiture Products, individually and collectively:

1. Budesonide INH Products (ANDA Number 202558);
2. Buprenorphine/Naloxone Products;
3. Cyclosporine Liquid Products;
4. Development Two Products;
5. Injectable Paclitaxel Products;
6. Fluocinonide Products;
7. Imiquimod Products;

Decision and Order

8. Modified Release Dexmethylphenidate Products;
9. Ramelteon Products;
10. Rotigotine Products; and
11. Tobramycin Products.

BBBB. "Pipeline Internal Manufacture Products" means, the following Divestiture Products, individually and collectively:

1. Clozapine II Products;
2. Ethinyl Estradiol/Etonogestrel Vaginal Ring Products;
3. Ezetimibe/Simvastatin Products;
4. Fentanyl Products;
5. Injectable Methotrexate Products;
6. Modified Release Aspirin/Dipyridamole Products;
7. Modified Release Metformin/Saxagliptin Products;
8. Modified Release Phentermine/Topiramate Products;
9. OC Ethinyl Estradiol/Levonorgestrel Products; and
10. OC Estradiol Valerate/Ethinyl Estradiol Valerate/Dienogest Products.

CCCC. "Prasco" means Prasco LLC, a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio with its principal executive offices located at 6125 Commerce Court, Mason, Ohio 45040.

Decision and Order

DDDD. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.

EEEE. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any Application related to that Product.

FFFF. “Product Contracts” means all contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent unless such contract applies generally to a Respondent’s sales of Products to that Third Party;
2. pursuant to which a Respondent had or has as of the Closing Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party, for use in connection with the manufacture of the specified Divestiture Product;

Decision and Order

3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the specific marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished dosage form Product on behalf of a Respondent;
7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of a Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;
9. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology related to the specified Divestiture Product;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the

Decision and Order

specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements; and/or

13. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), a Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

GGGG. "Product Copyrights" means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the United States of America, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and all educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing, or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto, and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports, and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and

Decision and Order

marketing materials, that Product's sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

HHHH. "Product Development Reports" means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including Reference Listed Drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including Reference Listed Drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;

Decision and Order

5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including,

Decision and Order

without limitation, identification and sources of impurities;

15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;
17. manufacturing batch records related to the specified Divestiture Product;
18. stability testing records related to the specified Divestiture Product;
19. change in control history related to the specified Divestiture Product; and
20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

III. “Product Employee Information” means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by a Respondent within ninety (90) days of the execution date of any Remedial Agreement); and
2. with respect to each such employee, the following information:
 - a. direct contact information for the employee, including telephone number;

Decision and Order

- b. the date of hire and effective service date;
 - c. job title or position held;
 - d. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, a Respondent may provide the employee's most recent performance appraisal;
 - e. the base salary or current wages;
 - f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
 - g. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
 - h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.
- JJJJ. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Licensed Intellectual Property) that is owned, licensed, held, or controlled by a Respondent as of the Closing Date:
1. Patents;
 2. Product Copyrights;

Decision and Order

3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof, and to bring suit against a Third Party for the past, present, or future infringement, misappropriation, dilution, misuse, or other violation of any of the foregoing;

provided, however, that “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Teva”, “Allergan”, or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by a Respondent or the related corporate logos thereof; or general registered images or symbols by which Teva or Allergan can be identified or defined.

KKKK. “Product Licensed Intellectual Property” means the following:

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, held, or controlled by a Respondent as of the Closing Date, as follows:
 - a. Patents that are related to a Divestiture Product that a Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued or withdrawn) NDA or ANDA as of the Acquisition Date; and
 - b. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business,

Decision and Order

research, Development, and other information, and all rights in the United States of America to limit the use or disclosure thereof, that are related to a Divestiture Product and that a Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued or withdrawn) NDA or ANDA as of the Acquisition Date; and

2. in those instances in which (i) a Respondent is the holder of an NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product that is the subject of an ANDA, (ii) the NDA is not subject to an exclusive license to a Third Party, and (iii) the Product subject to such NDA is a Retained Product, a full, complete, and unlimited Right of Reference or Use to the Drug Master File related to the NDA for this Retained Product to reference or use in any Application related to that Divestiture Product.

LLLL. "Product Manufacturing Employees" means all salaried employees of a Respondent who have directly participated in any of the following: (i) defining the commercial manufacturing process, (ii) confirming that the manufacturing process is capable of reproducible commercial manufacturing, (iii) formulating the manufacturing process performance qualification protocol, (iv) controlling the manufacturing process to assure performance Product quality, (v) assuring that during routine manufacturing the process remains in a state of control, (vi) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently delivering quality Products, (vii) managing the operation of the manufacturing process, or (viii) managing the technological transfer of the manufacturing process to a different facility, of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of

Decision and Order

working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

MMMM. “Product Manufacturing Technology” means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients, or packaging materials; and
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer’s option, all such equipment used to manufacture that Product.

NNNN. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the United States of America as of the Closing Date, including, without

Decision and Order

limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

OOOO. “Product Research and Development Employees” means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or Clinical Trials of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

PPPP. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.

QQQQ. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging and the lettering of the Product trade name or brand name.

RRRR. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and

Decision and Order

applications for registration therefor (and all renewals, modifications, and extensions thereof), and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.

SSSS. “Proposed Acquirer” means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed pursuant to this Order.

TTTT. “Reference Listed Drug” or “RLD” means the listed drug identified by the FDA as the drug product upon which an applicant for an ANDA relies in seeking approval of the applicant’s ANDA.

UUUU. “Regulatory Package” means, with respect to each Divestiture Product, all Applications and other regulatory applications submitted to any Agency, Product Approvals, pre-clinical and clinical data and information, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. 314.420 (or any non-United States equivalent thereof)), and any other reports, records regulatory correspondence and other materials relating to Product Approvals of such Divestiture Product or required to Develop, manufacture, distribute or otherwise commercialize such Divestiture Product, including information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database, in each case that is necessary or reasonably useful to the Clinical Trial(s).

VVVV. “Remedial Agreement(s)” means the following:

1. any agreement between a Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments,

Decision and Order

exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement to supply specified Products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

2. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
3. any agreement between a Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including, without limitation, any agreement by that Respondent to supply specified Products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of that Respondent related to a Divestiture Product to

Decision and Order

the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

WWWW. “Retained Product(s)” means any Product(s) other than a Divestiture Product.

XXXX. “Right of Reference or Use” means the authority to rely upon, and otherwise use all of the following:

1. an investigation of the quality, safety, or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials);
2. Product Development Reports; or
3. Product Scientific and Regulatory Material;

for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

YYYY. “Sagent” means Sagent Pharmaceuticals, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 1901 N. Roselle Road, Suite 700, Schaumburg, Illinois 60195.

ZZZZ. “Shire” means Shire PLC, a corporation organized, existing, and doing business under and by virtue of the laws of Jersey (Channel Islands) with its principal executive offices located at 5 Riverwalk, Citywest Business Campus, Dublin 24, Republic of Ireland.

AAAAA. “SKU” means stock keeping unit.

Decision and Order

BBBBB. “Supply Cost” means a cost not to exceed any of the following: (i) a Respondent’s average direct cost per SKU or NDC Number in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date, or (ii) a Respondent’s lowest net price (*i.e.*, the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent’s top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers) for the relevant Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product, but only if the “Supply Cost” specified in such Remedial Agreement during the first twelve (12) month period of a Respondent supplying the Contract Manufacture Product does not exceed a Respondent’s lowest net price (*i.e.*, the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent’s top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers) for the relevant Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date.

CCCCC. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and

Decision and Order

meaningful manner. Such standards and requirements shall include, *inter alia*:

1. designating employees of a Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee;
4. permitting employees of the relevant Acquirer to visit the Respondent's facility from which the Divestiture Product will be transferred for the purposes of evaluating and learning the manufacturing process of such Divestiture Product and/or discussing the process with employees of Respondent involved in the manufacturing process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, methods to ensure batch consistency), pharmaceutical development, and validation of the manufacturing of the Divestiture Product at the Respondent's facility; and

Decision and Order

5. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture the specified Divestiture Product in the quality and quantities achieved by a Respondent, or the manufacturer and/or developer of such Divestiture Product;
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
 - c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

DDDDD. "Teva Limited License" means a non-exclusive and non-renewable license to Teva to the Product Intellectual Property, the Product Manufacturing Technology, the Product Marketing Materials, the content that is displayed on any Website (to the extent any content is not in the public domain), and the Applications related to the Modified Release Methylphenidate CAP Product(s): (i) to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Modified Release Methylphenidate CAP Product(s) within the United States of America; (ii) to import or export the Modified Release Methylphenidate CAP Product(s) to or from the United States of America to the extent related to the marketing, distribution, or sale of these Products in the United States of America; and (iii) to use any Confidential Business Information related to the Modified Release Methylphenidate CAP Product(s), but solely as is necessary to give effect to this license. The Teva Limited License shall terminate

Decision and Order

on or before the date three (3) years after the Closing Date for the Modified Release Methylphenidate CAP Product(s).

The Teva Limited License is contained in Non-Public Appendix II.A. to this Order.

EEEEEE. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

FFFFF. “3M” means 3 M Company a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 3M Center, St. Paul, Minnesota 55144.

GGGGG. “Trimipramine Product Divestiture Agreements” means *Termination of the Asset Purchase Agreement and Master Supply Agreement* by Actavis LLC, accepted and agreed to by Mikah Pharma LLC, dated as of May 25, 2016, that makes reference to both the *Asset Purchase Agreement*, by and between Actavis LLC (assignee of Actavis Totowa LLC and Mikah Pharma LLC, dated as of June 16, 2010, as amended August 27, 2012, and the *Supply and Distribution Agreement* by and between Actavis LLC and Mikah Pharma LLC, dated as of November 21, 2011. The Trimipramine Product Divestiture Agreements are contained in Non-Public Appendix II.I. The Trimipramine Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective are Remedial Agreements.

HHHHH. “Third Party(ies)” means any non-governmental Person other than the following: a Respondent; or an Acquirer of particular assets or rights pursuant to this Order.

Decision and Order

- IIII. “United States of America” means the United States of America, and its territories, districts, commonwealths and possessions.
- JJJJ. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.
- KKKK. “Zydus” means Zydus Worldwide DMCC, a corporation organized, existing and doing business under and by virtue of the rules and regulations of Dubai Multi Commodities Center Authority. “Zydus” also includes Zydus Pharmaceuticals (USA) Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey with its principal executive offices located at 73 Route 31 N, Pennington, New Jersey 08534. Zydus Pharmaceuticals (USA) Inc. is a step down subsidiary of Cadila Healthcare Limited.

II.**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group A Product Assets and grant the Divestiture Product Licenses related to the Group A Products, absolutely and in good faith, to Mayne pursuant to, and in accordance with, the Group A Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any

Decision and Order

rights or benefits of Mayne or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group A Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group A Product Assets to Mayne prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Mayne is not an acceptable purchaser of any of the Group A Product Assets, then Respondents shall immediately rescind the transaction with Mayne, in whole or in part, as directed by the Commission, and shall divest the relevant Group A Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group A Product Assets to Mayne prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group A Product Assets to Mayne (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group B Product Assets and grant the Divestiture Product Licenses related to the Group B Products, absolutely and in good faith, to

Decision and Order

Impax pursuant to, and in accordance with, the Group B Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Impax or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group B Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group B Product Assets to Impax prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Impax is not an acceptable purchaser of any of the Group B Product Assets, then Respondents shall immediately rescind the transaction with Impax, in whole or in part, as directed by the Commission, and shall divest the relevant Group B Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group B Product Assets to Impax prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group B Product Assets to Impax (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

Decision and Order

- C. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group C Product Assets and grant the Divestiture Product Licenses related to the Group C Products, absolutely and in good faith, to Sagent pursuant to, and in accordance with, the Group C Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Sagent or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group C Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group C Product Assets to Sagent prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Sagent is not an acceptable purchaser of any of the Group C Product Assets, then Respondents shall immediately rescind the transaction with Sagent, in whole or in part, as directed by the Commission, and shall divest the relevant Group C Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group C Product Assets to Sagent prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the

Decision and Order

Group C Product Assets to Sagent (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- D. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group D Product Assets and grant the Divestiture Product Licenses related to the Group D Products, absolutely and in good faith, to Cipla pursuant to, and in accordance with, the Group D Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Cipla or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group D Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group D Product Assets to Cipla prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Cipla is not an acceptable purchaser of any of the Group D Product Assets, then Respondents shall immediately rescind the transaction with Cipla, in whole or in part, as directed by the Commission, and shall divest the relevant Group D Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group D Product Assets to Cipla prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in

Decision and Order

which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group D Product Assets to Cipla (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- E. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group E Product Assets and grant the Divestiture Product Licenses related to the Group E Products, absolutely and in good faith, to Zydus pursuant to, and in accordance with, the Group E Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Zydus or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group E Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group E Product Assets to Zydus prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Zydus is not an acceptable purchaser of any of the Group E Product Assets, then Respondents shall immediately rescind the transaction with Zydus, in whole or in part, as directed by the Commission, and shall divest the relevant Group E Product Assets within one hundred eighty (180) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

Decision and Order

provided further, however, that if Respondents have divested the Group E Product Assets to Zydus prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group E Product Assets to Zydus (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- F. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group F Product Assets and grant the Divestiture Product Licenses related to the Group F Products, absolutely and in good faith, to Dr. Reddy's pursuant to, and in accordance with, the Group F Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Dr. Reddy's or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group F Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Group F Product Assets to Dr. Reddy's prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Dr. Reddy's is not an acceptable purchaser of any of the Group F Product Assets, then Respondents shall immediately rescind the transaction with Dr. Reddy's, in whole or in part, as directed by the Commission, and shall divest the relevant Group F Product Assets within one hundred eighty (180) days after the Order Date,

Decision and Order

absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondents have divested the Group F Product Assets to Dr. Reddy's prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group F Product Assets to Dr. Reddy's (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- G. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall divest the Benzoyl Peroxide/Clindamycin Product Assets, absolutely and in good faith, to Perrigo pursuant to, and in accordance with, the Benzoyl Peroxide/Clindamycin Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Perrigo or to reduce any obligations of Respondent Teva under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Benzoyl Peroxide/Clindamycin Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Teva has divested the Benzoyl Peroxide/Clindamycin Product Assets to Perrigo prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies

Decision and Order

Respondent Teva that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Teva, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Benzoyl Peroxide/Clindamycin Product Assets to Perrigo (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- H. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall divest the Development Two Product Assets, absolutely and in good faith, to 3M pursuant to, and in accordance with, the Development Two Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of 3M or to reduce any obligations of Respondent Teva under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Development Two Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Teva has divested the Development Two Product Assets to 3M prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Teva that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Teva, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Development Two Product Assets to 3M (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

Decision and Order

- I. Not later than ten (10) days after the Acquisition Date, Respondent Allergan shall divest the Trimipramine Product Assets, absolutely and in good faith, to Mikah Pharma pursuant to, and in accordance with, the Trimipramine Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mikah Pharma or to reduce any obligations of Respondent Allergan under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Trimipramine Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Allergan has divested the Trimipramine Product Assets to Mikah Pharma prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Allergan that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Allergan, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Trimipramine Product Assets to Mikah Pharma (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- J. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall divest the Modified Release Amphetamine Sulfate Product Assets, absolutely and in good faith, to Prasco pursuant to, and in accordance with, the Modified Release Amphetamine Sulfate Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Prasco or to reduce any

Decision and Order

obligations of Respondent Teva under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Modified Release Amphetamine Sulfate Product Assets is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent Teva has divested the Modified Release Amphetamine Sulfate Product Assets to Prasco prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Teva that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Teva, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Modified Release Amphetamine Sulfate Product Assets to Prasco (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- K. Prior to the Closing Date for each respective Divestiture Product, Respondent shall provide each Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of the Acquirer's determination whether to assume such contracts or agreements.
- L. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Divestiture Product Assets to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product Assets has executed all

Decision and Order

such agreements directly with each of the relevant Third Parties.

M. Respondents shall:

1. submit to each Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 1. in good faith;
 2. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 3. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:

Decision and Order

1. the requirements of this Order;
2. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
3. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information (*e.g.*, employees of a Respondent responsible for the Contract Manufacture of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, (iv) the Monitor (if any has been appointed); or (v) Persons necessary to give effect to the Teva Limited License;
6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products; and
7. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the research and Development of the Development Divestiture Products to any employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products or in Development to become the Therapeutic Equivalent of a Divestiture Product *unless* authorized by the Acquirer of the particular Divestiture Product to do so.

Decision and Order

- N. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product or a Pipeline Internal Manufacture Product, Respondents shall provide, or cause to be provided, to that Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to a Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondents shall obtain any consents from Third Parties required to comply with this provision. Respondents shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

- O. Respondent Teva shall employ a staff of sufficient size, training, and expertise as is necessary to complete all of the transfers of the Product Manufacturing

Decision and Order

Technology to each of the Acquirers in a timely manner and to ensure that each Acquirer has sufficient assistance from Respondent Teva to validate the manufacture of the Contract Manufacture Products being acquired by that Acquirer in commercial quantities, and in a manner consistent with cGMP at a facility chosen by the Acquirer.

- P. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent Teva shall:
1. upon reasonable written notice and request from the Acquirer to Respondent Teva, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished dosage form drug product independently of Respondent Teva, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of a Respondent from Persons other than Respondent Teva; *provided, however*, that for each Contract Manufacture Product that is also a Pipeline Internal Manufacture Product, Respondent Teva shall not be required to supply that Contract Manufacture Product to that Acquirer until the FDA has approved the Application related to that Contract Manufacture Product for manufacture within Respondent Teva's facilities for commercial sales within the United States;
 2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s)

Decision and Order

supplied by Respondent Teva pursuant to a Remedial Agreement meet the relevant Agency-approved specifications;

3. for the Contract Manufacture Product(s) to be marketed or sold in the United States of America, the supplying Respondent shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondent Teva prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the supplying Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the supplying Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however,* that this obligation shall not require such Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the supplying Respondent to the Acquirer in an agreement to Contract Manufacture;

4. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondent Teva's own use or sale;
5. agree to hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from

Decision and Order

the failure of the Contract Manufacture Products to be delivered in a timely manner *unless* (i) Respondent Teva can demonstrate that the failure was beyond the control of Respondent Teva and in no part the result of negligence or willful misconduct by Respondent Teva, and (ii) Respondent Teva is able to cure the supply failure not later than thirty (30) days after the receipt of notice from the relevant Acquirer of a supply failure; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondent Teva's aggregate liability for any penalty incurred by an Acquirer from a customer directly related to that Acquirer's inability to supply the Divestiture Product to that customer that was the result of Respondent Teva's failure to supply the Divestiture Product to the Acquirer;

6. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
7. for each Contract Manufacturer Product for which Teva purchases the active pharmaceutical ingredient(s), component(s), or excipient(s) from a Third Party, provide that Acquirer with the actual price paid by Respondent Teva for each active pharmaceutical ingredient(s), component(s), and excipient(s), respectively, used to manufacture that Contract Manufacture Product;

Decision and Order

8. for each Contract Manufacturer Product for which Teva is the source of the active pharmaceutical ingredient(s), component(s), or excipient(s), not charge the Acquirer any intracompany transfer profit for such active pharmaceutical ingredient(s), component(s) or excipient(s) in calculating the total price for the final finished Contract Manufacture Product to the Acquirer, but such charges shall only reflect Respondent Teva's actual cost;
9. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
10. in the event Respondent Teva becomes (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANDA: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent Teva uses or has used to source its own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;
11. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture;
12. not be entitled to terminate any agreement to Contract Manufacture due to an Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of

Decision and Order

creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency Law;

13. shall notify the Commission at least sixty (60) days prior to terminating any agreement with an Acquirer to Contract Manufacture for any reason, and shall submit at the same time a copy of such notice to the Monitor; and
14. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of Respondent Teva and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, a Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent Teva and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing requirements to Contract Manufacture shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture such Contract Manufacture Product for sale in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Teva; (ii) the date the Acquirer notifies the Commission and Respondent Teva of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written

Decision and Order

notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) five (5) years after the Closing Date.

- Q. For each Divestiture Product for which Teva is listed in the Application as a qualified source of any of the active pharmaceutical ingredient(s), at the option of the Acquirer of that Divestiture Product, Respondent Teva shall:
1. supply to that Acquirer the active pharmaceutical ingredient(s) for which Teva is listed a qualified source in the Application for use in the manufacture of the Divestiture Product for a period of at least four (4) years after the Closing Date at a price not to exceed the prices contained in the relevant binding letters of intent submitted by Respondent Teva to the Commission;
 2. at the Acquirer's option, the quantity shall be for commercial quantities;
 3. the manufacturing and delivery of the active pharmaceutical ingredient(s) by Respondent Teva to the Acquirer shall be in a timely manner;
 4. in the event any purchase order by an Acquirer is rejected by Respondent Teva, Respondent Teva will provide that Acquirer reasons for the rejection in writing and cooperate in good faith to expeditiously resolve any issues raised by such purchase order;
 5. the Acquirer shall not be required to purchase a minimum amount of the active pharmaceutical ingredient(s) from Respondent Teva in order for that Acquirer to receive the pricing and terms contained in the relevant letter of intent;

Decision and Order

6. the quality assurance covenants by Respondent Teva to the Acquirer shall be equivalent to the quality assurances Respondent Teva offers to its other customers that purchase active pharmaceutical ingredients from Respondent Teva;
7. the pricing and terms for the supply of the active pharmaceutical ingredient(s) to the Acquirer shall not be contingent on purchases of other products by the Acquirer from Respondent Teva;
8. the supply of the active pharmaceutical ingredients by Respondent Teva to the Acquirer shall not be interrupted or reduced (other than at the option of the Acquirer) during the four (4) year term required by this Order *except* for circumstances beyond the control of, and not the fault of, Respondent Teva; and
9. should the overall supply of the active pharmaceutical ingredient(s) be interrupted or reduced due to circumstances beyond the control of, and not the fault of, Respondent Teva, Respondent Teva shall provide a fair allocation of that active pharmaceutical ingredient(s) to the Acquirer based on the proportion of the overall volume of that active pharmaceutical ingredient(s) used to produce the Divestiture Product during the one (1) year period immediately preceding the interruption or reduction of the supply *unless* such prior year's usage was in amounts lower than commercial scale (*e.g.*, for pilot batches prior to commercial scale-up) in which instance the allocation shall take into account the commercial scale-up projections of the Acquirer.

The binding letters of intent for the purchase of the relevant active pharmaceutical ingredients are contained in Non-Public Appendix V.

Decision and Order

- R. For each Acquirer, Respondent Teva shall designate employees of Respondent Teva knowledgeable about the marketing, distribution, warehousing, and sale (including administrative logistics of sales to the respective High Volume Accounts) related to each of the Divestiture Products to assist the Acquirer, in the transfer and integration of the Business related to the Divestiture Products into the Acquirer's business.
- S. Respondents shall require, as a condition of continued employment post-divestiture of the Divestiture Product Assets, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the Respondents (other than as necessary to comply with the requirements of this Order).
- T. Not later than thirty (30) days after the Closing Date, each Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Each Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date.

Decision and Order

Each Respondent shall provide a copy of the notification to the relevant Acquirer. Each Respondent shall maintain complete records of all such notifications at that Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Each Respondent shall provide the relevant Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.

- U. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondents shall:
1. for a period of twelve (12) months after the Closing Date, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"
 2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed

Decision and Order

Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of a Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with a Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, a Respondent shall not make any counteroffer to any Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit a Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with a Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

Decision and Order

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Business related to the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by a Respondent until the Closing Date(s) for the divestiture of the Divestiture Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that this Paragraph does not require nor shall be construed to require a Respondent to terminate the employment of any employee or to prevent a Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year after the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, a Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with that Respondent, as long as that

Decision and Order

employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that a Respondent may do the following: (i) advertise for employees in newspapers, trade publications, or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts a Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from that Respondent.

- V. Until Respondents complete the divestitures required by this Order and fully provide, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer:
1. Respondents shall take actions as are necessary to:
 1. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;
 2. minimize any risk of loss of competitive potential for that Business;
 3. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
 4. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product;
 5. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and

Decision and Order

2. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Divestiture Product.
- W. Respondents shall not, in the United States of America:
1. use any of the Product Trademarks related to Divestiture Products or any mark confusingly similar to the Product Trademarks as a trademark, tradename, or service mark *except* as may be necessary to sell stocks of Divestiture Products in existence as of the Acquisition Date;
 2. attempt to register the Product Trademarks;
 3. attempt to register any mark confusingly similar to the Product Trademarks;
 4. challenge or interfere with an Acquirer's use and registration of the Product Trademarks acquired by that Acquirer; or
 5. challenge or interfere with an Acquirer's efforts to enforce its trademark registrations for and trademark rights in the relevant Product Trademarks against Third Parties.
- X. For each Acquirer of a Pipeline External Manufacture Product or Pipeline Internal Manufacture Product that requires a Clinical Trial(s) prior to receiving final FDA approval of the Application related to that Pipeline External Manufacture Product or Pipeline Internal Manufacture Product, as applicable, Respondents shall:
1. designate employees of the Respondents that have worked on or been involved in the planning of

Decision and Order

such Clinical Trial(s) who will be responsible for communicating directly with the Acquirer and/or its Clinical Research Organization Designee(s), and the Interim Monitor (if one has been appointed), for the purpose of effecting any transition agreed upon between the Respondents and the Acquirer for the purposes of ensuring the continued prosecution of such Clinical Trials in a timely manner;

2. coordinate with the Acquirer to prepare any protocols necessary to transfer the Clinical Trials to the Acquirer or the Acquirer's Clinical Research Organization Designee(s);
3. assist the Acquirer to prepare and implement any Clinical Plan(s) and Regulatory Package(s) for the Clinical Trial until either (i) the completion of the trial, or (ii) such other event as the Respondent and the Acquirer agree upon in a Remedial Agreement related to the Divestiture Product;
4. prepare and implement a detailed transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such information related to such Clinical Trial(s) to the Acquirer and/or its Clinical Research Organization Designee(s); and
5. provide, in a timely manner, assistance and advice to enable the Acquirer and/or its Clinical Research Organization Designee(s) to commence or continue such Clinical Trial in the same quality, scope, and pace as was planned or being achieved by the specified Respondent (as that Respondent is identified in the definition of the Divestiture Product) and in a manner consistent with Good Clinical Practices.

Decision and Order

- Y. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer:
1. under any Patent owned by or licensed to a Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
 2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to a Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America. Respondents shall also covenant to that Acquirer that as a condition of any assignment or license from Respondents to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of

Decision and Order

marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from a Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date;

provided, however, with respect to the Fentanyl Product(s), this provision shall take effect on October 1, 2017;

provided further, however, with respect to the OC Ethinyl Estradiol/Levonorgestrel Product, this provision shall take effect on the later of the following dates: (i) the date of the expiration of the first-to-file exclusivity period for a generic version of *Quartette*® (NDA No. 204061) as granted by the FDA to the first-to-file ANDA holder(s) of a Therapeutic Equivalent of *Quartette*; or April 1, 2017.

- Z. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the

Decision and Order

Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America.

- AA. For any patent infringement suit filed prior to the Closing Date in which a Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that a Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States of America, that Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
 2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
 3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to that Divestiture Product.
- BB. Respondent Teva may enter into the Teva Limited License with the Acquirer of the Modified Release Methylphenidate CAP Product(s), in the form as is

Decision and Order

approved by the Commission in connection with the Commission's determination to make the Order final and effective;

provided, however, that Respondent Teva shall not modify, amend, extend, or renew the Teva Limited License without the prior approval of the Commission or enter into any subsequent agreement to license the rights that are the subject of the Teva Limited License without the prior approval of the Commission;

provided further, however, that any payment or fee from the Respondent Teva to the Acquirer under the Teva Limited License shall not be based, in whole or in part, on the actual sales of the Modified Release Methylphenidate CAP Product(s) or the actual profits from these Products.

- CC. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for the Contract Manufacture Products) and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the United States of America;
 2. to create a viable and effective competitor that is independent of Respondent Teva in the Business of each Divestiture Product within the United States of America; and
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

Decision and Order

III.**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall supply the Armodafinil Products to Aurobindo, in timely manner, pursuant to, and in accordance with, the Armodafinil Supply Agreement (which agreement shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Aurobindo or to reduce any obligations of Respondent Teva under such agreement) for period of at least three (3) years.

provided, however, that if Respondent Teva has executed the Armodafinil Supply Agreement with Aurobindo prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Teva that Aurobindo is not acceptable for the purposes of the agreement to supply the Armodafinil Products, then Respondent Teva shall immediately rescind the Armodafinil Supply Agreement and shall execute an agreement to supply the Armodafinil Products within ninety (90) days after the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, however, that if Respondent Teva has executed the Armodafinil Supply Agreement with Aurobindo prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent Teva that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent Teva, or appoint a Divestiture Trustee, to effect such modifications to the manner of

Decision and Order

the supply of the Armodafinil Products with Aurobindo (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Respondent Teva shall, in connection with any Remedial Agreement by Respondent Teva to supply the Armodafinil Products to an Acquirer,
1. not later than ten (10) days after the Acquisition Date, deliver, absolutely and in good faith, to that Acquirer sufficient commercial quantities of the Armodafinil Products in final dosage form and packaged for sale to the ultimate consumer/patient by the Acquirer (including all Acquirer approved packaging) in sufficient time to allow the Acquirer to market, distribute and sell the Armodafinil Products in commercial quantities;
 2. continue to manufacture and deliver such Armodafinil Products to the Acquirer in such quantities and in a timely manner to allow such Acquirer to continue to market, distribute and sell the Armodafinil Products for a period of at least three (3) years *unless* the Acquirer obtains FDA approval to market, distribute and sell its own Product in commercial quantities that is the Therapeutic Equivalent of the Armodafinil Products during this three (3) year period;
 3. make representations and warranties to that Acquirer that the Armodafinil Products supplied by Respondent Teva meet the relevant Agency-approved specifications;
 4. indemnify, defend and hold that Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Armodafinil Products supplied to that Acquirer by Respondent Teva to meet cGMP.

Decision and Order

This obligation may be made contingent upon that Acquirer giving Respondent Teva prompt written notice of such claim and cooperating fully in the defense of such claim;

5. give priority to supplying the Armodafinil Products to that Acquirer over manufacturing and supplying of Products for Respondent Teva's own use or sale; and
 6. hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondent Teva to deliver the Armodafinil Products in a timely manner as required by the Remedial Agreement(s) *unless* (i) Respondent Teva can demonstrate that the failure was beyond the control of Respondent Teva and in no part the result of negligence or willful misconduct by Respondent Teva, and (ii) Respondent Teva is able to cure the supply failure not later than thirty (30) days after the receipt of notice from the Acquirer of a supply failure; *provided, however*, that in each instance where: (i) an agreement to supply Armodafinil is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for the Armodafinil Products, that agreement may contain limits on Respondent Teva's aggregate liability for any penalty incurred by an Acquirer from a customer directly related to that Acquirer's inability to supply the Divestiture Product to that customer that was the result of Respondent Teva's failure to supply the Armodafinil Product to the Acquirer.
- C. Respondent Teva shall maintain manufacturing facilities necessary to manufacture the Armodafinil Products to the Acquirer of the agreement to supply Armodafinil Products.

Decision and Order

- D. From the date of the execution of the agreement to supply Armodafinil Products with an Acquirer, Respondents shall not, directly or indirectly (i) enforce or seek to enforce against the FDA or that Acquirer, or (ii) seek to have the FDA enforce against that Acquirer, any rights that Respondents may have to market on an exclusive basis any Product that is the subject of an ANDA that references or is based on Nuvigil (*i.e.*, NDA Number 021875) as the Reference Listed Drug at 200 mg dosage strength of armodafinil. Not later than ten (10) days after the Acquisition Date, Respondent Teva shall provide written notification to the FDA and the Commission that Respondents shall not enforce any such rights against the Acquirer of the agreement to supply the Armodafinil Products.
- E. The purpose of requiring Respondent Teva to supply the Armodafinil Products and the related obligations imposed on Respondent Teva by this Order is to remedy the lessening of competition in the sales and marketing of the Armodafinil Products and their Therapeutic Equivalents resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

IV.**IT IS FURTHER ORDERED** that:

- A. During the three (3) year period immediately following the Order Date, upon the request of any API Customer, Respondent Teva shall, in good faith, offer that API Customer the option to enter into a contract(s) for Respondent Teva to supply the API Product(s) that that API Customer has previously purchased from Respondent Teva under the following terms and conditions:
1. the term of the contract to supply shall be renewable for a period of up to three (3) years after the Order Date;

Decision and Order

2. the price for each API Product charged by Respondent Teva shall not exceed:
 - a. the average price charged by Respondent Teva to that API Customer over the one (1) year period immediately preceding the Order Date or the date the contract is executed whichever price is lower, *plus*
 - b. an annual adjustment equal to any increase in the actual cost of raw material inputs used to manufacture the API Product during the year immediately preceding the adjustment;
3. at the API Customer's option, the quantity shall be for commercial quantities but may be limited to amounts solely to be used in the API Finished Dosage Form Product that contains the API Product;
4. the manufacturing and delivery of the API Products by Respondent Teva to the API Customer shall be in a timely manner and consistent with past practice with that API Customer;
5. in the event any purchase order by an API Customer pursuant to the contract is rejected by Respondent Teva, Respondent Teva will provide that API Customer reasons for the rejection in writing and cooperate in good faith to expeditiously resolve any issues raised by such purchase order;
6. the API Customer shall not be required to purchase a minimum amount of the API Product from Respondent Teva in order for that API Customer to receive the pricing and terms required by this Order;

Decision and Order

7. the quality assurance covenants by Respondent Teva to the API Customer shall be the equivalent to the quality assurances Respondent Teva offers to its other customers that purchase active pharmaceutical ingredients from Respondent Teva;
 8. the pricing and terms for the supply of the API Products under such a contract shall not be contingent on purchases of other products by the API Customer from Respondent Teva;
 9. the supply of the API Products by Respondent Teva to the API Customer shall not be interrupted or reduced (other than at the option of the API Customer) during the term of the contract *except* for circumstances beyond the control of, and not the fault of, Respondent Teva; and
 10. should the overall supply of the API Products be interrupted or reduced due to circumstances beyond the control of, and not the fault of, Respondent Teva, Respondent Teva shall provide a fair allocation of the API Products to the API Customer based on the proportion of the overall volume of the API Products purchased by that API Customer during the one (1) year period immediately preceding the interruption or reduction of the supply *unless* such prior year's purchases by the API Customer were in quantities lower than commercial scale (*e.g.*, for pilot batches prior to commercial scale-up) in which instance the allocation shall take into account the commercial scale-up projections of the API Customer.
- B. Not later than ten (10) days from the Order Date, Respondent Teva shall notify each of the API Customers of their right to enter into a contract to purchase the API Products with Respondent Teva under the terms described in this Order. Such notifications shall be sent by certified mail with return receipt requested to (i) the employee(s) of the API

Decision and Order

Customer that have submitted the most recent purchase orders for the API Product to Respondent Teva, and (ii) the Chief Executive Officer and the General Counsel of the API Customer.

- C. Not later than ten (10) days after a request by any API Customer to negotiate a contract with Respondent Teva to supply the API Products to that API Customer under the terms described in this Order, Respondent Teva shall notify the Commission of the request.
- D. Not later than ten (10) days after the date of the execution of a contract with Respondent Teva to supply the API Products to an API Customer under the terms described in this Order, Respondent Teva shall submit a copy of that contract to the Commission.
- E. The obligations in this Paragraph IV shall only apply to the supply of API Products to be used in the manufacture of API Finished Dosage Form Product(s) that will be marketed or sold in the United States of America.
- F. The purpose of the provisions of this Order related to the supply of the API Products is to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner and to ensure that none of the API Customers are subjected to an unfair method of competition due to the Acquisition because of their reliance upon Respondent Teva as a source for their API Products.

V.**IT IS FURTHER ORDERED** that:

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Monitor") to assure that the Respondents expeditiously comply with all of their

Decision and Order

obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements.

- B. The Commission shall select the Monitor, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondent Teva shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor each Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If a Monitor is appointed, each Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor each Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
 - 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

Decision and Order

3. The Monitor shall serve until divestiture of all Divestiture Product Assets has been completed, and the transfer and delivery of the related Product Manufacturing Technology has been completed, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture the finished dosage form Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Teva; (ii) the date the Acquirer of that Divestiture Product notifies the Commission and Respondent Teva of its intention to abandon its efforts to manufacture that Divestiture Product; or (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate

Decision and Order

with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.

- F. The Monitor shall serve, without bond or other security, at the expense of Respondent Teva, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Teva, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Each Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Each Respondent shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by a Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondent Teva has filed its final report pursuant to Paragraph IX.C., and

Decision and Order

ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Teva.

- I. Each Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

Decision and Order

VI.**IT IS FURTHER ORDERED** that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by a Respondent to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

Decision and Order

- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the

Decision and Order

Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers,

Decision and Order

appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.

Decision and Order

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
 9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

VII.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, each Respondent shall assure that its own counsel (including its own in-house counsel under

Decision and Order

appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. to assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph VII pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided further, however, that pursuant to this Paragraph VII, a Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

Decision and Order

VIII.**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. For each Divestiture Product that is a Contract Manufacture Product, Respondents shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of Respondent Teva, all as soon as reasonably practicable.
- E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise

Decision and Order

provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

IX.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition Date, Respondent Teva shall submit to the Commission a letter certifying the date on which the Acquisition Date occurred.
- B. Within five (5) days of each Closing Date, Respondent Teva shall submit to the Commission a letter certifying the date on which that particular divestiture occurred.
- C. Within thirty (30) days after the Order Date, and every ninety (90) days thereafter until Respondent Teva has (i) completed its obligations to Contract Manufacture the Contract Manufacture Products for an Acquirer, (ii) fully provided the Product Manufacturing Technology related to the Divestiture Products to each relevant Acquirer, and (iii) completed its obligations with respect to Clinical Trials related to a Pipeline External Manufacture Product or a Pipeline Internal Manufacture Product, Respondent Teva shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with these requirements of this Order. Respondent Teva shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor, if any Monitor has been appointed. Respondent Teva shall include in its reports, among other things that are required from time to time, a full description of the

Decision and Order

efforts being made to comply with the relevant paragraphs of the Orders, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by Respondent Teva to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 2. a detailed description of the timing for the completion of such obligations.
- D. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order. In addition to the foregoing, Respondents shall include in these reports a list containing (i) all of the Retained Products that are the Therapeutic Equivalent of a Divestiture Product and (ii) total sales in units and dollars in the United States of each of these Retained Products by the Respondents for either the one-year period immediately preceding the report or the full calendar or fiscal year that immediately precedes the report.

X.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger, or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution

Decision and Order

of subsidiaries, if such change might affect compliance obligations arising out of this Order.

XI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

XII.

IT IS FURTHER ORDERED that Respondent Allergan's obligations under this Decision and Order, other than the covenant not to sue an Acquirer under certain Patents contained in Paragraph II.Y of this Order, shall terminate on the date on which all of the following have occurred:

- A. Respondent Teva has acquired over fifty percent of the voting securities of each of the Allergan Generic Pharmaceutical Entities;

Decision and Order

- B. with respect to any Divestiture Product that is owned or controlled by Allergan prior to the Acquisition, Respondent Allergan has:
1. transferred all rights and assets that were owned or controlled by Allergan prior to the Acquisition and necessary to effect the related divestitures (including, without limitation, the transfer of the relevant Product Manufacturing Technology) to either Respondent Teva or the relevant Acquirer;
 2. transferred all rights and assets that were owned or controlled by Allergan prior to the Acquisition and necessary to Contract Manufacture such Divestiture Products that are Contract Manufacture Products to Respondent Teva; and
 3. secured all consents and waivers from all Third Parties that are necessary to divest the related Divestiture Product Assets to an Acquirer or certified that the relevant Acquirer for the Divestiture Product Assets has executed all such agreements directly with each of the relevant Third Parties; and
- C. Respondent Allergan certifies to the Commission that all of the above-described acquisitions and transfers have occurred and all of the above-described consents and waivers from Third Parties have been provided to the relevant Acquirer.

XIII.

IT IS FURTHER ORDERED that on the Acquisition Date, Respondent Teva shall become a respondent under the following final Decision and Orders of the Commission: *In the Matter of Watson Pharmaceuticals, Inc. and Andrx Corporation*, FTC Docket C-4172, issued December 6, 2006 (terminates December 6, 2016); *In the Matter of Actavis Group hf. and Abrika Pharmaceuticals, Inc.* FTC Docket No. C-4190, issued May 18, 2007 (terminates May 18, 2017); *In the of Matter Watson*

Decision and Order

Pharmaceuticals, Inc. and Robin Hood Holdings Limited, FTC Docket No. C-4276, issued January 7, 2010 (terminates January 7, 2020). *In the Matter of Watson Pharmaceuticals Inc., Actavis Inc., Actavis Pharma Holding 4 EHF. and Actavis S.A.R.L.*, FTC Docket No. C-4373, issued December 13, 2012 (terminates December 13, 2022); *In the Matter of Actavis, Inc. and Warner Chilcott PLC*, FTC Docket No. C-4414, issued December 4, 2013 (terminates December 4, 2023); and *In the Matter of Actavis PLC and Forest Laboratories, Inc.*, FTC Docket No. C-4474, issued August 29, 2014 (terminates August 29, 2024).

XIV.

IT IS FURTHER ORDERED that this Order shall terminate on September 7, 2026.

By the Commission.

**NON-PUBLIC APPENDIX I
ACQUISITION AGREEMENT**

[Cover Page]

[Redacted From the Public Record Version, But Incorporated
By Reference]

**NON-PUBLIC APPENDIX II.A
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP A DIVESTITURE PRODUCTS**

[Cover Page]

[Redacted From the Public Record Version, But Incorporated
By Reference]

Decision and Order

**NON-PUBLIC APPENDIX II.B
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP B DIVESTITURE PRODUCTS**

[Cover Page]

[Redacted From the Public Record Version, But Incorporated
By Reference]

**NON-PUBLIC APPENDIX II.C
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP C DIVESTITURE PRODUCTS**

[Cover Page]

[Redacted From the Public Record Version, But Incorporated
By Reference]

**NON-PUBLIC APPENDIX II.D
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP D DIVESTITURE PRODUCTS**

[Cover Page]

[Redacted From the Public Record Version, But Incorporated
By Reference]

Decision and Order

**NON-PUBLIC APPENDIX II.E
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP E DIVESTITURE PRODUCTS**

[Cover Page]

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**NON-PUBLIC APPENDIX II.F
AGREEMENTS RELATED TO THE DIVESTITURES
OF THE GROUP F DIVESTITURE PRODUCTS**

[Cover Page]

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**NON-PUBLIC APPENDIX II.G.
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE BENZOYL PEROXIDE/CLINDAMYCIN
PRODUCTS**

[Cover Page]

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Decision and Order

**NON-PUBLIC APPENDIX II.H
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE DEVELOPMENT TWO PRODUCTS**

[Cover Page]

[Redacted From the Public Record Version, But
Incorporated By Reference]

**NON-PUBLIC APPENDIX II.I
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE TRIMIPRAMINE PRODUCTS**

[Cover Page]

[Redacted From the Public Record Version, But Incorporated
By Reference]

**NON-PUBLIC APPENDIX II.J
AGREEMENTS RELATED TO THE DIVESTITURE
OF THE MODIFIED RELEASE AMPHETAMINE
SULFATE PRODUCTS**

[Cover Page]

[Redacted From the Public Record Version, But Incorporated
By Reference]

Decision and Order

**NON-PUBLIC APPENDIX III
ARMODAFINIL SUPPLY AGREEMENT**

[Cover Page]

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**NON-PUBLIC APPENDIX IV
DEVELOPMENT DIVESTITURE PRODUCTS
DEVELOPMENT DIVESTITURE PRODUCT ASSETS**

[Cover Page]

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**NON-PUBLIC APPENDIX IV
DEVELOPMENT DIVESTITURE PRODUCTS
DEVELOPMENT DIVESTITURE PRODUCT ASSETS**

[Cover Page]

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Analysis to Aid Public Comment

**NON-PUBLIC APPENDIX V
LETTERS OF INTENT RELATED TO THE PURCHASE
OF THE ACTIVE PHARCEUTICAL INGREDIENTS USED
IN CERTAIN DIVESTITURE PRODUCTS**

[Cover Page]

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**NON-PUBLIC APPENDIX VI
API FINISHED DOSAGE FORM PRODUCTS:
FLUOCINOLONE PRODUCTS
FLUOROURACIL PRODUCTS**

[Cover Page]

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Teva Pharmaceutical Industries Ltd. (“Teva”) and Allergan plc (“Allergan”), which is designed to remedy the anticompetitive effects resulting from Teva’s proposed acquisition of Allergan’s generic pharmaceutical business. The proposed Consent Agreement requires the parties (1) to divest rights and assets related to pharmaceutical markets for one or more strengths of seventy-nine pharmaceutical products and (2) provide certain Teva active pharmaceutical ingredient (“API”) customers that

Analysis to Aid Public Comment

market one or more of fifteen pharmaceutical products with the option to enter into long-term API supply contracts.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (“Order”).

On July 26, 2015, Teva proposed to acquire Allergan’s generic pharmaceutical business for approximately \$40.5 billion. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening current or future competition in pharmaceutical markets for one or more strengths of ninety-four pharmaceutical products in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

The Products and Structure of the Markets

a. Horizontal Competition in Pharmaceutical Markets

Generic drugs are chemically and therapeutically equivalent to branded drugs. When a physician prescribes a particular branded drug, a pharmacy may only dispense that branded drug or its generic equivalent, which is “AB-rated” to the branded product. State laws permit or require pharmacies to automatically substitute the generic equivalent for the prescribed branded drug unless a physician expressly states not to do so.

The 1984 Hatch-Waxman Act provides the statutory framework for the Food and Drug Administration (“FDA”) to approve generic drugs. Under Hatch-Waxman, a generic drug manufacturer can rely on an already-approved branded drug’s

Analysis to Aid Public Comment

safety and efficacy data in its own application—called an Abbreviated New Drug Application (“ANDA”)—to the FDA, substantially lowering the research and development cost of the generic drug. Upon FDA approval, a generic drug typically launches at a discount to the branded drug’s price. When there is only one generic drug on the market, the branded drug usually competes with the generic drug on price, either directly or through an authorized generic version. As subsequent generic drugs launch, a generic-only market typically forms, with competition among generics driving pricing. When multiple generic drugs are available, customers usually substitute between the generics only—not the branded drug—and solicit bids exclusively from generic drug suppliers.

Teva’s proposed acquisition of Allergan’s generic pharmaceutical business will lessen current or future competition by reducing the number of current or future suppliers in the pharmaceutical markets for one or more strengths of seventy-nine pharmaceutical products. Those markets fall into three categories: (1) current competition between Teva and Allergan; (2) future competition between Teva and Allergan in an existing generic market; and (3) future competition between Teva and Allergan in a future generic market (*i.e.*, the generic market has not yet formed and only the branded drug is on the market). Absent a remedy, the proposed acquisition would reduce the number of suppliers in each market as indicated below.

- **Current Competition between Teva and Allergan, 2-to-1 Supplier Consolidation**
 - Armodafinil Oral Tablet, 200 mg
 - Desogestrel/Ethinyl Estradiol Oral Tablet, 0.025/0.1 mg then 0.025/0.125 mg then 0.025/0.15 mg (AB-rated to Cyclessa)
 - Estazolam Oral Tablet, 1 mg
 - Estazolam Oral Tablet, 2 mg
 - Ethinyl Estradiol/Ethinodiol Diacetate Oral Tablet, 0.035/1mg (AB-rated to Demulen 1/35)
 - Ethinyl Estradiol/Norethindrone Oral Tablet, 0.035/1mg (AB-rated to Tri-Norinyl 28-Day)

Analysis to Aid Public Comment

- Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.02/0.03/0.035/1/1/1 mg (AB-rated to Estrostep FE)
- Metoclopramide HCl Oral Tablet, 5 mg
- Trimipramine Maleate Oral Capsule, 25 mg
- Trimipramine Maleate Oral Capsule, 50 mg
- Trimipramine Maleate Oral Capsule, 100 mg
- **Current Competition between Teva and Allergan, 3-to-2 Supplier Consolidation**
 - Budesonide Inhalation Suspension, 0.25 mg/2 mL
 - Budesonide Inhalation Suspension, 0.5 mg/2 mL
 - Clarithromycin Extended Release Oral Tablet, 500 mg
 - Clonidine HCl Extended Release Transdermal Film, 0.1 mg/24 hr
 - Clonidine HCl Extended Release Transdermal Film, 0.2 mg/24 hr
 - Clonidine HCl Extended Release Transdermal Film, 0.3 mg/24 hr
 - Cyclosporine Oral Solution, 100 mg/mL
 - Desmopressin Acetate Oral Tablet, 0.1 mg
 - Desogestrel/Ethinyl Estradiol/Ethinyl Estradiol Oral Tablet, 0.15/0.02 mg/0.01 mg (AB-rated to Mircette)
 - Disopyramide Phosphate Oral Capsule, 100 mg
 - Disopyramide Phosphate Oral Capsule, 150 mg
 - Estradiol Oral Tablet, 0.5 mg
 - Estradiol Oral Tablet, 1 mg
 - Estradiol Oral Tablet, 2 mg
 - Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.1mg (AB-rated to Levlite-28)
 - Ethinyl Estradiol/Levonorgestrel Oral Tablet 0.03/0.04/0.03/0.05/0.075/0.125 mg (AB-rated to Triphasil-28)
 - Ethinyl Estradiol/Norethindrone Oral Tablet, 0.035/0.5mg (AB-rated to Modicon 28)
 - Ethinyl Estradiol/Norgestrel Oral Tablet, 0.03/0.3mg (AB-rated to Lo/Ovral-28)
 - Fludarabine Lyophilized Vial Injection, 50 mg
 - Fluocinonide Topical Cream, 0.05%
 - Flutamide Oral Capsule, 125 mg
 - Griseofulvin Microcrystalline Oral Liquid Suspension, 125 mg/5 mL

Analysis to Aid Public Comment

- Metoclopramide HCl Oral Tablet, 10 mg
- Mirtazapine Oral Disintegrating Tab, 15 mg
- Mirtazapine Oral Disintegrating Tab, 30 mg
- Mirtazapine Oral Disintegrating Tab, 45 mg
- Nabumetone Oral Tablet, 500 mg
- Nabumetone Oral Tablet, 750 mg
- Nortriptyline HCl Oral Capsule, 10 mg
- Nortriptyline HCl Oral Capsule, 25 mg
- Nortriptyline HCl Oral Capsule, 50 mg
- Nortriptyline HCl Oral Capsule, 75 mg
- Tamoxifen Citrate Oral Tablet, 10 mg
- Tamoxifen Citrate Oral Tablet, 20 mg
- Trimethoprim Oral Tablet, 100 mg
- **Current Competition between Teva and Allergan, 4-to-3 Supplier Consolidation**
 - Acitretin Oral Capsule, 17.5 mg
 - Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 5 mg
 - Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 10 mg
 - Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 15 mg
 - Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 20 mg
 - Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 25 mg
 - Amphetamine Aspartate / Amphetamine Sulfate / Dextroamphetamine Saccharate / Dextroamphetamine Sulfate Oral Capsule, 30 mg
 - Carbidopa/Levodopa Oral Tablet, 10/100 mg
 - Carbidopa/Levodopa Oral Tablet, 25/100 mg
 - Carbidopa/Levodopa Oral Tablet, 25/250 mg
 - Cyclosporine Oral Capsule, 25 mg
 - Cyclosporine Oral Capsule, 100 mg
 - Desmopressin Acetate Oral Tablet, 0.2 mg

Analysis to Aid Public Comment

- Dexmethylphenidate HCl Extended Release Oral Capsule, 5 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 10 mg
- Dexmethylphenidate HCl Extended Release Oral Capsule, 20 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 5 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 10 mg
- Dextroamphetamine Sulfate Extended Release Oral Capsule, 15 mg
- Diazepam Oral Tablet, 2 mg
- Diazepam Oral Tablet, 5 mg
- Diazepam Oral Tablet, 10 mg
- Epirubicin Injection Vial 50 mg/25 mL
- Epirubicin Injection Vial 200 mg/100 mL
- Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.01/0.1mg (AB-rated to Lo Seasonique)
- Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, 0.02/1mg (AB-rated to Loestrin 21 1/20)
- Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, 0.03/1.5mg (AB-rated to Loestrin 21 1.5/30)
- Glyburide/Metformin HCl Oral Tablet, 1.25/250 mg
- Glyburide/Metformin HCl Oral Tablet, 2.5/500 mg
- Glyburide/Metformin HCl Oral Tablet, 5/500 mg
- Hydroxyzine Pamoate Oral Capsule, 25 mg
- Hydroxyzine Pamoate Oral Capsule, 50 mg
- Levalbuterol HCl Inhalation Solution, 0.0103%
- Levalbuterol HCl Inhalation Solution, 0.0210%
- Levalbuterol HCl Inhalation Solution, 0.042%
- Minocycline HCl Oral Capsule, 50 mg
- Minocycline HCl Oral Capsule, 75 mg
- Minocycline HCl Oral Capsule, 100 mg
- Nitrofurantoin Oral Capsules, 50 mg
- Nitrofurantoin Oral Capsules, 100 mg
- Propofol Injection Emulsion, 10 mg/mL 20 mL vial
- Propofol Injection Emulsion, 10 mg/mL 50 mL vial
- Propofol Injection Emulsion, 10 mg/mL 100 mL vial
- Propranolol HCl Oral Tablet, 10 mg
- Propranolol HCl Oral Tablet, 20 mg

Analysis to Aid Public Comment

- Propranolol HCl Oral Tablet, 40 mg
- Propranolol HCl Oral Tablet, 80 mg
- **Current Competition between Teva and Allergan, 5-to-4 Supplier Consolidation**
 - Acitretin Oral Capsule, 10 mg
 - Acitretin Oral Capsule, 25 mg
 - Alendronate Sodium Oral Tablet, 35 mg
 - Buspirone HCl Oral Tablet, 15 mg
 - Clozapine Oral Tablet, 25 mg
 - Clozapine Oral Tablet, 100 mg
 - Drospirenone/Ethinyl Estradiol Oral Tablet, 3/0.03 mg (AB-rated to Yasmin-28)
 - Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.1 mg (AB-rated to Alesse-28)
 - Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.03/0.15 mg (AB-rated to Nordette)
 - Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.03/0.01/0.15 mg (AB-rated to Seasonique)
 - Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.02/1 mg (AB-rated to Loestrin FE 1/20)
 - Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, 0.03/1.5 mg (AB-rated to Loestrin FE 1.5/30)
 - Norethindrone Oral Tablet, 0.35 mg (AB-rated to Micronor 28)
 - Norethindrone Oral Tablet, 0.35 mg (AB-rated to Nor-QD)
- **Future Competition between Teva and Allergan in an Existing Generic Market, 3-to-2 Supplier Consolidation**
 - Budesonide Inhalation Suspension, 1 mg/2 mL
 - Fluocinonide Cream Emulsified Base 0.05%
 - Methylphenidate HCl Extended Release Capsule, 20 mg
 - Methylphenidate HCl Extended Release Capsule, 30 mg
 - Methylphenidate HCl Extended Release Capsule, 40 mg
- **Future Competition between Teva and Allergan in an Existing Generic Market, 4-to-3 Supplier Consolidation**
 - Aspirin/Dipyridamole Extended Release Oral Capsule 25/200 mg
- **Future Competition between Teva and Allergan in an Existing Generic Market, 5-to-4 Supplier Consolidation**
 - Benzoyl Peroxide/Clindamycin Phosphate Gel, 5%/1%
 - Clozapine Oral Tablet, 200 mg

Analysis to Aid Public Comment

- Methotrexate Injection, 25 mg/mL in 2 mL vial
- Methotrexate Injection, 25 mg/mL in 10 mL vial
- Methylphenidate HCl Extended Release Tablet, 18 mg
- Methylphenidate HCl Extended Release Tablet, 27 mg
- Methylphenidate HCl Extended Release Tablet, 36 mg
- Methylphenidate HCl Extended Release Tablet, 54 mg
- Tobramycin Inhalant Solution, 300 mg/5 mL
- **Future Competition between Teva and Allergan in a Future Generic Market, 2-to-1 Supplier Consolidation**
 - Methylphenidate HCl Extended Release Capsule, 10 mg
 - Ramelteon Tablet, 8 mg
- **Future Competition between Teva and Allergan in a Future Generic Market, 3-to-2 Supplier Consolidation**
 - Buprenorphine/Naloxone Buccal Film, 12/3 mg
 - Buprenorphine/Naloxone Buccal Film, 4/1 mg
 - Ethinyl Estradiol/Etonogestrel Vaginal Ring 0.015mg/24hr; 0.012mg/24hr
 - NAB Paclitaxel Injectable Suspension, 100 mg/vial
 - Phentermine HCl/Topiramate Extended Release Capsule, 11.25/69 mg
 - Phentermine HCl/Topiramate Extended Release Capsule, 15/92 mg
 - Phentermine HCl/Topiramate Extended Release Capsule, 3.75/23 mg
 - Phentermine HCl/Topiramate Extended Release Capsule, 7.5/46 mg
 - Rotigotine Transdermal Patch, 1 mg
 - Rotigotine Transdermal Patch, 2 mg
 - Rotigotine Transdermal Patch, 3 mg
 - Rotigotine Transdermal Patch, 4 mg
 - Rotigotine Transdermal Patch, 6 mg
 - Rotigotine Transdermal Patch, 8 mg
- **Future Competition between Teva and Allergan in a Future Generic Market, 4-to-3 Supplier Consolidation**
 - Buprenorphine/Naloxone Buccal Film, 2/0.5 mg
 - Buprenorphine/Naloxone Buccal Film, 8/2 mg
 - Dienogest/Estradiol Valerate and Estradiol Valerate Oral Tablet, 3 mg, 2/2 mg, 3/2 mg, 1 mg (AB-rated to Natazia)
 - Ethinyl Estradiol/Levonorgestrel Oral Tablet, 0.02/0.15 mg; 0.025/0.15 mg; 0.03 mg/0.15 mg; 0.01 mg (AB-rated to Quartette)

Analysis to Aid Public Comment

- Ezetimibe/Simvastatin Tablets, 10/10 mg
- Ezetimibe/Simvastatin Tablets, 10/20 mg
- Ezetimibe/Simvastatin Tablets, 10/40 mg
- Ezetimibe/Simvastatin Tablets, 10/80 mg
- Imiquimod Topical Cream, 3.75%
- Four pipeline products¹
- **Future Competition between Teva and Allergan in a Future Generic Market, 5-to-4 Supplier Consolidation**
 - Dexmethylphenidate HCl Extended Release Oral Capsule, 25 mg
 - Dexmethylphenidate HCl Extended Release Oral Capsule, 35 mg
 - Fentanyl Buccal Tablet, 100 mcg
 - Fentanyl Buccal Tablet, 200 mcg
 - Fentanyl Buccal Tablet, 400 mcg
 - Fentanyl Buccal Tablet, 600 mcg
 - Fentanyl Buccal Tablet, 800 mcg
 - Metformin HCl/Saxagliptin Extended Release Tablet, 500/5 mg
 - Metformin HCl/Saxagliptin Extended Release Tablet, 1000/2.5 mg
 - Metformin HCl/Saxagliptin Extended Release Tablet, 1000/5 mg

b. API Supply and Competition in Pharmaceutical Markets

APIs are central inputs in the manufacture of finished dose form pharmaceutical products. API supply sources must be designated in a drug's FDA marketing authorization. Switching to a non-designated API source requires a drug maker to supplement its New Drug Application or ANDA, a process that can take as long as two years or even more. Consequently, a generic drug manufacturer's API supply options are limited to the sources

¹ Teva's and Allergan's independent development projects for two overlapping pharmaceutical products are not public, and their existence is confidential business information. But for the proposed acquisition, certain strengths of the Teva and Allergan products would likely compete in four future markets. To preserve the confidentiality of these development programs, the specific future markets in which these products would compete are not identified in this document, and references to these products have been redacted from the public version of the Complaint.

Analysis to Aid Public Comment

qualified under its ANDA. If only one API supplier is qualified under an ANDA, the ANDA holder has no immediate recourse if its designated API supplier elects to raise its prices or refuse to supply.

Teva is world's largest API supplier and supplies API to Allergan's competitors in a number of generic markets. The proposed acquisition may lessen current or future competition in fifteen pharmaceutical products markets by creating the incentive and ability for Teva to foreclose rival suppliers of fifteen newly acquired Allergan pharmaceutical products by withholding supply of the following eight Teva API products:

- Betamethasone dipropionate API;
- Betamethasone valerate API;
- Clobetasol propionate API;
- Desonide API;
- Fluocinolone API;
- Fluorouracil API;
- Probenecid API; and
- Triamcinolone acetonide API.

The fifteen downstream pharmaceutical markets in which competition would be lessened as a result of the acquisition are:

- Betamethasone dipropionate augmented ointment, 0.05%;
- Betamethasone dipropionate cream, 0.05%;
- Betamethasone dipropionate lotion, 0.05%;
- Betamethasone dipropionate ointment, 0.05%;
- Betamethasone valerate cream, 0.1%;
- Betamethasone valerate ointment, 0.1%;
- Clobetasol propionate shampoo, 0.05%;
- Clobetasol propionate ointment, 0.05%;
- Desonide cream, 0.05%;
- Probenecid tablets, 500 mg;
- Probenecid/colchicine tablets, 500 mg/0.5 mg;
- Nystatin/triamcinolone acetonide cream, 100,000 units/gm/0.1%;
- Nystatin/triamcinolone acetonide ointment, 100,000 units/gm/0.1%; and

Analysis to Aid Public Comment

- Two pipeline products.²

Entry

Entry into these pharmaceutical markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. Introducing generic pharmaceutical products is costly and lengthy due to drug development times and regulatory requirements, including approval by the FDA. Additionally, it can take up to two years for an API manufacturer to qualify as a new API supplier for a generic pharmaceutical product, leaving the generic pharmaceutical product with no alternative to its existing qualified API supplier or suppliers.

Effects

The proposed acquisition likely would cause significant anticompetitive harm by eliminating current or future competition in markets for one or more strengths of seventy-nine pharmaceutical products where the parties currently sell or are developing generic drugs. In each of these markets, Teva and Allergan are two of a limited number of current or likely future suppliers in the United States. Customers and competitors have observed that the price of generic pharmaceutical products decreases with new entry even after several suppliers have entered the market. Removal of an independent generic pharmaceutical supplier from the relevant markets in which Teva and Allergan currently compete would result in significantly higher prices post-acquisition. Similarly, the elimination of a future independent competitor would prevent the price decreases that are likely to result from the firm's entry. Thus, absent a remedy, the proposed acquisition would likely result in significantly higher prices for these generic drugs.

² Allergan has not yet made public the development of two pharmaceutical products that would likely compete with products for which Teva supplies API. To preserve the confidentiality of these Allergan development programs, the specific markets in which these likely future products would compete are not identified in this document, and references to these products have been redacted from the public version of the Complaint.

Analysis to Aid Public Comment

Additionally, the proposed acquisition likely would cause competitive harm in markets for fifteen pharmaceutical products in which Teva supplies API for a generic pharmaceutical product that currently competes or will compete in the near future with an Allergan generic pharmaceutical product. Those generic pharmaceutical markets already have or will have a limited number of competitors, some of which are supplied API by Teva. Teva has the ability to foreclose these competitors by denying them API from their only approved source. Post-acquisition, Teva would have the incentive to foreclose one or more competitors because the lost API sales would be less than the recouped profits on additional sales gained from the foreclosed competitor(s) and the increased prices. Such foreclosure would harm consumers because market concentration and price would result in significantly higher prices.

The Consent Agreement

The remedy reflected in the proposed Consent Agreement would eliminate the likely anticompetitive effects of the proposed acquisition by requiring the parties to divest rights and assets related to the pharmaceutical products in each relevant market. The acquirers are: Mayne Pharma Group Ltd. (“Mayne”), Impax Laboratories, Inc. (“Impax”), Dr. Reddy’s Laboratories Ltd. (“Dr. Reddy’s”), Sagent Pharmaceuticals, Inc. (“Sagent”), Cipla Limited (“Cipla”), Zydus Worldwide DMCC (“Zydus”), Mikah Pharma LLC (“Mikah”), Perrigo Pharma International D.A.C. (“Perrigo”), Aurobindo Pharma USA, Inc. (“Aurobindo”), Prasco LLC (“Prasco”), and 3M Company (“3M”) (collectively, the “Acquirers”). The parties must divest the products no later than ten days after the acquisition.

The Commission’s goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. The Commission thoroughly reviewed the assets to be divested, the transitional services to be provided by Teva, and the capabilities and plans of each Acquirer. The interim monitors, who will oversee the divestiture process, have worked closely with Commission staff to ensure the viability of the divestiture and anticipate logistical and technical challenges. Additionally, Teva—in conjunction with the

Analysis to Aid Public Comment

Acquirers, Allergan, and interim monitors—has prepared a comprehensive divestiture plan to guide the process of transferring the divested products to their new proposed owners. If the Commission determines that an Acquirer is not acceptable, or that the manner of the divestitures is not acceptable, the parties must unwind the sale or release of rights to that Acquirer and divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the products if the parties fail to divest the products as required.

The proposed Consent Agreement contains provisions to help ensure the divestitures are successful. The parties must take all action to maintain the economic viability, marketability, and competitiveness of the divestiture products until they are divested. The parties must provide transitional services to the Acquirers to assist them in establishing independent manufacturing capabilities. These transitional services include technical assistance to manufacture the divestiture products in substantially the same manner and quality employed or achieved by the parties, as well as advice and training from knowledgeable employees. The goal of the transitional services is to ensure that the acquirers will be able to operate independently of the parties in the manufacture and sale of the divested products. The proposed Consent Agreement also requires the parties to supply product to the Acquirers so that the Acquirers can market them independently while the parties transfer the associated technology to the production facilities of the Acquirer or its chosen third-party manufacturer(s). The Consent Agreement allows sufficient time to complete the manufacturing transfers, and for products in development, to gain FDA approval before completing manufacturing transfers. To ensure that the buyers of divestiture products for which Teva or Allergan supply API will have access to adequate supplies of reasonably priced API until they are able to qualify alternative suppliers, the proposed Consent Agreement requires Teva to supply API for up to four years after closing at prices not to exceed those set forth in binding letters of intent, recently executed by Teva and the buyers. Nothing in the Consent Agreement precludes the buyers from sourcing other divestiture product inputs from Teva on a negotiated basis.

Analysis to Aid Public Comment

In addition, to address the anticompetitive effects likely to arise in the fifteen pharmaceutical markets where Teva supplies API to Allergan competitors, the Consent Agreement requires Teva to give API customers in those markets the option of entering into long-term API supply contracts. Teva must notify each affected API customer of the option to enter a contract within ten days of consummating the proposed acquisition, and such customers may exercise their options at any point up to three years after the date of the Consent Agreement. Any such API supply contracts executed pursuant to the option shall be renewable for up three years after the date of the Consent Agreement, which will give the customers sufficient time to qualify alternative API suppliers if they wish to do so.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

MYLAN N.V.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4590; File No. 161 0102*
Complaint, July 26, 2016 – Decision, September 7, 2016

This consent order addresses the \$7.2 billion acquisition by Mylan N.V. of certain assets of Meda AB. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current competition in the markets for 400 mg and 600 mg generic felbamate tablets and future competition in the market for 250 mg generic carisoprodol tablets in the United States. The consent order requires Mylan to divest all of its rights and assets related to 400 mg and 600 mg generic felbamate tablets to Alvogen Pharma US, Inc., and to return all of its marketing rights and ownership interests in generic carisoprodol tablets to Indicus Pharma LLC, the abbreviated new drug application owner for this product.

Participants

For the *Commission*: Susan Huber, and Christina Perez.

For the *Respondents*: Yonatan Even and Margaret Segal
D'Amico, Cravath, Swaine & Moore LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Mylan N.V. (“Respondent” or “Mylan”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Meda AB (“Meda”) in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the

Complaint

public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent is a company organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its principal executive offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, United Kingdom AL10 9UL, and its United States address for service of process of the Complaint, the Decision and Order and the Order to Maintain Assets, as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

2. The Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE ACQUIRED COMPANY

3. Meda is a company organized, existing, and doing business under and by virtue of the laws of Sweden, with its principal executive offices located at Pipers vag 2A, Box 906, SE- 107 09 Solna, Sweden.

4. Meda is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

5. Pursuant to a public offer to the shareholders of Meda announced on February 10, 2016, Respondent intends to acquire 100% of the issued and outstanding shares of Meda for a total equity value at announcement of approximately \$7.2 billion in a

Complaint

combination of cash and the Respondent's ordinary shares (the "Acquisition"). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

IV. THE RELEVANT MARKETS

6. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following pharmaceutical products:

- a. 400 mg and 600 mg generic felbamate tablets; and
- b. 250 mg generic carisoprodol tablets.

7. For the purposes of this Complaint, the United States is the relevant geographic market in which to assess the competitive effects of the Acquisition in each of the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

8. Generic felbamate tablets treat severe refractory epilepsy and are available in 400 mg and 600 mg strengths. Three firms—Mylan, Meda, and Amneal Pharmaceuticals LLC—currently sell generic felbamate in the United States. A fourth firm, CorePharma LLC, has received U.S. Food and Drug Administration ("FDA") approval for both strengths of generic felbamate tablets, but is not yet on the market. Entry into the markets for these strengths by other firms in the near future is unlikely. Thus, the Acquisition would reduce the number of suppliers of 400 mg and 600 mg generic felbamate tablets from four to three.

9. Generic carisoprodol is a muscle relaxer that works by blocking pain sensations between the nerves and the brain. Two firms currently market generic carisoprodol tablets: Meda and Vensun Pharmaceuticals. Mylan owns the U.S. marketing rights to a generic carisoprodol product that was recently approved by the FDA. Once it begins marketing generic carisoprodol, Mylan likely would be the third supplier of generic carisoprodol tablets.

Complaint

Thus, the Acquisition would eliminate the entry of a third independent market participant.

VI. ENTRY CONDITIONS

10. Entry into the relevant markets described in Paragraphs 6 and 7 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. De novo entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VII. EFFECTS OF THE ACQUISITION

11. The effects of the Acquisition, if consummated, would likely be to substantially lessen competition or tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Mylan and Meda and reducing the number of independent significant competitors in the markets for generic 400 mg and 600 mg felbamate tablets, thereby increasing the likelihood that: (1) Mylan would be able to unilaterally exercise market power in these markets; (2) the remaining competitors would engage in coordinated interaction between or among each other; and (3) customers would be forced to pay higher prices; and
- b. by eliminating future competition between Mylan and Meda in the market for generic carisoprodol tablets, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of the generic carisoprodol tablets to which Mylan owns the U.S. marketing rights; and (2) increasing the

Order to Maintain Assets

likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from an additional supplier of these products.

VIII. VIOLATIONS CHARGED

12. The Acquisition described in Paragraph 5 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

13. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-sixth day of July, 2016, issues its Complaint against said Respondent.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan N.V. (“Mylan” or “Respondent”) of Meda AB, and Respondent having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Order to Maintain Assets

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Mylan N.V. is a corporation organized, existing, and doing business under and by virtue of the laws of the Netherlands. Its principal executive offices are located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL109UL, England, and its United States address for service of process in this matter is as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317. Mylan Pharmaceuticals Inc., a corporation organized, existing and doing business under and by virtue of the laws of West Virginia, is a wholly-owned subsidiary of Mylan N.V. with its offices at 781 Chestnut Ridge Road, Morgantown, WV 26505.
2. Meda AB is a corporation organized, existing, and doing business under and by virtue of the laws of Sweden with its principal executive offices located at Box 906, SE-170 09 Solna, Sweden.

Order to Maintain Assets

3. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Mylan” or “Respondent” means Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Mylan N.V. (including but not limited to Mylan Pharmaceuticals Inc.) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Meda AB.
- B. “Commission” means the Federal Trade Commission.
- C. “Decision and Order” means the
 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- D. “Felbamate Products Business” means the Business of the Respondent within the Geographic Territory

Order to Maintain Assets

specified in the Decision and Order related to the Felbamate Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.

- E. “Meda” means Meda AB or any of Meda AB’s subsidiaries.
- F. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph V of the Decision and Order.
- G. “Transition Period” means the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the Felbamate Acquirer directs the Respondent to cease the marketing, distribution, and sale of the Felbamate Products; (ii) the date on which the Felbamate Acquirer commences the marketing, distribution, and sale of the Felbamate Products; or (iii) the date four (4) months after the Felbamate Closing Date.
- H. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.**IT IS FURTHER ORDERED** that

- A. Until Respondent fully transfers and delivers the Felbamate Product Assets to the Felbamate Acquirer, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Felbamate Products Business, to minimize any risk of loss of competitive potential for that Business and to prevent the destruction, removal, wasting, deterioration, or impairment of the Felbamate Product Assets except for ordinary wear

Order to Maintain Assets

and tear. Respondent shall not sell, transfer, encumber, or otherwise impair the Felbamate Product Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Felbamate Products Business.

- B. Until Respondent fully transfers and delivers the Felbamate Product Assets to the Felbamate Acquirer, Respondent shall maintain the operations of the Felbamate Products Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic marketability, viability, and competitiveness of the Felbamate Products Business and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with the Felbamate Products Business. Respondent's responsibilities shall include, but are not limited to, the following:
1. providing the Felbamate Products Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Felbamate Product Business;
 2. continuing, at least at their scheduled pace, any additional expenditures for the Felbamate Products Business authorized prior to the date the Consent Agreement was signed by Respondent including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;

Order to Maintain Assets

3. providing such resources as may be necessary to respond to competition against each of the Felbamate Products and/or to prevent any diminution in sales of each of the Felbamate Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Felbamate Product Assets to the Felbamate Acquirer;
 4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Felbamate Products at the related High Volume Accounts;
 5. making available for use by the Felbamate Products Business funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to the Felbamate Products Business; and
 6. providing such support services to the Felbamate Products Business as were being provided to the Business by Respondent as of the date the Consent Agreement was signed by Respondent.
- C. Until Respondent fully transfers and delivers the Felbamate Product Assets to the Felbamate Acquirer, Respondent shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Felbamate Products for the last fiscal year.
- D. Respondent shall deliver to the Acquirer the following information regarding each Felbamate Product Core Employee no later than ten (10) days after such information is requested by either the Acquirer or staff of the Commission:

Order to Maintain Assets

1. direct contact information for the employee, including telephone number;
2. the date of hire and effective service date;
3. job title or position held;
4. a specific description of the employee's responsibilities related to the Felbamate Products; provided, however, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;
5. the base salary or current wages;
6. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
7. employment status (i.e., active or on leave or disability; full-time or part-time);
8. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
9. at the Acquirer's option, a copy of all applicable employee benefit plans and summary plan descriptions (if any),

provided that, the provision of such information may be conditioned upon the Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing to a Felbamate Product Core Employee the opportunity to enter into employment contracts during the Felbamate Product Core Employee Access Period, and (iii) restrict access

Order to Maintain Assets

to the information to the Acquirer's employees or representatives who need such access in connection with the specified and permitted use.

- E. For a period of twelve (12) months after the Felbamate Closing Date, Respondent shall
1. provide Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Felbamate Product Core Employees. This period is hereinafter referred to as the "Felbamate Product Core Employee Access Period";
 2. not interfere with the hiring or employing by the Felbamate Acquirer or its Manufacturing Designee of the Felbamate Product Core Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any non-compete or nondisclosure provision of employment with respect to a Felbamate Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Felbamate Acquirer or its Manufacturing Designee;
 3. not make any counteroffer to any Felbamate Product Core Employee who has received a written offer of employment from the Felbamate Acquirer or its Manufacturing Designee; and
 4. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Felbamate Product ("Covered Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee, or hire such Covered Employee;

Order to Maintain Assets

provided, however, Respondent may hire any former Covered Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the terms of the Order, and

provided further, that Respondent may advertise for employees in newspapers, trade publications, or other media not targeted specifically at Covered Employees; or hire a Covered Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent;

Failure by Respondent to provide any information requested in Paragraph II.D above within the time provided therein shall extend the time period in this Paragraph II.E in an amount equal to the delay.

- F. Until the Felbamate Closing Date, Respondent shall provide all Felbamate Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Felbamate Products consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Business related to the Felbamate Products and to ensure successful execution of the pre-Acquisition plans for the Felbamate Products. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Divestiture Closing Date for the Felbamate Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law).
- G. During the Transition Period, Respondent, in consultation with the Felbamate Acquirer, for the

Order to Maintain Assets

purposes of ensuring an orderly marketing and distribution transition, shall:

1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution and sale the Felbamate Products by the Felbamate Acquirer is not delayed or impaired by the Respondent;
2. designate employees of Respondent knowledgeable about the marketing, distribution and sale of the Felbamate Products who will be responsible for communicating directly with the Felbamate Acquirer, and the Monitor, for the purposes of assisting in the transfer of the Felbamate Products Business to the Felbamate Acquirer;
3. maintain and manage inventory levels of each Felbamate Product in consideration of the marketing and distribution transition to the Felbamate Acquirer;
4. continue to market, distribute and sell the Felbamate Products in the United States;
5. beginning on the Acquisition Date, allow the Felbamate Acquirer access at reasonable business hours to all Confidential Business Information related to the Felbamate Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Felbamate Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Felbamate Acquirer;
6. beginning on the Acquisition Date, provide the Felbamate Acquirer with a listing of inventory levels (weeks of supply) for each customer (i.e.,

Order to Maintain Assets

retailer, group purchasing organization, wholesaler or distributor) on a regular basis and in a timely manner;

7. beginning on the Acquisition Date, provide the Felbamate Acquirer with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Felbamate Acquirer in an efficient and timely manner.

H. Respondent shall:

1. pending complete delivery of all Felbamate Confidential Business Information provide the Felbamate Acquirer and the Monitor with access to the Felbamate Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files that contain Felbamate Confidential Business Information and facilitating delivery of the Felbamate Confidential Business Information in a manner consistent with this Order;
2. on or before the Felbamate Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Felbamate Confidential Business Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Felbamate Confidential Business Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete

Order to Maintain Assets

records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and

3. not later than thirty (30) days after the Felbamate Closing Date, provide written notification of the restrictions on the use and disclosure of Felbamate Confidential Business Information to all of its employees who may be in possession of or have access to Felbamate Confidential Business Information. Respondent shall give the above-described notification by email with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Felbamate Closing Date. Respondent shall provide a copy of the notification to the Felbamate Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Felbamate Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

I. Respondent shall:

1. pending complete delivery of all Carisoprodol Confidential Business Information to Indicus, provide Indicus and the Monitor with access to the Carisoprodol Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files that contain Carisoprodol Confidential Business Information and facilitating delivery of the Carisoprodol Confidential Business Information in a manner consistent with this Order;

Order to Maintain Assets

2. on or before the Carisoprodol Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Carisoprodol Confidential Business Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Carisoprodol Confidential Business Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed;
3. not later than thirty (30) days after the Carisoprodol Closing Date, provide written notification of the restrictions on the use and disclosure of Carisoprodol Confidential Business Information to all of its employees who may be in possession of, or have access to Carisoprodol Confidential Business Information. Respondent shall give the above-described notification by e mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Carisoprodol Closing Date. Respondent shall provide a copy of the notification to the Carisoprodol Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Carisoprodol Acquirer with copies of all

Order to Maintain Assets

certifications, notifications, and reminders sent to Respondent's personnel.

- J. Respondent shall not
1. use, directly or indirectly, any Confidential Business Information related to a Divestiture Product other than as necessary to comply with the requirements of this Order, Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement, or applicable Law;
 2. not disclose or convey any Confidential Business Information related to a Divestiture Product, directly or indirectly, to any Person except (i) the Acquirer of the relevant Divestiture Product, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of a Divestiture Product to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Product.
- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Felbamate Product Business within the Geographic Territory through its full transfer and delivery to an Acquirer, to maintain the confidentiality of the Confidential Business Information related to the Divestiture Products, and to minimize any risk of loss of competitive potential for the Felbamate Product Business within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the

Order to Maintain Assets

Divestiture Product Assets except for ordinary wear and tear.

III.**IT IS FURTHER ORDERED** that:

- A. The Commission may appoint a monitor or monitors (“Monitor”) to assure that Respondent expeditiously complies with all obligations and performs all responsibilities required by this Order, the Order to Maintain Assets and the Remedial Agreements. The Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions to which the Monitor and Respondent agree and that the Commission approves.
- B. The Commission appoints F. William Rahe of Quantic Regulatory Services, LLC as a Monitor and approves the agreement between Quantic Regulatory Services, LLC and Respondent, attached as Public Appendix C and Non-Public Appendix C-1 to the Decision and Order.
- C. The Monitor’s duties and responsibilities shall include the following:
 - 1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 - 2. The Monitor shall have the power and authority to monitor Respondent’s compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission;

Order to Maintain Assets

3. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities; and
 4. The Monitor shall evaluate the reports submitted to the Commission by any Respondent pursuant to this Order, the Decision and Order, and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning a) the performance by the submitting Respondent of its obligations under the Order, and b) the progress by the Felbamate Acquirer (or its Manufacturing Designee) toward obtaining FDA approval to manufacture (independently of Respondent) each Felbamate Product and the ability to manufacture each Felbamate Product in commercial quantities, in a manner consistent with cGMP.
- D. Respondent shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including, but not limited to, the following:
1. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor;

Order to Maintain Assets

2. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Orders;
 3. Subject to any demonstrated legally recognized privilege, the Respondent shall provide the Monitor with full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets; and
 4. Respondent shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to this Order, the Decision and Order, or the Consent Agreement.
- E. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement; however such agreement shall not limit the ability of the Monitor to provide information to the Commission without the consent of Respondent.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Respondent's materials and information received in connection with the performance of the Monitor's duties,

provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to the

Order to Maintain Assets

Respondent the substance of communications to or from the Commission or the Acquirer.

- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor.
- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.
- J. The Monitor shall serve until the later of a) the completion of the divestitures of the Carisoprodol Product Assets and the Felbamate Product Assets, including the transfer and delivery of the related Product Manufacturing Technology; b) the date the Felbamate Acquirer (or its Manufacturing Designee) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture final finished Felbamate Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent; c) the date the Felbamate Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the Felbamate Products; d) the date of written notification

Order to Maintain Assets

from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Felbamate Acquirer has abandoned its efforts to manufacture the Felbamate Products; or e) five (5) years.

IV.**IT IS FURTHER ORDERED** that:

- A. Respondent shall submit to the Commission and to the Monitor verified written reports within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission and every sixty (60) days thereafter until Respondent has fully complied with this Order to Maintain Assets and Paragraphs II and III of the Decision and Order, setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the Orders. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Orders, including:
1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 2. a detailed description of the timing for the completion of such obligations;

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph IX of the Decision and Order.

Order to Maintain Assets

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger, or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and or electronically stored information as defined in Rule 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), books, ledgers, accounts, correspondence, memoranda and all other records and documents (in whatever form such records and documents are kept) in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

Order to Maintain Assets

- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII.**IT IS FURTHER ORDERED** that

- A. The Order to Maintain Assets shall terminate as of
1. the later of the following dates:
 - a. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. §2.34,
 - b. the day after the later of (i) divestiture of all the Felbamate Product Assets, as required and described in the Decision and Order, or the (ii) delivery of the Carisoprodol Confidential Business Information, as required by and described in the Decision and Order, or
 - c. the day after the Product Manufacturing Technology related to the Felbamate Products has been provided to the Felbamate Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Felbamate Acquirer, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transactions related to the provision of the Product Manufacturing Technology are complete;
 2. the day after Respondent provides written notice to the Commission that the Acquisition will not be consummated; or

Decision and Order

3. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan N.V. (“Mylan” or “Respondent”) of Meda AB, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waives and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent

Decision and Order

Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Mylan N.V. is a corporation organized, existing, and doing business under and by virtue of the laws of the Netherlands. Its principal executive offices are located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL109UL, England, and its United States address for service of process in this matter is as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317. Mylan Pharmaceuticals Inc., a corporation organized, existing and doing business under and by virtue of the laws of West Virginia, is a wholly-owned subsidiary of Mylan N.V. with its offices at 781 Chestnut Ridge Road, Morgantown, WV 26505.
2. Meda AB is a corporation organized, existing, and doing business under and by virtue of the laws of Sweden with its principal executive offices located at Box 906, SE-170 09 Solna, Sweden.
3. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

- A. “Mylan” or “Respondent” means Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled

Decision and Order

by Mylan N.V. (including but not limited to Mylan Pharmaceuticals Inc.) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Meda AB.

- B. “Commission” means the Federal Trade Commission.
- C. “Meda” means Meda AB or any of Meda AB’s subsidiaries.
- D. “Indicus” means USV Limited, a company organized under the laws of India with its principal offices at BSD Marg, Govandi East, Mumbai 400 088 or any of its subsidiaries, including Indicus Pharma LLC.
- E. “Alvogen” means Alvogen Group, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal executive offices located at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058, or any of Alvogen Group, Inc.’s subsidiaries.
- F. “Acquirer(s)” means the Carisoprodol Acquirer, the Felbamate Acquirer or any other Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- G. “Acquisition” means Respondent Mylan’s acquisition of Meda AB pursuant to Mylan’s public offer to the shareholders of Meda AB to acquire all of the outstanding shares of Meda AB.
- H. “Acquisition Date” means the date on which the Acquisition is consummated.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s),

Decision and Order

license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).

- J. “Application(s)” means any of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- K. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.
- L. “Carisoprodol Acquirer” means Indicus or any other Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- M. “Carisoprodol Closing Date” means the later of (1) the Acquisition Date and (2) the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer,

Decision and Order

deliver, or otherwise convey the Carisoprodol Product Assets to an Acquirer.

- N. “Carisoprodol Divestiture Agreement” means the Second Amendment to the Master Collaboration and Supply Agreement by and between USV Limited, Indicus Pharma LLC and Mylan Pharmaceuticals Inc., dated as of June 22, 2016, contained in Non-Public Appendix A, or any other agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) to accomplish the requirements of this Order concerning the Carisoprodol Products, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission (except as provided under Rule §2.41(f), 16 C.F.R. §2.41(f)).
- O. “Carisoprodol Products” means all Products in Development, marketed, or sold by Mylan that are manufactured pursuant to Application ANDA No. 205126 and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, carisoprodol, at the following strengths: 250mg and 350mg.
- P. “Carisoprodol Product Assets” means all rights, title and interest in all assets of Mylan as of the Acquisition Date related to the Business of the Carisoprodol Products, including but not limited to the following related to the Business of the Carisoprodol Products:
1. rights to all Applications;
 2. all Product Intellectual Property;
 3. all Product Approvals;
 4. all Product Marketing Materials;
 5. all Product Scientific and Regulatory Material;

Decision and Order

6. all Website(s) related exclusively to the Carisoprodol Products and all content related exclusively to the Carisoprodol Products that is displayed on any Website that is not dedicated exclusively to the Carisoprodol Products;
 7. all Product Development Reports; and
 8. at the option of the Acquirer, all Product Contracts to purchase Carisoprodol Product(s).
- Q. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- R. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- S. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is related to the conduct of the Business of a specified Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:
1. information relating to the Respondent’s general business strategies or practices that does not discuss with particularity the specified Divestiture Product(s);
 2. information that is contained in documents, records, or books of the Respondent that is provided to an Acquirer by the Respondent that is

Decision and Order

unrelated to the specified Divestiture Product(s) acquired by that Acquirer; and

3. information prepared in connection with the Acquisition that relates to United States, state, or foreign antitrust or competition Laws and that is protected by the attorney work product, attorney-client, joint defense, or other privilege.

T. “Contract Manufacture” means the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent of, and in the identical dosage strength, formulation, and presentation as, a Contract Manufacture Product on behalf of an Acquirer; or
3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

U. “Contract Manufacture Product(s)” means the Felbamate Products and any ingredient, material, or component used in the manufacture of a Felbamate Product including the active pharmaceutical ingredient(s), excipient(s), or packaging materials (including, without limitation, drug vials),

provided, however, that with the consent of the Acquirer, the Respondent may substitute a Therapeutic Equivalent form of a Felbamate Product in performance of Respondent’s agreement to Contract Manufacture.

Decision and Order

- V. “Development” means all preclinical and clinical drug development activities, including test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- W. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of the Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee,
- provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.*
- X. “Divestiture Closing Date” means the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey a Divestiture Product to an Acquirer

Decision and Order

- Y. “Divestiture Product(s)” means individually and collectively the Carisoprodol Products and the Felbamate Products.
- Z. “Divestiture Product Assets” means, individually and collectively the Carisoprodol Product Assets and the Felbamate Product Assets.
- AA. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- BB. “Domain Name” means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- CC. “Drug Master File(s)” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- DD. “Felbamate Acquirer” means Alvogen or any other Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- EE. “Felbamate Closing Date” means the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Felbamate Product Assets to an Acquirer.
- FF. “Felbamate Divestiture Agreements” means the Asset Purchase Agreement by and between Mylan N.V. and Alvogen Pharma US, Inc. and the Supply and Technology Transfer Agreement by and between

Decision and Order

Mylan Pharmaceuticals Inc. and Alvogen Malta Operations Ltd. contained in Non-Public Appendix B, or any other agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) to accomplish the requirements of this Order concerning the Felbamate Products, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission (except as provided under Rule §2.41(f), 16 C.F.R. §2.41(f)).

- GG. “Felbamate Products” means the products manufactured, in Development, marketed, sold, owned, or controlled by Mylan pursuant to Application ANDA No. 204595 and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, felbamate, at the following strengths: 400mg, and 600mg.
- HH. “Felbamate Product Assets” means all rights, title, and interest in and to all assets of Mylan as of the Acquisition Date that are related to the Business of the Felbamate Products, to the extent legally transferable, including but not limited to the following related to the Business of the Felbamate Products:
1. rights to all Applications;
 2. all Product Intellectual Property;
 3. all Product Approvals;
 4. all Product Manufacturing Technology;
 5. all Product Marketing Materials;
 6. all Product Scientific and Regulatory Material;
 7. all Website(s) related exclusively to the Felbamate Products and all content related exclusively to the

Decision and Order

Felbamate Products that is displayed on any Website that is not dedicated exclusively to the Felbamate;

8. a list of all of the NDC Numbers related to each Felbamate Product (“Felbamate NDC Numbers”), and, to the extent permitted by Law, the right to
 - a. require Respondent to discontinue the use of the Felbamate NDC Numbers in the sale or marketing of the Felbamate Products *except* (i) for returns, rebates, allowances, and adjustments for such Products sold prior to the Felbamate Closing Date, (ii) as may be required by applicable Law, or (iii) as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement,
 - b. prohibit Respondent from seeking from any customer any type of cross- referencing of the Felbamate NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for the Felbamate Products sold prior to the Felbamate Closing Date and *except* as may be required by applicable Law,
 - c. seek to change any cross-referencing by a customer of the Felbamate NDC Numbers with a Retained Product and to receive notification from the Respondent of any such cross-referencing that is discovered by the Respondent,
 - d. seek cross-referencing by a customer of the Respondent’s NDC Numbers related to a Felbamate Product with the Acquirer’s NDC Numbers related to the Felbamate Product,

Decision and Order

- e. approve the timing of Respondent's discontinued use of the Felbamate NDC Numbers in the sale or marketing of the Felbamate Products *except* (i) for returns, rebates, allowances, and adjustments for Felbamate Products sold prior to the Felbamate Closing Date, (ii) as may be required by applicable Law, or (iii) as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement, and
 - f. approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of the Felbamate NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);
9. all Product Development Reports;
10. at the option of the Acquirer, all Product Contracts related a Felbamate Product;
11. all patient registries related to the Felbamate Products, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the Felbamate Products (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);
12. the following information for each High Volume Account for a Felbamate Product:
- a. the name and business contact information for the employee(s) of the High Volume Account that is or has been responsible for the purchase of the specified Felbamate Product,

Decision and Order

- b. net sales (in either units or dollars) on an annual, quarterly, or monthly basis of each Felbamate Product, and
 - c. separately for each SKU or NDC Number of a Felbamate Product purchased by such customer, (i) the final price as of the Felbamate Closing Date, i.e., the final price charged by Respondent net of all discounts, rebates, or promotions, (ii) all adjustments made to the net price during the one (1) year period immediately prior to the Felbamate Closing Date, (iii) any supply outages (failures to supply) during the one (1) year period immediately prior to the Felbamate Closing Date, and (iv) to the extent known by the Respondent, the status of the product on the customer's respective formulary (i.e., primary, secondary, or backup),
 - d. inventory levels (weeks of supply) of each Felbamate Product as of the Felbamate Closing Date, and
 - e. the anticipated reorder dates for each customer as of the Felbamate Closing Date;
13. the following information for each customer and targeted customer for a Felbamate Product (other than High Volume Accounts):
- a. the net sales (in either units or dollars) for each Felbamate Product on either an annual, quarterly, or monthly basis,
 - b. inventory levels (weeks of supply) of each Felbamate Product as of the Felbamate Closing Date, and
 - c. the anticipated reorder dates for each customer as of the Felbamate Closing Date;

Decision and Order

14. the wholesale acquisition cost for each Felbamate Product for each of the twelve (12) months immediately prior to the Felbamate Closing Date;
15. the following information for each Felbamate Product that has had any batch determined to be out-of-specification during the five (5) year period immediately preceding the Felbamate Closing Date: (i) a detailed description of the deficiencies (e.g., impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure) with respect to any out-of-specification batch; (ii) the corrective actions taken to remediate the cGMP deficiencies in the Felbamate Product; and (iii) to the extent known by Respondent, the employees (whether current or former) responsible for taking such corrective actions;
16. a list of all active pharmaceutical ingredient suppliers identified on an Application of a Retained Product that is the Therapeutic Equivalent of a Felbamate Product;
17. copies of all unfilled customer purchase orders for the Felbamate Products as of the Felbamate Closing Date, to be provided to the Acquirer no later than five (5) days after the Felbamate Closing Date;
18. at the option of the Acquirer and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Felbamate Closing Date including, but not limited to, raw materials, packaging materials, work-in-process, and finished goods related to the Felbamate Products;
19. at the option of the Acquirer, all unfilled customer purchase orders for the Felbamate Products; and

Decision and Order

20. all of the Respondent's books, records, and files directly related the Felbamate Products, including all books, records and files directly related to the foregoing items,

provided, however, that the Felbamate Product Assets shall not include: (i) documents relating to the Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the Felbamate Products; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the Felbamate Products by the Monitor or the Acquirer; (iv) information that is exclusively related to the Retained Products; and (v) any real estate and the buildings and other permanent structures located on such real estate;

provided further, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the Felbamate Products and to Retained Products and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Felbamate Products; or (ii) for which Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, Respondent shall provide Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

Decision and Order

- II. “Felbamate Product Core Employee” means a salaried employee or former employee of the Respondent who directly participated in any of the following activities within the eighteen (18) month period immediately prior to the Felbamate Closing Date (irrespective of the portion of working time involved) unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance:
1. research, Development, regulatory approval process, or clinical studies of the Felbamate Products; or
 2. planning, design, implementation, or operational management of the Product Manufacturing Technology of the Felbamate Products.
- JJ. “Felbamate Product License” means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) with rights to sublicense to the following as of the Felbamate Closing Date:
1. all Patents owned, licensed or controlled by Respondent related to a Felbamate Product that the Respondent can demonstrate were being used prior to the Acquisition Date for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date;
 2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information owned, licensed or controlled by Respondent, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product that Respondent can demonstrate were being used prior to the Acquisition Date for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date;

Decision and Order

3. all Product Manufacturing Technology related to general manufacturing know-how (i.e. manufacturing know-how not exclusively related to a Felbamate Product) owned, licensed, or controlled by Respondent to:
 - a. research and Develop the Felbamate Products for marketing, distribution, or sale within the Geographic Territory,
 - b. use, make, have made, distribute, offer for sale, promote, advertise, or sell the Felbamate Product(s) within the Geographic Territory,
 - c. import or export the Felbamate Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution, or sale of the Felbamate Products in the Geographic Territory, and
 - d. have the Felbamate Product(s) made anywhere in the world for distribution or sale within or import into the Geographic Territory; and
4. a full, complete, and unlimited Right of Reference or Use to the Drug Master File related to the NDA for any Retained Product that is the Therapeutic Equivalent of a Felbamate Product to reference or use in any Application related to a Felbamate Product,

provided, however, that for any intellectual property that is licensed by Respondent from a Third Party under a license entered prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondent.

- KK. “Geographic Territory” means the United States of America, including all of its territories and possessions, unless otherwise specified.

Decision and Order

- LL. “Government Entity” means any Federal, state, local, or non-U.S. government; or any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.
- MM. “High Volume Accounts” mean any customer (retailer, wholesaler or distributor) whose annual or projected annual aggregate purchase amount (on a company-wide level), in units or in dollars, of a specified Divestiture Product in the Geographic Territory from the Respondent was, or is projected to be, among the top twenty highest of such purchase amounts by the Respondent’s U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; or (iii) the end of the last quarter that immediately preceded the Divestiture Closing Date.
- NN. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- OO. “Manufacturing Designee” means any Person other than the Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- PP. “Monitor” means any monitor appointed pursuant to Paragraph V of this Order or Paragraph III of the related Order to Maintain Assets.
- QQ. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- RR. “Orders” means this Decision and Order and the related Order to Maintain Assets.

Decision and Order

- SS. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- TT. “Patent(s)” means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the specified Divestiture Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- UU. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups, or affiliates thereof.
- VV. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- WW. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefore, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in

Decision and Order

connection with any Application related to that Product.

- XX. “Product Contracts” means all contracts or agreements:
1. pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, only the specified Divestiture Product from the Respondent (for avoidance of doubt, this provision does not include contracts or agreements that include products other than Divestiture Products);
 2. pursuant to which the Respondent had as of the Acquisition Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party, for use in connection with the manufacture of the specified Divestiture Product;
 3. relating to any Clinical Trials involving the specified Divestiture Product;
 4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
 5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
 6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished Product on behalf of the Respondent;

Decision and Order

7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;
9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product,

provided, however, that where any such contract or agreement also relates to a Retained Product(s), the Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently

Decision and Order

may retain similar rights for the purposes of the Retained Product(s).

- YY. “Product Copyrights” means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and all educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing, or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto, and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports, and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product’s sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of the Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data

Decision and Order

contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

ZZ. “Product Development Reports” means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;

Decision and Order

9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including, without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;
17. manufacturing batch records related to the specified Divestiture Product;

Decision and Order

18. stability testing records related to the specified Divestiture Product;
 19. change in control history related to the specified Divestiture Product; and
 20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- AAA. “Product Intellectual Property” means all of the intellectual property related to a Product (other than intellectual property licensed under the Felbamate Product License) that is owned, licensed, or controlled by the Respondent as of the specified Divestiture Closing Date:
1. Patents;
 2. Product Copyrights;
 3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information; and
 4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof, and to bring suit against a Third Party for the past, present, or future infringement, misappropriation, dilution, misuse, or other violation of any of the foregoing,

provided, however, that “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Mylan” or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof; or general

Decision and Order

registered images or symbols by which Mylan can be identified or defined.

BBB. “Product Manufacturing Technology” means all of the following related to a Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients, or packaging materials; and
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer’s option, all such equipment used to manufacture that Product.

CCC. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the specified Divestiture Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales

Decision and Order

materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

- DDD. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.
- EEE. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging and the lettering of the Product trade name or brand name.
- FFF. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefore (and all renewals, modifications, and extensions thereof), and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- GGG. “Remedial Agreement(s)” means any Carisoprodol Divestiture Agreement or Felbamate Divestiture Agreement that has been approved by the Commission.
- HHH. “Retained Product(s)” means any Product(s) other than a Divestiture Product.

Decision and Order

- III. “Right of Reference or Use” means the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety, or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials); (ii) Product Development Reports; or (iii) Product Scientific and Regulatory Material for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.
- JJJ. “Supply Cost” means a cost not to exceed (i) the Respondent’s average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date, or (ii) the lowest average net price per unit (i.e., the final price per SKU or NDC Number charged by the Respondent net of all discounts, rebates, or promotions) charged for the specified Divestiture Product during the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit;
- provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.
- KKK. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and

Decision and Order

meaningful manner. Such standards and requirements shall include, *inter alia*:

1. designating employees of the Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
 - a. manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product,
 - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee to manufacture, distribute, market, and sell the specified Divestiture Product in commercial

Decision and Order

quantities and to meet all Agency-approved specifications for such Divestiture Product, and

- c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

LLL. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

MMM. “Third Party(ies)” means any non-governmental Person other than the following: the Respondent; or the Acquirer of particular assets or rights pursuant to this Order.

NNN. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by the Respondent,

provided, however, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that

- A. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the Felbamate Product Assets and grant the Felbamate Product License, absolutely and in good faith, to Alvogen to, and in accordance with, the Felbamate Divestiture Agreements,

Decision and Order

provided, however, if Respondent has divested the Felbamate Product Assets and granted the Felbamate Product License to Alvogen prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Alvogen is not an acceptable purchaser of the Felbamate Product Assets or licensee of the Felbamate Product License, then Respondent shall immediately rescind the transaction with Alvogen, in whole or in part, as directed by the Commission, and shall divest the Felbamate Product Assets and grant the Felbamate Product License (as applicable) within one hundred eighty (180) days after the date this Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

provided further, if Respondent has divested the Felbamate Product Assets and granted the Felbamate Product License to Alvogen prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture or license grant was accomplished was not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Felbamate Product Assets or the grant of the Felbamate Product License to Alvogen (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Felbamate Closing Date, Respondent shall
1. provide the Felbamate Acquirer with the opportunity to review all Product Contracts related to the Felbamate Products for the purposes of

Decision and Order

determining whether to assume such contracts or agreements; and

2. secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the Felbamate Product Assets and grant the Felbamate Product License to the Felbamate Acquirer, and to permit the Felbamate Acquirer to continue the Business of the Felbamate Products,

provided, however, Respondent may satisfy this requirement by certifying that the Felbamate Acquirer has executed all such agreements directly with each of the relevant Third Parties.

- C. Within five (5) days after the Felbamate Closing Date, Respondent shall provide to the Felbamate Acquirer
 1. copies of all unfilled customer purchase orders for the Felbamate Products as of the Felbamate Closing Date; and
 2. the information included in the Felbamate Product Assets at Paragraphs I.HH(12), I.HH(13), I.HH(14), I.HH(15) and I.HH(16).
- D. Respondent shall provide, or cause to be provided, to the Felbamate Acquirer all Product Manufacturing Technology related to the Felbamate Products in a manner consistent with the Technology Transfer Standards.
- E. Respondent shall
 1. not enforce any agreement that limits or otherwise impairs the ability of the Felbamate Acquirer to use or to acquire the Felbamate Product Assets and the Felbamate Product License, including but not limited to, all Product Manufacturing Technology, and Confidential Business Information related to the Felbamate Products

Decision and Order

2. No later than ten (10) days after the Felbamate Closing Date, grant to each Third Party subject to an agreement that limits or otherwise impairs the ability of the Felbamate Acquirer to use or to acquire the Felbamate Product Assets or Felbamate Product License (including but not limited to Product Manufacturing Technology and related intellectual property and Felbamate Confidential Business Information), a release that allows the Third Party to provide the relevant information to the Felbamate Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to that Acquirer and the Monitor (if one has been appointed).

F. Respondent shall:

- a. upon reasonable written notice and request from the Felbamate Acquirer to Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, in a timely manner and under reasonable terms and conditions, a supply of any requested Contract Manufacture Product at the Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of the Respondent from Persons other than the Respondent;
- b. make representations and warranties to the Felbamate Acquirer that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract

Decision and Order

Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent shall agree to indemnify, defend, and hold the Felbamate Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Felbamate Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Felbamate Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim,

provided, however, that the Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however,* that this obligation shall not require Respondent to be liable for any negligent act or omission of the Felbamate Acquirer or for any representations and warranties, express or implied, made by the Felbamate Acquirer that exceed the representations and warranties made by the Respondent to the Felbamate Acquirer in an agreement to Contract Manufacture;

provided further, however, that where (i) an agreement to divest the Felbamate Product Assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, the agreement may contain limits on the Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

Decision and Order

- c. give priority to supplying a Contract Manufacture Product to the Felbamate Acquirer over manufacturing and supplying of Products for Respondent's own use or sale;
- d. make representations and warranties to the Felbamate Acquirer that Respondent shall hold harmless and indemnify the Felbamate Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent,

provided, however, that where (i) an agreement to divest the Felbamate Product Assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, the agreement may contain limits on the Respondent's aggregate liability for such a failure;

- e. during the term of any agreement to Contract Manufacture, upon written request of the Felbamate Acquirer or the Monitor (if any has been appointed), make available to the Felbamate Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Felbamate Closing Date;
- f. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Products;
- g. in the event Respondent becomes unable to supply or produce a Contract Manufacture Product from

Decision and Order

the facility or facilities originally contemplated under a Remedial Agreement with the Felbamate Acquirer: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent uses or has used to source its own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;

- h. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture;
- i. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Felbamate Acquirer and at a facility chosen by the Felbamate Acquirer, for the purposes of enabling the Felbamate Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the Contract Manufacture Products in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Felbamate Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products; and
- j. notify the Commission and the Monitor in writing at least sixty (60) days prior to exercising any right under a Divestiture Agreement to terminate an agreement to Contract Manufacture any Contract Manufacture Products.

Decision and Order

This Paragraph II.F. shall remain in effect until the earliest of: (i) the date the Felbamate Acquirer (or its Manufacturing Designee) is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (ii) the date the Felbamate Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Felbamate Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) five (5) years after the Felbamate Closing Date.

G. Respondent shall:

1. submit to the Felbamate Acquirer, at Respondent's expense, all Confidential Business Information related to the Felbamate Products or the Business of the Felbamate Products ("Felbamate Confidential Business Information");
2. deliver all Felbamate Confidential Business Information to the Felbamate Acquirer in good faith, in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information, and in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all Felbamate Confidential Business Information provide the Felbamate Acquirer and the Monitor (if any has been appointed) with access to the Felbamate Confidential Business Information and employees who possess or are able to locate such information

Decision and Order

for the purposes of identifying the books, records, and files that contain Felbamate Confidential Business Information and facilitating delivery of the Felbamate Confidential Business Information in a manner consistent with this Order;

4. on or before the Felbamate Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Felbamate Confidential Business Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Felbamate Confidential Business Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and
5. not later than thirty (30) days after the Felbamate Closing Date, provide written notification of the restrictions on the use and disclosure of Felbamate Confidential Business Information to all of its employees who may be in possession of or have access to Felbamate Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Felbamate Closing Date. Respondent shall provide a copy of the notification to the Felbamate Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall

Decision and Order

provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Felbamate Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

- H. Respondent shall deliver to the Acquirer the following information regarding each Felbamate Product Core Employee no later than ten (10) days after such information is requested by either the Acquirer or staff of the Commission:
1. direct contact information for the employee, including telephone number;
 2. the date of hire and effective service date;
 3. job title or position held;
 4. a specific description of the employee's responsibilities related to the Felbamate Products; provided, however, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;
 5. the base salary or current wages;
 6. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
 7. employment status (i.e., active or on leave or disability; full-time or part-time);
 8. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

Decision and Order

9. at the Acquirer's option, a copy of all applicable employee benefit plans and summary plan descriptions (if any),

provided that, the provision of such information may be conditioned upon the Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing to a Felbamate Product Core Employee the opportunity to enter into employment contracts during the Felbamate Product Core Employee Access Period, and (iii) restrict access to the information to the Acquirer's employees or representatives who need such access in connection with the specified and permitted use.

- I. For a period ending twelve (12) months after the Felbamate Closing Date, Respondent shall
 1. provide Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Felbamate Product Core Employees. This period is hereinafter referred to as the "Felbamate Product Core Employee Access Period";
 2. not interfere with the hiring or employing by the Felbamate Acquirer or its Manufacturing Designee of the Felbamate Product Core Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any non-compete or nondisclosure provision of employment with respect to a Felbamate Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Felbamate Acquirer or its Manufacturing Designee;

Decision and Order

3. not make any counteroffer to any Felbamate Product Core Employee who has received a written offer of employment from the Felbamate Acquirer or its Manufacturing Designee; and
4. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Felbamate Product ("Covered Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee, or hire such Covered Employee;

provided, however, Respondent may hire any former Covered Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the terms of the Order, and

provided further, that Respondent may advertise for employees in newspapers, trade publications, or other media not targeted specifically at Covered Employees; or hire a Covered Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent;

Failure by Respondent to provide any information requested in Paragraph II.H above within the time provided therein shall extend the time period in this Paragraph II.I in an amount equal to the delay.

- J. Until the Felbamate Closing Date, Respondent shall provide all Felbamate Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Felbamate Products consistent with past practices and/or as may be necessary to preserve

Decision and Order

the marketability, viability, and competitiveness of the Business related to the Felbamate Products and to ensure successful execution of the pre-Acquisition plans for the Felbamate Products. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Divestiture Closing Date for the Felbamate Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law),

- K. Until Respondent completes the divestiture of the Felbamate Product Assets (including fully providing Product Manufacturing Technology to the Felbamate Acquirer) Respondent shall take all actions necessary to:
1. maintain the full economic viability and marketability of the Business associated with the Felbamate Products;
 2. minimize any risk of loss of competitive potential for that Business;
 3. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Felbamate Products;
 4. ensure the assets related to the Felbamate Products are provided to the Felbamate Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the associated Business; and
 5. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology.
- L. Respondent shall not sell, transfer, encumber, or otherwise impair the Felbamate Product Assets (other than in the manner prescribed in this Order), nor take

Decision and Order

any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to the Divestiture Products.

III.**IT IS FURTHER ORDERED** that

- A. Not later than ten (10) days after the Acquisition Date, Respondent shall terminate the Addendum to the Master Collaboration and Supply Agreement between USV Limited, Indicus Pharma LLC and Mylan Pharmaceuticals dated January 9, 2013, pursuant to the Carisoprodol Divestiture Agreement and shall divest the Carisoprodol Product Assets, absolutely and in good faith, to Indicus in accordance with the Carisoprodol Divestiture Agreement;

provided, however, if Respondent has divested the Carisoprodol Product Assets to Indicus prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Carisoprodol Product Assets to Indicus (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Carisoprodol Closing Date, Respondent shall provide the Carisoprodol Acquirer with the opportunity to review all Product Contracts related to the Carisoprodol Products for the purposes of the Acquirer determining whether to assume such contracts or agreements.

Decision and Order

- C. Respondent shall:
1. submit to Indicus, at Respondent's expense, all Confidential Business Information related to the Carisoprodol Products or the Business of the Carisoprodol Products ("Carisoprodol Confidential Business Information");
 2. deliver all Carisoprodol Confidential Business Information to Indicus in good faith, in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
 3. pending complete delivery of all Carisoprodol Confidential Business Information to Indicus, provide Indicus and the Monitor (if any has been appointed) with access to the Carisoprodol Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files that contain Carisoprodol Confidential Business Information and facilitating delivery of the Carisoprodol Confidential Business Information in a manner consistent with this Order;
 4. on or before the Carisoprodol Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Carisoprodol Confidential Business Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Carisoprodol Confidential Business Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this

Decision and Order

Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed;

5. not later than thirty (30) days after the Carisoprodol Closing Date, provide written notification of the restrictions on the use and disclosure of Carisoprodol Confidential Business Information to all of its employees who may be in possession of, or have access to Carisoprodol Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Carisoprodol Closing Date. Respondent shall provide a copy of the notification to the Carisoprodol Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Carisoprodol Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

IV.

IT IS FURTHER ORDERED that

- A. Respondent shall not
 1. use, directly or indirectly, any Confidential Business Information related to a Divestiture Product other than as necessary to comply with the requirements of this Order, Respondent's obligations to each respective Acquirer under the

Decision and Order

terms of any related Remedial Agreement, or applicable Law;

2. not disclose or convey any Confidential Business Information related to a Divestiture Product, directly or indirectly, to any Person except (i) the Acquirer of the relevant Divestiture Product, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of a Divestiture Product to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Product.
- B. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer, any Person controlled by or under common control with the Acquirer, the Manufacturing Designee of the Acquirer, or any Person that has an agreement with the Acquirer to commercialize, distribute, market or import a Divestiture Product:
1. under any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
 2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter

Decision and Order

of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from the Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

- C. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or

Decision and Order

otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

- D. For any patent infringement suit filed prior to the relevant Divestiture Closing Date in which the Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that the Respondent has prepared or is preparing to defend against as of such Divestiture Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer, the Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;

Decision and Order

2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
 3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of the Respondent's outside counsel related to that Divestiture Product.
- E. The purpose of the divestiture of the Divestiture Product Assets, the provision of the related Product Manufacturing Technology for the Contract Manufacture Products and the related obligations imposed on the Respondent by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory;
 2. to create a viable and effective competitor that is independent of the Respondent in the Business of each Divestiture Product within the Geographic Territory; and
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

V.**IT IS FURTHER ORDERED** that:

- A. The Commission may appoint a monitor or monitors ("Monitor") to assure that Respondent expeditiously complies with all obligations and performs all responsibilities required by this Order, the Order to Maintain Assets and the Remedial Agreements. The Monitor shall serve, without bond or other security, at

Decision and Order

the expense of Respondent, on such reasonable and customary terms and conditions to which the Monitor and Respondent agree and that the Commission approves.

- B. The Commission appoints F. William Rahe of Quantic Regulatory Services, LLC as a Monitor and approves the agreement between Quantic Regulatory Services, LLC and Respondent, attached as Public Appendix C and Non-Public Appendix C-1 to this Order.
- C. The Monitor's duties and responsibilities shall include the following:
1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 2. The Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission;
 3. The Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities; and
 4. The Monitor shall evaluate the reports submitted to the Commission by the Respondent pursuant to this Order, the Order to Maintain Assets, and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning a) the performance by the submitting Respondent of its obligations under the Order, and b) the progress by the Felbamate Acquirer (or its Manufacturing

Decision and Order

Designee) toward obtaining FDA approval to manufacture (independently of Respondent) each Felbamate Product and the ability to manufacture each Felbamate Product in commercial quantities, in a manner consistent with cGMP.

- D. Respondent shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including, but not limited to, the following:
1. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor;
 2. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Orders;
 3. Subject to any demonstrated legally recognized privilege, the Respondent shall provide the Monitor with full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets; and

Decision and Order

4. Respondent shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to this Order, the Order to Maintain Assets or the Consent Agreement.
- E. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement; however such agreement shall not limit the ability of the Monitor to provide information to the Commission without the consent of Respondent.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Respondent's materials and information received in connection with the performance of the Monitor's duties,
provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to the Respondent the substance of communications to or from the Commission or the Acquirer.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff

Decision and Order

of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor.

- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the this Order.
- J. The Monitor shall serve until the later of a) the completion of the divestitures of the Carisoprodol Product Assets and the Felbamate Product Assets, including the transfer and delivery of the related Product Manufacturing Technology; b) the date the Felbamate Acquirer (or its Manufacturing Designee) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture final finished Felbamate Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent; c) the date the Felbamate Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the Felbamate Products; d) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Felbamate Acquirer has abandoned its efforts to manufacture the Felbamate Products; or e) five (5) years.

VI.**IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the

Decision and Order

Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and

Decision and Order

conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the

Decision and Order

delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power

Decision and Order

shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Divestiture Trustee

Decision and Order

from providing any information to the Commission.

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

VII.**IT IS FURTHER ORDERED** that

- A. It shall not be violation of this Order for Respondent's counsel (including in house counsel under appropriate confidentiality arrangements) to retain documents or other materials provided to an Acquirer, or access original documents provided to an Acquirer to
 - 1. assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable

Decision and Order

Government Entity, or any taxation requirements;
or

2. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products,

so long as copies of such documents are insufficient or otherwise unavailable, Respondent requires those who view such un-redacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably), and Respondent uses best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VIII.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be incorporated by reference into this Order and made a part hereof, and Respondent shall comply with all terms of the Remedial Agreement. A breach by Respondent of any term of a Remedial Agreement shall constitute a violation of this Order.
- B. A Remedial Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order and nothing in this Order shall be construed to reduce any rights or benefits of the Acquirer or to reduce any obligations of Respondent under any Remedial Agreement. To the extent that any term of a Remedial Agreement conflict with a term of this Order such that Respondent cannot fully comply with both, Respondent shall comply with the term of this Order.

Decision and Order

- C. Respondent shall not modify, replace or extend the terms of a Remedial Agreement without the prior approval of the Commission, except as otherwise provided under Rule §2.41(f), 16 C.F.R. §2.41(f).
- D. Respondent shall include in each Remedial Agreement related to the Felbamate Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondent's obligation to the Acquirer pursuant to this Order.
- E. Respondent shall include in the Remedial Agreement related to the Felbamate Products a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, the Felbamate Products, and to have any such manufacture to be independent of the Respondent, all as soon as reasonably practicable.
- F. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

IX.**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Respondent shall submit to the Commission and to the Monitor verified written reports within thirty (30) days after the date this Order becomes final and every sixty

Decision and Order

(60) days thereafter until Respondent has fully complied with Paragraphs II and III, setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 2. a detailed description of the timing for the completion of such obligations.
- C. One (1) year after this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

X.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger, or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

Decision and Order

XI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and or electronically stored information as defined in Rule 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), books, ledgers, accounts, correspondence, memoranda and all other records and documents (in whatever form such records and documents are kept) in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XII.

IT IS FURTHER ORDERED that this Order shall terminate on September 7, 2026.

By the Commission.

Decision and Order

In re Mylan N.V.

Non-Public Appendix A

Carisoprodol Divestiture Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

In re Mylan N.V.

Non-Public Appendix B

Felbamate Divestiture Agreements

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

In re Mylan N.V.

Public Appendix C

Monitor Agreement

Analysis to Aid Public Comment

In re Mylan N.V.

Non-Public Appendix C-1

Confidential Appendix A to the Monitor Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Mylan N.V. (“Mylan”) that is designed to remedy the anticompetitive effects resulting from Mylan’s acquisition of Meda AB (“Meda”). Under the terms of the proposed Consent Agreement, Mylan is required to divest all of its rights and assets related to 400 mg and 600 mg generic felbamate tablets to Alvogen Pharma US, Inc. (“Alvogen”), and to return all of its marketing rights and ownership interests in generic carisoprodol tablets to Indicus Pharma LLC (“Indicus”) the abbreviated new drug application owner for this product.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed consent Agreement or make final the Decision and Order (“Order”).

Analysis to Aid Public Comment

Pursuant to a public offer to the shareholders of Meda announced on February 10, 2016, Mylan intends to acquire 100% of the issued and outstanding shares of Meda for a total equity value at announcement of approximately \$7.2 billion. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. §18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. §45, by lessening current competition in the markets for 400 mg and 600 mg generic felbamate tablets and future competition in the market for 250 mg generic carisoprodol tablets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

The proposed acquisition would reduce the number of current suppliers in the markets for 400 mg and 600 mg generic felbamate tablets and reduce the number of future suppliers in the market for 250 mg generic carisoprodol tablets.

Generic felbamate tablets treat severe refractory epilepsy and are available in 400mg and 600 mg strengths. Three firms—Mylan, Meda, and Amneal Pharmaceuticals LLC—sell generic felbamate in the United States. A fourth firm, CorePharma LLC, has received U.S. Food and Drug Administration (“FDA”) approval for each strength of generic felbamate tablets, but it is not yet on the market

Generic carisoprodol is a muscle relaxer that works by blocking pain sensations between the nerves and the brain. Two firms market generic carisoprodol tablets: Meda and Vensun Pharmaceuticals. Mylan owns the U.S. marketing rights to a generic carisoprodol product that was recently approved by the FDA. Once it begins marketing generic carisoprodol, Mylan likely would have been the third supplier of generic carisoprodol tablets. Mylan is one of a limited number of suppliers capable of entering the United States market in the near future.

Analysis to Aid Public Comment

II. Entry

Entry into the three relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (“FDA”), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating competition between Mylan and Meda in the markets for 400 mg and 600 mg generic felbamate tablets. Market participants characterize generic felbamate tablets as commodity products, and prices are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The proposed acquisition would combine two of three companies offering the 400 mg and 600 mg strengths of generic felbamate tablets, likely leading consumers to pay higher prices.

In addition, the proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred in the 250 mg generic carisoprodol market if Mylan and Meda remained independent. The evidence shows that anticompetitive effects are likely to result from the proposed acquisition due to the elimination of an additional independent entrant in the market for 250 mg generic carisoprodol. Customers expect that the price of this pharmaceutical product will decrease with new entry by Mylan. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for 250 mg generic carisoprodol tablets.

Analysis to Aid Public Comment

IV. The Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the acquisition in the markets at issue by requiring Mylan to divest all its rights and assets relating to 400 mg and 600 mg generic felbamate tablets to Alvogen. Founded in 2009, Alvogen is an international pharmaceutical company with commercial operations in thirty-four countries. In addition, the proposed Consent Agreement requires Mylan to return its rights to market generic carisoprodol tablets in the United States to Indicus, the abbreviated new drug application owner for this product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed Order requires that Mylan transfer its manufacturing technology for felbamate to Alvogen and provide transitional services to assist Alvogen in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. The transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable employees of Mylan. In addition, Mylan must supply Alvogen with 400 mg and 600 mg generic felbamate tablets until Alvogen is able to manufacture generic felbamate successfully in commercial quantities.

To remedy competitive concerns raised by the acquisition in the market for generic 250 mg carisoprodol tablets, the proposed Order requires Mylan to terminate its agreement with Indicus that

Analysis to Aid Public Comment

gives Mylan the exclusive right to market and sell in the United States all strengths of carisoprodol tablets manufactured by Indicus. Indicus has existing relationships with suppliers of generic drugs that it can and expects to use to replace Mylan as its marketing partner for its carisoprodol products.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

FORTILINE, LLCCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4592; File No. 151 0000**Complaint, September 23, 2016 – Decision, September 23, 2016*

This consent order addresses Fortiline, LLC's invitation to collude while in both a horizontal (interbrand) and a vertical (intra-brand) relationship with the invitee. The complaint alleges that Fortiline violated Section 5 of the Federal Trade Commission Act by inviting a competing seller of ductile iron pipe to raise and fix prices. The consent order prohibits Fortiline from entering into, attempting to enter into, participating in, maintaining, organizing, implementing, enforcing, inviting, encouraging, offering or soliciting an agreement or understanding with any competitor to raise or fix prices or any other pricing action, or to allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories.

Participants

For the *Commission*: Mark Taylor.

For the *Respondent*: Timothy Muris, Kirkland & Ellis LLP.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41, *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Fortiline, LLC (hereinafter sometimes referred to as "Fortiline" or "Respondent"), has violated the provisions of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

Nature of the Case

1. Fortiline, a distributor of ductile iron pipe ("DIP"), invited a rival to raise and fix prices in North Carolina and Virginia. By

Complaint

inviting collusion, Fortiline endangered competition and violated Section 5 of the FTC Act.

Respondent

2. Fortiline is a limited liability company organized, existing, and doing business under and by virtue of the laws of North Carolina, with its principal place of business located in Concord, North Carolina.

3. Fortiline distributes waterworks infrastructure products, such as pipe (including DIP), tubing, valves, fittings, and piping accessories.

4. Fortiline is the third largest distributor of waterworks infrastructure products in the United States, operating approximately 37 branches in 12 states throughout the Southeast, the Mid-Atlantic, the Midwest, and Texas.

Jurisdiction

5. At all times relevant herein, Fortiline has been, and is now, a corporation as “corporation” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

6. The business practices of Fortiline, including the acts and practices alleged herein, are in commerce or affect commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

DIP Industry

7. DIP is a commodity product used in underground waterworks distribution systems and water treatment plants. End users of DIP are primarily municipalities and water utilities. For a typical project, the end user seeks bids from multiple contractors.

8. Contractors, in turn, solicit DIP bids from waterworks infrastructure distributors (such as Fortiline) and/or directly from

Complaint

DIP manufacturers. Contractors that buy direct from DIP manufacturers often pay a lower price, but forgo value-added services that distributors provide.

9. At all times relevant herein, each of the major DIP manufacturers in the United States periodically published to its distributors a nationwide “price list” or “pricing schedule.” Sometimes, instead of publishing a new price list, a DIP manufacturer announced a price adjustment stated in terms of a “multiplier,” a decimal number by which the published price was multiplied to arrive at the new price. A higher multiplier translated to a higher price for DIP.

The Manufacturer A – Fortiline Relationship

10. From its founding in 1997 until late 2009, most Fortiline branches distributed only DIP manufactured by Manufacturer A.

11. On or about December 14, 2009, Fortiline terminated Manufacturer A as its DIP supplier in North Carolina and in most of Virginia. After December 14, 2009, Fortiline branches in this region bid on new waterworks projects with DIP manufactured by Manufacturer B, a rival of Manufacturer A.

12. After December 14, 2009, some Fortiline branches outside of North Carolina and most of Virginia continued to distribute Manufacturer A’s DIP. In addition, even though Fortiline terminated Manufacturer A in North Carolina, Fortiline continued to supply Manufacturer A’s DIP to North Carolina contractors as needed to complete projects where Fortiline had, prior to December 14, 2009, submitted to the contractor a bid specifying Manufacturer A’s DIP.

13. Fortiline’s termination of Manufacturer A in North Carolina and most of Virginia left Manufacturer A without a major distributor in that region. In response, Manufacturer A began to market and sell DIP direct to contractors in North Carolina and most of Virginia, in competition with North Carolina/Virginia distributors and their DIP suppliers, including Fortiline and its new supplier Manufacturer B.

Complaint

14. Manufacturer A did not offer North Carolina and Virginia contractors the value-added services provided by distributors. In order to entice contractors to forgo those services and to buy directly from Manufacturer A, Manufacturer A offered lower prices to contractors.

15. Fortiline and other distributors (in conjunction with their DIP suppliers) reduced their prices in order to compete with Manufacturer A's lower prices.

Invitations to Collude

16. On two occasions in 2010, when Fortiline and Manufacturer A were competing against one another to sell DIP in North Carolina and most of Virginia, Fortiline communicated to Manufacturer A an invitation to collude on DIP pricing in that region.

17. On February 12, 2010, the chief executive officer and the vice president of sales for Fortiline met with Manufacturer A's vice president of sales. Among other things, they discussed Manufacturer A's practice of selling direct in North Carolina and most of Virginia at low prices.

18. During the evening of February 12, 2010, Fortiline's vice president of sales forwarded to Manufacturer A's vice president of sales an email reporting on market conditions in North Carolina. The email detailed Manufacturer A's practice of undercutting its rivals' prices. In contrast, the email stated, other major DIP manufacturers "have been trying to keep their numbers up thus far." The Fortiline email included the following commentary: "This is the type of irrational behavior [by Manufacturer A] that we were discussing earlier today. With this approach we will be at a .22 [multiplier] soon instead of a needed .42."

19. In substance, the February 12, 2010, email communicated Fortiline's dissatisfaction with Manufacturer A's low pricing in North Carolina, and its preference that both Fortiline and Manufacturer A bid to contractors using the higher .42 multiplier.

Decision and Order

20. Eight months later, on October 26, 2010, executives from Fortiline and Manufacturer A met again, this time at a trade association meeting. At the meeting, Fortiline complained that Manufacturer A had sold direct to a Virginia customer (that had previously purchased from Fortiline) at a 0.31 multiplier, and that this price was “20% below market.”

21. In substance, this conversation communicated Fortiline’s dissatisfaction with Manufacturer A’s low pricing in Virginia, and its preference that both Fortiline and Manufacturer A bid to contractors using a substantially higher multiplier in that region.

Violation Charged

22. As set forth in Paragraphs 16 through 21 above, Fortiline invited a competitor to raise and fix prices for DIP in North Carolina and Virginia, in violation of Section 5 of the Federal Trade Commission Act, as amended. The acts and practices of Fortiline, as alleged herein, constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended. Such acts and practices of Fortiline may continue or recur in the absence of appropriate relief.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-third day of September, 2016, issues its complaint against Respondent.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of Fortiline, LLC, a North Carolina limited liability company (“Fortiline”), and Fortiline having been furnished thereafter with a copy of the

Decision and Order

draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Fortiline with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Fortiline, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Fortiline of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said consent agreement is for settlement purposes only and does not constitute an admission by Fortiline that the law has been violated as alleged in such complaint or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Fortiline has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Order:

1. Fortiline, LLC, is a limited liability company organized, existing, and doing business under and by virtue of the laws of North Carolina, with its principal place of business in Concord, North Carolina.
2. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Fortiline, and this proceeding is in the public interest.

Decision and Order

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Respondent” means Fortiline, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and any joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates in each case controlled by Fortiline, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Competitor” means any Person engaged in the business of selling or distributing ductile iron pipe, and any such Person’s employees, agents, and representatives. The term “Competitor” does not include any Contractor.
- D. “Contractor” means any Person who constructs and installs waterworks infrastructure that uses ductile iron pipe according to stated requirements or specifications, at a mutually agreed upon price and within a specified timeframe, for another Person who shall be the ultimate owner of the infrastructure and its component ductile iron pipe.
- E. “Designated Employee” means any employee of Respondent with responsibility for the purchase, sale, or pricing of ductile iron pipe.
- F. “Manufacturer” means any Person engaged in the business of manufacturing or fabricating ductile iron pipe, and any such Person’s employees, agents, and representatives.

Decision and Order

- G. "Person" includes Respondent and means both natural persons and artificial persons, including, but not limited to, corporations, partnerships, unincorporated entities, or governments. For the purpose of this Order, any corporation includes the subsidiaries, divisions, groups, and affiliates controlled by it.

II.

IT IS FURTHER ORDERED that in connection with the sale or distribution of any ductile iron pipe, in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15, U.S.C. §44, Respondent shall cease and desist from, either directly or indirectly, or through any corporate or other device:

Entering into, attempting to enter into, adhering to, participating in, maintaining, organizing, implementing, enforcing, inviting, encouraging, offering or soliciting any agreement or understanding, express or implied, between or among Respondent and any Competitor:

- A. To raise, fix, maintain, or stabilize prices or price levels, rates or rate levels, or payment terms, or to engage in any other pricing action; or
- B. To allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories.

Provided, however, that it shall not, of itself, constitute a violation of Paragraph II. of this Order for Respondent to engage in any conduct that is (1) reasonably related to a lawful manufacturer-distributor relationship, lawful joint venture agreement, or lawful merger, acquisition or sale agreement; and (2) reasonably necessary to achieve the procompetitive benefits of such manufacturer-distributor relationship or of such agreement. For the avoidance of doubt, it shall not constitute a violation of Paragraph II of this Order for Respondent: (i) to communicate with a Manufacturer regarding Respondent's desire to receive prices or rates

Decision and Order

(including rebates and discounts) at least as favorable as those granted by that Manufacturer to a Competitor or Contractor; (ii) to request, negotiate, or enter into an agreement with a Manufacturer under which Respondent shall be that Manufacturer's exclusive or quasi-exclusive distributor; or (iii) to request or enter into an agreement with a Manufacturer under which Respondent distributes that Manufacturer's ductile iron pipe to a Contractor previously or potentially served by that Manufacturer.

Provided, further, however, that it shall not, of itself, constitute a violation of Paragraph II. of this Order for Respondent to negotiate with a Competitor regarding the terms of an agreement, or to enter into an agreement, if that negotiation or agreement relates exclusively to the terms under which Respondent either will buy ductile iron pipe from that Competitor, or will sell ductile iron pipe to that Competitor.

III.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Order is issued, provide to each of Respondent's officers, directors and Designated Employees a copy of this Order and the Complaint.
- B. For a period of three (3) years from the date this Order is issued, provide a copy of this Order and the Complaint to any Person who becomes a director, officer, or Designated Employee of Respondent, and provide such copies within thirty (30) days of the commencement of such Person's employment or term as an officer, director, or Designated Employee.
- C. Require each Person to whom a copy of this Order is furnished, pursuant to Paragraph III.A. and III.B. above, to sign and submit to Respondent within thirty (30) days of the receipt thereof a statement that (1) represents that the undersigned has read and

Decision and Order

understands the Order, and (2) acknowledges that the undersigned has been advised and understands that non-compliance with the Order may subject Respondent to penalties for violation of the Order.

- D. Retain documents and records sufficient to record Respondent's compliance with its obligations under Paragraph III of this Order.

IV.

IT IS FURTHER ORDERED that Respondent shall file a verified written report within sixty (60) days from the date this Order is issued, annually thereafter for three (3) years on the anniversary of the date this Order is issued, and at such other times as the Commission may by written notice require. Each report shall include, among other information that may be necessary:

- A. A copy of the acknowledgement(s) required by III.C. of the Order; and
- B. A detailed description of the manner and form in which Respondent has complied and is complying with this Order.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission:

- A. Of any change in its principal address or place of business within twenty (20) days of such change in address; and
- B. At least thirty (30) days prior to:
 - 1. Any proposed dissolution of Respondent;
 - 2. Any proposed acquisition, merger, or consolidation of Respondent; or

Decision and Order

3. Any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this order, upon written request and upon five (5) days notice, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and obtain copies of relevant books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent relating to compliance with this Order, which copying services shall be provided at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and
- B. The opportunity to interview officers, directors, or employees of Respondent, who may have counsel present, related to compliance with this Order.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on September 23, 2036.

By the Commission.

Analysis to Aid Public Comment

Dissenting Statement of Maureen K. Ohlhausen

The proposed order settles the FTC's allegations that Fortiline, LLC violated Section 5 of the FTC Act. I agree with my colleagues that it is unlawful for a firm to invite its competitor to collude even if they have a vertical relationship in other markets. The evidence regarding whether Fortiline made an invitation to collude and whether the communications arose in a vertical or horizontal context is ambiguous, however. Because I am concerned that imposing liability in such equivocal factual circumstances may chill procompetitive vertical conduct in markets with dual distribution, I respectfully dissent.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing consent order ("Consent Agreement") from Fortiline, LLC ("Fortiline"). The Commission's Complaint alleges that Fortiline violated Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by inviting a competing seller of ductile iron pipe ("DIP"), Manufacturer A, to raise and fix prices.

This is the first Commission challenge to an invitation to collude by a firm that is in both a horizontal (interbrand) and a vertical (intra-brand) relationship with the invitee, sometimes referred to as a dual distribution relationship. During the time-period relevant to the Complaint, Fortiline, a DIP distributor, sold DIP to customers in competition with Manufacturer A (principally a manufacturer, but also engaged in direct sales), while it also served as Manufacturer A's distributor in certain circumstances. Fortiline thus had a vertical distributor relationship with Manufacturer A in certain areas and circumstances and a horizontal competitor relationship with Manufacturer A in others. This case makes clear that the existence of an intra-brand

Analysis to Aid Public Comment

relationship between firms does not immunize an invitation to fix prices for interbrand transactions falling outside of that intrabrand relationship just as the law would not condone an actual price fixing agreement under similar circumstances.

The Consent Agreement has been placed on the public record for 30 days for receipt of comments from interested members of the public. Comments received during this period will become part of the public record. After 30 days, the Commission will review the Consent Agreement again and the comments received, and will decide whether it should withdraw from the Consent Agreement or make final the accompanying Decision and Order (“Proposed Order”).

The purpose of this Analysis to Aid Public Comment is to invite and facilitate public comment. It is not intended to constitute an official interpretation of the proposed Consent Agreement and the accompanying Proposed Order or in any way to modify their terms.

I. The Complaint

The allegations of the Complaint are summarized below:

Fortiline distributes waterworks infrastructure products, such as pipe (including DIP), tubing, valves, fittings and piping accessories. DIP is a commodity product used in underground waterworks distribution systems and water treatment plants. End users of DIP are primarily municipalities and water utilities. For a typical project, the end user seeks bids from multiple contractors. Contractors, in turn, solicit DIP bids from waterworks distributors (such as Fortiline) and/or directly from DIP manufacturers. Contractors that buy direct from DIP manufacturers often pay a lower price, but forgo value-added services that distributors provide.

Each of the major DIP manufacturers in the United States periodically publishes a nationwide “price list” or “pricing schedule.” Sometimes, rather than publishing a new price list, a DIP manufacturer would announce a price adjustment stated in terms of a “multiplier,” a decimal number by which the published

Analysis to Aid Public Comment

price was multiplied to arrive at the new list price. A higher multiplier translated to a higher price for DIP. The price list and the multiplier would serve as the starting point for transaction price negotiations with customers; the final transaction price on each project was decided on a job-by-job basis.

From its founding in 1997 until late 2009, most Fortiline branches distributed only DIP manufactured by Manufacturer A. However, on or about December 14, 2009, Fortiline terminated Manufacturer A as its DIP supplier in North Carolina and in most of Virginia. After December 14, 2009, Fortiline branches in this area bid on new waterworks projects with DIP manufactured by Manufacturer B, a competitor of Manufacturer A.

After December 14, 2009, some Fortiline branches outside of North Carolina and in one part of Virginia continued to distribute Manufacturer A's DIP. In addition, even though Fortiline terminated Manufacturer A in North Carolina and in most of Virginia, Fortiline continued to supply Manufacturer A's DIP to contractors in that area as needed to complete projects where Fortiline had, prior to December 14, 2009, submitted a bid specifying Manufacturer A's DIP.

Fortiline's termination of Manufacturer A in North Carolina and most of Virginia left Manufacturer A without a major distributor in that region. In response, Manufacturer A began to market and sell DIP directly to contractors in North Carolina and most of Virginia, in competition with North Carolina and Virginia distributors and their DIP suppliers, including Fortiline and its new supplier, Manufacturer B.

Manufacturer A did not offer North Carolina and Virginia contractors the value-added services provided by distributors. In order to entice contractors to forgo those services and to buy directly from Manufacturer A, Manufacturer A offered lower prices. In response, Fortiline and other distributors (in conjunction with their DIP suppliers) reduced their own prices in order to compete with Manufacturer A's lower prices.

On two occasions in 2010, when Fortiline and Manufacturer A were competing against one another to sell DIP in North Carolina

Analysis to Aid Public Comment

and most of Virginia, Fortiline invited Manufacturer A to collude on DIP pricing in that region.

On February 12, 2010, the chief executive officer and the vice president of sales for Fortiline met with Manufacturer A's vice president of sales. Among other things, they discussed Manufacturer A's practice of selling direct in North Carolina and most of Virginia at low prices.

That evening, Fortiline's vice president of sales forwarded to his counterpart at Manufacturer A an email reporting on market conditions in North Carolina. The email detailed Manufacturer A's practice of undercutting its competitors' prices. In contrast, the email reported, other major DIP manufacturers "have been trying to keep their numbers up thus far." The Fortiline email included the following commentary: "This is the type of irrational behavior [by Manufacturer A] that we were discussing earlier today. With this approach we will be at a .22 [multiplier] soon instead of a needed .42."

In substance, the February 12th email communicated Fortiline's dissatisfaction with Manufacturer A's low pricing in North Carolina and parts of Virginia and its preference that both Fortiline and Manufacturer A should bid to contractors using the higher .42 multiplier.

Eight months later, on October 26, 2010, executives from Fortiline and Manufacturer A met again, this time at a trade association meeting. At that meeting, Fortiline complained that Manufacturer A had sold direct to a Virginia customer, which had previously purchased from Fortiline, at a 0.31 multiplier, and that this price was "20% below market."

In substance, this October 26th conversation communicated Fortiline's dissatisfaction with Manufacturer A's lower pricing in Virginia, and its preference that both Fortiline and Manufacturer A should bid to contractors using a substantially higher multiplier in that region.

Analysis to Aid Public Comment

II. Analysis

The term “invitation to collude” describes an improper communication from a firm to an actual or potential competitor that the firm is ready and willing to coordinate on price or output or other important terms of competition. The Commission has long held that invitations to collude violate Section 5 of the FTC Act. An invitation to collude is “potentially harmful and . . . serves no legitimate business purpose.”¹ For those reasons, the Commission treats such conduct as “inherently suspect” (that is, presumptively anticompetitive).² This means that, in the absence of a procompetitive justification, an invitation to collude can be condemned under Section 5 without a showing that the respondent possesses market power³ and without proof that the competitor accepted the invitation.⁴ There are various reasons for this. First, unaccepted solicitations may harm competition by facilitating coordination between competitors because they reveal information about the solicitor’s intentions or preferences.

1 *In re Valassis Commc’ns., Inc.*, 141 F.T.C. 247, 283 (2006) (Analysis of Agreement Containing Consent Order to Aid Public Comment); *see also* Address by FTC Chairwoman Edith Ramirez, Section 5 Enforcement Principles, George Washington University Law School at 5 (Aug. 13, 2015) (discussing invitations to collude), https://www.ftc.gov/system/files/documents/public_statements/735411/150813section5speech.pdf.

2 *See, e.g., In re North Carolina Bd. of Dental Examiners*, 152 F.T.C. 640, 668 (2011) (noting that inherently suspect conduct is such that be “reasonably characterized as ‘giv[ing] rise to an intuitively obviously inference of anticompetitive effect’”).

3 *See, e.g., In re Realcomp II, Ltd.*, 148 F.T.C. 137, No. 9320, 2009 FTC LEXIS 250 at *51 (Oct. 30, 2009) (Comm’n Op.) (explaining that if conduct is “inherently suspect” in nature, and there are no cognizable procompetitive justifications, the Commission can condemn it “without proof of market power or actual effects”).

4 *See, e.g., In re Valassis Commc’ns., Inc.*, 141 F.T.C. 247 (2006); *In re Stone Container*, 125 F.T.C. 853 (1998); *In re Precision Moulding*, 122 F.T.C. 104 (1996). *See also In re McWane, Inc.*, Docket No. 9351, Opinion of the Commission on Motions for Summary Decision at 20-21 (F.T.C. Aug. 9, 2012) (“an invitation to collude is ‘the quintessential example of the kind of conduct that should be . . . challenged as a violation of Section 5’”) (citing the Statement of Chairman Leibowitz and Commissioners Kovacic and Rosch, *In re U-Haul Int’l, Inc.*, 150 F.T.C. 1, 53 (2010)).

Analysis to Aid Public Comment

Second, it can be difficult to discern whether a competitor has accepted a solicitation. Finally, finding a violation may deter similar conduct that has no legitimate business purpose.⁵

As described above, during the relevant time period, Fortiline competed with Manufacturer A in selling DIP to customers while also serving as Manufacturer A's distributor. Fundamentally, the fact that the firms are competitors in some transactions and collaborators in others does not alter the legal analysis. An agreement between actual or potential competitors that restrains *interbrand* price competition between the two firms presumptively harms competition. The existence of an intrabrand component to the conspirators' relationship (such as a distribution agreement or a license agreement) does not necessarily foreclose *per se* analysis.⁶ The relevant issue is not whether the parties are in a vertical or horizontal *relationship*, but whether the *restraint* on competition is an intrabrand restraint or an interbrand restraint.⁷ A similar analysis applies in the context of an invitation to collude.

⁵ *In re Valassis Commc'ns*, 141 F.T.C. at 283 (Analysis of Agreement Containing Consent Order to Aid Public Comment).

⁶ See *Gen. Leaseways, Inc. v. Nat'l Truck Leasing Ass'n*, 744 F.2d 588, 594 (7th Cir. 1984) ("It does not follow that because two firms sometimes have a cooperative relationship there are no competitive gains from forbidding them to cooperate in ways that yield no economies but simply limit competition."). See also *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49 (1990) (*per se* liability where conspirators had both horizontal and vertical (licensor/licensee) relationship); *Eli Lilly and Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 172 F.Supp.2d 1060 (S.D. Ind. 2001) (*per se* liability where conspirators had both horizontal and vertical relationship); *United States v. General Electric Co.*, 1997-1 Trade Cas. (CCH) ¶ 71,765 (D. Mont. 1997) (same).

⁷ See *United States v. Apple, Inc.*, 791 F.3d 290, 322 (2d Cir. 2015) (internal citations omitted) (rejecting Apple's argument that its role in a horizontal conspiracy with publishers should be evaluated under rule of reason because it was in a vertical relationship with publishers, noting that "it is the type of restraint that Apple agreed with the publishers to impose that determines whether the *per se* rule or the rule of reason is appropriate. These rules are means of evaluating 'whether [a] *restraint* is unreasonable,' not the reasonableness of a particular defendant's role in the scheme.").

Analysis to Aid Public Comment

Here, the Complaint charges that Fortiline invited Manufacturer A to collude on pricing *across the board*, including on transactions in which Fortiline was distributing for a rival manufacturer, Manufacturer B.⁸ Certainly, market and price-related communications between a manufacturer and its distributor can be appropriate and procompetitive.⁹ A firm may not, however, use an intrabrand relationship to shield itself from anticompetitive interbrand conduct.¹⁰ As an intrabrand relationship will not immunize an otherwise unlawful agreement, it likewise will not immunize an unlawful invitation to collude. If Manufacturer A accepted Fortiline's requests to raise prices on projects for which the firms were interbrand competitors, the resulting agreement would be *per se* unlawful. It follows that Fortiline's communications to Manufacturer A—its attempts to secure an unlawful agreement—were unlawful invitations to collude.

III. The Proposed Consent Order

The Commission recognizes the need to tailor relief that will prevent Fortiline from engaging in the anticompetitive conduct described in the complaint, yet avoid chilling procompetitive communications and efficient contracting between Fortiline and each of its current and future suppliers.

⁸ The Commission has previously found similar communications to constitute unlawful invitations to collude. *E.g.*, *In re Step N Grip LLC*, 160 F.T.C. 1111, Docket No. C-4561 (Dec. 7, 2015), <https://www.ftc.gov/enforcement/cases-proceedings/151-0181/step-n-grip-llc-matter> (respondent communicated to competitor that both parties should sell at the same price); *In re Precision Moulding*, 122 F.T.C. 104 (1996) (respondent complained to competitor that the competitor's pricing was "ridiculously low" and that the competitor did not have to "give the product away"); *In re AE Clevite*, 116 F.T.C. 389, 391 (1993) (respondent complained to competitor about its pricing, and subsequently faxed the competitor comparative price lists from both companies).

⁹ See *Monsanto Co. v. Spray-Rite Service Corp.*, 465 U.S. 752, 764-65 (1984).

¹⁰ See *supra* notes 6-8.

Analysis to Aid Public Comment

The Proposed Order contains the following substantive provisions: Section II prohibits Fortiline from entering into, attempting to enter into, participating in, maintaining, organizing, implementing, enforcing, inviting, encouraging, offering or soliciting an agreement or understanding with any competitor to raise or fix prices or any other pricing action, or to allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories. Two provisos apply to Section II. The first proviso makes clear that Fortiline may engage in conduct that is reasonably related to, and reasonably necessary to achieve the procompetitive benefits of, a lawful manufacturer-distributor relationship, joint venture agreement, or lawful merger, acquisition, or sale agreement. The second proviso makes clear that Fortiline may negotiate and enter into an agreement to buy DIP from, or sell DIP to, a competitor.

Paragraphs III-VI of the Proposed Order impose certain standard reporting and compliance requirements on Fortiline.

The Proposed Order will expire in 20 years.

Complaint

IN THE MATTER OF

ON SEMICONDUCTOR CORPORATIONCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4593; File No. 161 0061**Complaint, September 30, 2016 – Decision, September 30, 2016*

This consent order addresses the \$2.4 billion acquisition by ON Semiconductor Corporation of certain assets of Fairchild Semiconductor International, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by substantially lessening competition in the worldwide market for insulated-gate bipolar transistors (“IGBTs”) used in automotive ignition systems (“Ignition IGBTs”). The consent order requires ON to divest its Ignition IGBT business to Littelfuse, Inc.

Participants

For the *Commission*: *Llewellyn Davis*, and *Joonsuk Lee*.

For the *Respondent*: *Jeff Jaeckel*, *Morrison and Foerster*.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent ON Semiconductor Corporation (“ON”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Fairchild Semiconductor International, Inc. (“Fairchild”), in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

Complaint

I. RESPONDENT

1. Respondent ON is a publicly traded corporation organized, existing, and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 5005 East McDowell Road, Phoenix, AZ 85008.

2. Respondent ON is engaged in the design, manufacture, and sale of a range of semiconductor products used in a variety of electronic systems for automotive, industrial, communications, consumer, computing, and other applications.

3. Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose businesses is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE ACQUIRED COMPANY

4. Fairchild is a publicly traded company organized, existing, and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 1272 Borregas Avenue, Sunnyvale, CA 94089.

5. Fairchild is engaged in the design, manufacture, and sale of a range of semiconductor products used in a variety of electronic systems for automotive, industrial, home appliance, mobile, server and cloud computing, lighting, consumer electronics, and other applications.

III. THE PROPOSED ACQUISITION

6. Pursuant to an Agreement and Plan of Merger dated November 18, 2015, ON entered into a definitive agreement pursuant to which it would commence an all cash tender offer to acquire all of the outstanding shares of common stock of Fairchild for approximately \$2.4 billion (“the Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

Complaint

IV. THE RELEVANT MARKET

7. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is insulated-gate bipolar transistors (IGBTs) used in automotive ignition systems (“Ignition IGBTs”). Ignition IGBTs are a type of power semiconductor specifically designed and calibrated for automotive ignition systems in gasoline engine vehicles. Ignition IGBTs are switches that control the electrical current that passes through the ignition coil.

8. For the purposes of this Complaint, the relevant geographic market in which to analyze the effects of the Acquisition in the Ignition IGBT market is worldwide. Transportation costs are low for Ignition IGBTs, which are routinely shipped from manufacturing facilities around the globe to customer locations worldwide.

V. STRUCTURE OF THE MARKET

9. ON and Fairchild are the two largest manufacturers of Ignition IGBTs in the world, with a combined market share in excess of 60% of worldwide revenues. The proposed merger would increase the Herfindahl-Hirschman Index in excess of 1500 points, and result in a highly concentrated market. Under the *Horizontal Merger Guidelines*, this increase in concentration far exceeds the thresholds set out for raising a presumption that the Acquisition would create or enhance market power.

VI. ENTRY CONDITIONS

10. Given the substantial time and investment required to develop Ignition IGBTs and to qualify these products with customers in the automotive industry, entry sufficient to deter or counteract the anticompetitive effects created by the Acquisition is unlikely.

VII. EFFECTS OF THE ACQUISITION

11. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the

Decision and Order

Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45. The Acquisition would eliminate the direct competition between ON and Fairchild, which may lead to anticompetitive unilateral effects in the form of higher prices and reduced innovation.

VIII. VIOLATIONS CHARGED

12. The allegations contained in Paragraphs 1 through 11 above are hereby incorporated by reference as though fully set forth here.

13. The Agreement described in Paragraph 6 constitutes a violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

14. The Acquisition described in Paragraph 6, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of September, 2016, issues its Complaint against said Respondent.

By the Commission.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission, having initiated an investigation of the proposed acquisition by Respondent ON Semiconductor Corporation (“ON”) of Fairchild Semiconductor International, Inc. (“Fairchild”) and Respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would

Decision and Order

charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing consent order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule § 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and enters the following Decision and Order (“Order”):

1. Respondent ON Semiconductor Corporation is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its corporate office and principal place of business located at 5005 E. McDowell Road, Phoenix, AZ 85008.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent and the proceeding is in the public interest.

Decision and Order

ORDER**I.**

IT IS HEREBY ORDERED that, as used in this Order, the following definitions shall apply:

- A. “ON” means ON Semiconductor Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and the subsidiaries (including Falcon Operations Sub, Inc.), divisions, groups, and affiliates in each case controlled by ON Semiconductor Corporation (including Fairchild, after the Acquisition), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer” means (i) Littelfuse or (ii) any other Person that acquires the Ignition IGBT Assets pursuant to this Order.
- D. “Acquisition” means the proposed acquisition described in the Agreement and Plan of Merger by and among ON Semiconductor Corporation, Falcon Operations Sub, Inc., and Fairchild Semiconductor International, Inc., dated November 18, 2015.
- E. “Acquisition Date” means the date the Acquisition is consummated.
- F. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondent, that is not in the public domain and that is related to the Ignition IGBT Assets. For avoidance of doubt, Confidential Business Information does not include any information related to Retained Intellectual Property or Retained Assets.

Decision and Order

- G. “Contract” means any agreement, contract, lease, license agreement, consensual obligation, promise or undertaking (whether written or oral and whether express or implied), whether or not legally binding with third parties.
- H. “Divestiture Agreement” means (i) the Littelfuse Acquisition Agreement or (ii) any other agreement between Respondent (or a Divestiture Trustee) and an Acquirer that receives the prior approval of the Commission to divest the Ignition IGBT Assets, including all related ancillary agreements, schedules, exhibits, and attachments thereto that have received the Commission’s prior approval.
- I. “Divestiture Date” means the date on which Respondent (or the Divestiture Trustee) closes the transaction to divest the Ignition IGBT Assets to an Acquirer.
- J. “Divestiture Trustee” means the Person appointed by the Commission pursuant to Paragraph V. of this Order.
- K. “Ignition IGBT Assets” means all of Respondent’s right, title, and interest in and to all property and assets, wherever located, relating to the operation of the Ignition IGBT Business, including, but not limited to:
1. the finished goods inventories relating to the Ignition IGBT Business in amounts equaling the monthly dollar average quantity of finished goods inventory held by Respondent at the end of the twelve months ending on March 31, 2016;
 2. all consents, licenses, registrations, or permits issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement, if any,

Decision and Order

and all pending applications therefor or renewals thereof, to the extent assignable;

3. all data and Records, including client and customer lists and Records, referral sources, research and development reports and Records, production reports and Records, service and warranty Records, equipment logs, operating guides and manuals, financial and accounting Records, creative materials, advertising materials, promotional materials, studies, reports, notices, orders, inquiries, correspondence, and other similar documents and Records;
4. all intangible rights and property, including Intellectual Property owned or licensed (as licensor or licensee) by Respondent;
5. all part numbers and product identifying numbers for the Ignition IGBTs.

Provided, however, that the Ignition IGBT Assets does not include Respondent's right, title, and interest in the (i) Retained Assets or (ii) Retained Intellectual Property.

- L. "Ignition IGBT Business" means the business conducted by ON as of November 18, 2015, the date of the announcement of the Acquisition, in respect of researching, designing, developing, testing, manufacturing, commercializing, packaging, marketing, distributing, selling and/or servicing automotive Ignition IGBTs.
- M. "Ignition IGBT Employee" means any individual (i) employed by ON on a full-time, part-time, or contract basis at any time as of, and after, November 18, 2015, the date of the announcement of the Acquisition and (ii) whose job responsibilities relate to the Ignition IGBT Business.

Decision and Order

- N. “Ignition IGBT License” means a worldwide, royalty-free, fully paid-up, perpetual, irrevocable, transferable, and sublicensable license under:
1. The Retained Intellectual Property sufficient for Littelfuse or any other Acquirer to operate the Ignition IGBT Business in substantially the same manner as ON prior to the Acquisition, including the freedom under such Retained Intellectual Property to improve existing products and develop modifications, improvements and derivatives thereof within the field of planar ignition insulated-gate bipolar transistors;
 2. Any Intellectual Property owned or licensed (as licensor, or licensee if sublicensable) by ON sufficient for Littelfuse or any other Acquirer to research, design, develop, test, manufacture, commercialize, package, market, distribute, sell and service automotive Ignition IGBTs; and
 3. Such tangible embodiments of the licensed rights (including, but not limited to, physical and electronic copies) as may be necessary or appropriate to enable Littelfuse or any other Acquirer to use the rights.
- O. “Ignition IGBTs” means the planar automotive ignition insulated-gate bipolar transistors sold by ON prior to the Acquisition Date.
- P. “Intellectual Property” means all intellectual property, including (i) commercial names, all assumed fictional business names, trade names, “doing business as” (d/b/a names), registered and unregistered trademarks, service marks and applications, and tradedress, excluding “ON” and “ON Semiconductor”; (ii) all patents, patent applications and inventions and discoveries that may be patentable; (iii) all registered and unregistered copyrights in both published works and unpublished works; (iv) all know-how, trade

Decision and Order

secrets, and confidential or proprietary information in customer lists, software, technical information, data, process technology, plans, drawings, and blue prints; and (v) all rights in internet web sites and internet domain names, in each case, presently used by ON in the operation of the Ignition IGBT Business. Intellectual Property does not include any intellectual property acquired by ON pursuant to the Acquisition.

- Q. “Littelfuse” means Littelfuse Inc., a limited liability company organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its corporate office and principal place of business located at 8755 West Higgins Road, Suite 500, Chicago, IL, 60631.
- R. “Littelfuse Acquisition Agreement” means the asset purchase agreement between ON Semiconductor Trading SARL, ON Management C.V., Semiconductor Components Industries, LLC, Littelfuse, Inc., Littelfuse Netherland C.V., and ON Semiconductor Corporation, dated August 11, 2016, including related ancillary agreements, amendments, schedules, exhibits, and attachments, thereto, that have been approved by the Commission to accomplish the requirements of this Order.
- S. “License-Back” means a worldwide, royalty-free, fully paid-up, perpetual, irrevocable, transferable, and sublicensable license to Respondent from Acquirer under any Intellectual Property included in the Ignition IGBT Assets (that is not exclusively related to the operation of the Ignition IGBT Business) for use in any business operated by Respondent that does not compete with the Ignition IGBT Business.
- T. “Monitor” means the Person appointed by the Commission pursuant to Paragraph IV. of this Order.
- U. “Person” means any individual, partnership, corporation, business trust, limited liability company,

Decision and Order

limited liability partnership, joint stock company, trust, unincorporated association, joint venture or other entity or a governmental body.

- V. “Products” means Ignition IGBTs.
- W. “Record” means information that is inscribed on a tangible medium, or that is stored in an electronic or other medium.
- X. “Retained Assets” means:
1. all Contracts to which ON is a party and all outstanding offers or solicitations for ON to enter into any Contract, if any, and all rights thereunder and related thereto;
 2. all property and assets acquired by ON pursuant to the Acquisition;
 3. all real property, manufacturing facilities and equipment;
 4. all consents, licenses, registrations, or permits issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement, and all pending applications therefor or renewals thereof, in each case, that do not relate exclusively to the Ignition IGBT Business;
 5. all data and Records, including client and customer lists and Records, referral sources, research and development reports and Records, production reports and Records, service and warranty Records, equipment logs, operating guides and manuals, financial and accounting Records, creative materials, advertising materials, promotional materials, studies, reports, notices, orders, inquiries, correspondence, and other similar documents and Records, in each case, that are not

Decision and Order

reasonably required to conduct the Ignition IGBT Business, are not otherwise reasonably required to utilize the Acquired Assets (as defined in the Littelfuse Acquisition Agreement), or are not expressly transferred to Acquirer or any of its affiliates pursuant to the Littelfuse Acquisition Agreement; and

6. all intangible rights and property, including intellectual property owned or licensed (as licensor or licensee) by Respondent, that do not relate predominantly to the Ignition IGBTs or that are acquired by ON pursuant to the Acquisition.
- Y. “Retained Intellectual Property” means any Intellectual Property owned or licensed (as licensor or licensee if sublicensable) by ON relating to both the operation of the Ignition IGBT Business and any other business owned by ON prior to the Acquisition, unless such Intellectual Property is predominantly used by the Ignition IGBT Business and is owned by ON prior to the Acquisition. The Retained Intellectual Property also includes, without limitation, all Intellectual Property related to processes for manufacturing semiconductors owned by ON prior to the Acquisition.
- Z. “Support Services” means administrative and technical services and training related to ON’s operation of the Ignition IGBT Business as of the Divestiture Date, including but not limited to, such services and training relating to (i) manufacturing and manufacturing transfer activities, (ii) front end transfer services and support, (iii) back end transfer services and support, (iv) product audits and reports, (v) business operations training, (vi) exporting, (vii) finance and accounting, (viii) information technology, (ix) intellectual property, (x) manufacturing support, (xi) purchasing, (xii) quality control, (xiii) sales and marketing, (xiv) supply chain management, (xv) technology transfer, (xvi) order fulfillment services, and (xvii) warehousing.

Decision and Order

II.**IT IS FURTHER ORDERED** that:

- A. No later than ten (10) days after the Acquisition Date, Respondent shall divest the Ignition IGBT Assets and grant the Ignition IGBT License, absolutely and in good faith, to Littelfuse pursuant to the Littelfuse Acquisition Agreement.
- B. Notwithstanding any other provision of this Order, Respondent may enter into an agreement with Littelfuse or any other Acquirer for a License-Back (subject to the prior approval of the Commission).
- C. If Respondent has divested the Ignition IGBT Assets to Littelfuse prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that:
 - 1. Littelfuse is not acceptable as the acquirer of the Ignition IGBT Assets, then Respondent shall immediately rescind the Littelfuse Acquisition Agreement, and shall divest the Ignition IGBT Assets and grant the Ignition IGBT License no later than 120 days from the date this Order is issued, absolutely and in good faith, at no minimum price, to a Person that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission; or
 - 2. The manner in which the divestiture or grant of the Ignition IGBT License to Littelfuse was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Ignition IGBT Assets or grant of the Ignition IGBT License as the Commission may determine are necessary to satisfy the requirements of this Order.

Decision and Order

- D. No later than the Divestiture Date, Respondent shall secure all consents, assignments, and waivers from all Persons that are necessary for the divestiture of the Ignition IGBT Assets and grant of the Ignition IGBT License; *provided, however*, that Respondent may satisfy this requirement by certifying that the Acquirer has executed appropriate agreements directly with each of the relevant Persons; and *provided further* that in the event Respondent is unable to obtain any consent, assignment, or waiver required by this Paragraph II.C., Respondent shall (i) provide such assistance as the Acquirer may reasonably request in its efforts to obtain the consent or (ii) with the acceptance of the Acquirer and the prior approval of the Commission, Respondent may substitute equivalent assets or arrangements.
- E. Respondent shall:
1. At the request of Acquirer and in a manner that receives the prior approval of the Commission, provide (a) Product for a period of up to thirty-six (36) months, and (b) Support Services for a period of up to thirty-six (36) months, from the Divestiture Date;
 2. Provide the Product required by this Order at the price(s) set forth in Exhibit D (Planar Ignition IGBT Transitional Manufacturing and Supply Agreement) of the Littelfuse Acquisition Agreement, and in quality and quantity sufficient to enable Acquirer to operate the Ignition IGBT Business in substantially the same manner as ON prior to the Acquisition, including the ability to increase sales of current products; and
 3. Provide the Support Services required by this Order at the price(s) set forth in Exhibit E (Planar Ignition IGBT Transition Services Agreement) of the Littelfuse Acquisition Agreement.

Decision and Order

Provided, however, that after the expiration of thirty-six (36) months, at the request of any Acquirer, the Acquirer shall have an option to extend the length of time that it receives Product and Support Services from Respondent pursuant to Paragraph II.D.1 for up to an additional twelve (12) months. After the expiration of forty-eight (48) months, the Acquirer shall have an additional option to extend the time that it receives Product and Support Services from Respondent pursuant to Paragraph II.D.1 for up to an additional twelve (12) months.

- F. Notwithstanding any provision of this Order, Respondent shall permit Acquirer to use any trademarks owned by ON, or any abbreviation thereof, or any name, logo, or lettering which is similar, in the operation of the Ignition IGBT Business for a period of up to six (6) months from the Divestiture Date.
- G. Respondent shall cooperate with and assist Acquirer to evaluate and retain any and all Ignition IGBT Employees necessary to operate the Ignition IGBT Business in substantially the same manner as ON prior to the divestiture, including but not limited to:
 - 1. Not later than twenty (20) days before the Divestiture Date, Respondent shall (i) identify all Ignition IGBT Employees, (ii) allow Acquirer to inspect the personnel files and other documentation of all Ignition IGBT Employees, to the extent permissible under applicable laws, and (iii) allow Acquirer an opportunity to interview any Ignition IGBT Employee;
 - 2. Respondent shall (i) not offer any incentive to any Ignition IGBT Employee to decline employment with Acquirer, (ii) remove any contractual impediments that may deter any Ignition IGBT Employee from accepting employment with Acquirer, including but not limited to, any non-compete or confidentiality provision of

Decision and Order

employment or other contracts with Respondent that would affect the ability of such employee to be employed by Acquirer, and (iii) not otherwise interfere with the recruitment, hiring, or employment of any Ignition IGBT Employee by Acquirer;

3. Respondent shall (i) vest all current and accrued pension benefits as of the date of transition of employment with Acquirer for any Ignition IGBT Employee who accepts an offer of employment from Acquirer and (ii) provide each Ignition IGBT Employee with reasonable financial incentive as necessary to accept offers of employment with Acquirer; and
 4. For a period of two (2) years after the Ignition IGBT Assets are divested, Respondent shall not solicit the employment of any Ignition IGBT Employee who becomes employed by Acquirer; *provided, however*, that a violation of this provision will not occur if: (i) the individual's employment has been terminated by Acquirer, (ii) Respondent hires an individual who responds to an advertisement for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (iii) Respondent hires employees who apply for employment with Respondent, so long as such employees were not solicited by Respondent in violation of this paragraph.
- H. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against Acquirer or any Person working on behalf of Acquirer, under the Intellectual Property transferred pursuant to this Order to any Acquirer, if such suit would have the potential to limit or interfere with Acquirer's freedom to use the Ignition IGBT Assets in any application of the Ignition IGBT Business.

Decision and Order

- I. Respondent shall grant Acquirer an irrevocable, worldwide, perpetual immunity from suit based on claims of infringement under all of Respondent's Intellectual Property for the development, manufacture, having manufactured, using, having used, selling, offering for sale, having sold, and importing, of any Ignition IGBTs for any use anywhere in the world.
- J. The purpose of the divestiture of the Ignition IGBT Assets is to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

III.**IT IS FURTHER ORDERED** that:

- A. Respondent shall (i) keep confidential (including as to Respondent's employees) and (ii) not use for any reason or purpose, any Confidential Business Information received or maintained by Respondent relating to the Ignition IGBT Assets; *provided, however,* that Respondent may disclose or use such Confidential Business Information in the course of:
 - 1. Performing its obligations or as permitted under this Order, or the Divestiture Agreement; or
 - 2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the Ignition IGBT Business or Ignition IGBT Assets, or as required by law.
- B. If disclosure or use of any Confidential Business Information is permitted to Respondent's employees or to any other Person under Paragraph III.A. of this Order, Respondent and Respondent's employees shall not use or share, directly or indirectly, any

Decision and Order

Confidential Business Information with any of Respondent's employees who manage, market, produce, or sell, Respondent's automotive Ignition IGBTs, and shall limit such disclosure or use (i) only to the extent such information is required, (ii) only to those employees or Persons who require such information for the purposes permitted under Paragraph III.A., and (iii) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.

- C. Respondent shall enforce the terms of this Paragraph III. as to its employees or any other Person, and shall take such action as is necessary to cause each of its employees and any other Person to comply with the terms of this Paragraph III., including implementation of access and data controls, training of its employees, and all other actions that Respondent would take to protect its own trade secrets and proprietary information.

IV.**IT IS FURTHER ORDERED** that:

- A. Charlotte Diener shall serve as the Monitor pursuant to the agreement executed by the Monitor and Respondent and attached as Appendix III ("Monitor Agreement") and Non-Public Appendix IV ("Monitor Compensation"). The Monitor is appointed to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order.
- B. No later than one (1) day after the Acquisition Date, Respondent shall transfer to the Monitor all rights, powers, and authorities necessary to permit the Monitor to perform her duties and responsibilities, pursuant to the Order and consistent with the purposes of the Order.

Decision and Order

- C. Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall (i) monitor Respondent's compliance with the obligations set forth in this Order and (ii) act in a fiduciary capacity for the benefit of the Commission;
 2. Respondent shall (i) insure that the Monitor has full and complete access to all Respondent's personnel, books, records, documents, and facilities relating to compliance with this Order or to any other relevant information as the Monitor may reasonably request, and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform her duties pursuant to this Order;
 3. The Monitor (i) shall serve at the expense of Respondent, without bond or other security, on such reasonable and customary terms and conditions as the Commission may set, and (ii) may employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
 4. Respondent shall indemnify the Monitor and hold her harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of her duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitor's gross negligence or willful misconduct; and

Decision and Order

5. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- D. The Monitor shall report in writing to the Commission (i) every thirty (30) days after the Acquisition Date for a period of one (1) year, (ii) every ninety (90) days thereafter until Respondent has completed all obligations required by Paragraph II. of this Order (including a final report when Respondent has completed all such obligations), and (iii) at any other time as requested by the staff of the Commission, concerning Respondent's compliance with this Order.
 - E. The Commission may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
 - F. The Monitor's power and duties shall terminate ten (10) business days after the Monitor has completed her final report pursuant to Paragraph IV.D. of this Order, or at such other time as directed by the Commission.
 - G. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld:
 1. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within five (5) days after notice by the staff of the Commission to

Decision and Order

Respondent of the identity of any substitute Monitor, then Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor; and

2. Respondent shall, no later than five (5) days after the Commission appoints a substitute Monitor, enter into an agreement with the substitute Monitor that, subject to the approval of the Commission, confers on the substitute Monitor all the rights, powers, and authority necessary to permit the substitute Monitor to perform her duties and responsibilities pursuant to this Order on the same terms and conditions as provided in this Paragraph IV.
- H. The Monitor appointed pursuant to this Order may be the same Person appointed as the Divestiture Trustee pursuant to the relevant provisions of this Order.
- I. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

V.**IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the divestiture and other obligations as required by Paragraph II. of this Order, the Commission may appoint a Divestiture Trustee to divest the Ignition IGBT Assets and perform Respondent's other obligations in a manner that satisfies the requirements of this Order. The Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as the Monitor.
- B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the

Decision and Order

Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondent to comply with this Order.

- C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- D. Within ten (10) days after appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture or other action required by the Order.
- E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

Decision and Order

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the relevant assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and to take such other action as may be required to divest the Divestiture Assets.
2. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or in the case of a court-appointed Divestiture Trustee, by the court.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph V in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

Decision and Order

4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however,* if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; *provided further, however,* that Respondent shall select such entity within five (5) days of receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the

Decision and Order

Divestiture Trustee shall be based at least in significant part on a Commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph V.E.6., the term "Divestiture Trustee" shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph V.E.5. of this Order.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

Decision and Order

- F. The Commission may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- G. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph V.
- H. The Divestiture Trustee appointed pursuant to this Order may be the same Person appointed as the Monitor pursuant to the relevant provisions of this Order.
- I. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures and other obligations or action required by this Order.

VI.**IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreement shall be incorporated by reference into this Order and made a part hereof, and Respondent shall comply with all terms of the agreement. The Divestiture Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order and nothing in this Order shall be construed to reduce any rights or benefits of the Acquirer or to reduce any obligations of Respondent under such agreement.

Decision and Order

- B. If any term of the Divestiture Agreement varies from the terms of this Order (“Order Term”), then to the extent that Respondent cannot fully comply with both terms, the Order Term shall determine Respondent’s obligations under this Order. Respondent shall not modify, replace, or extend the terms of the Divestiture Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission’s Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5).

VII.**IT IS FURTHER ORDERED** that:

- A. Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order:
1. Thirty (30) days from the date this Order is issued and every thirty (30) days thereafter for a period of one (1) year, and every ninety (90) days thereafter until Respondent has fully complied with the provisions of Paragraph II.A. and Paragraph II.D. of this Order; and
 2. No later than one (1) year after the date this Order is issued and annually thereafter until this Order terminates, and at such other times as the Commission staff may request.
- B. With respect to the divestiture required by Paragraph II. of this Order, Respondent shall include in its compliance reports (i) the status of the divestiture and transfer of the Ignition IGBT Assets; and (ii) a statement that the divestiture approved by the Commission has been accomplished, including a description of the manner in which Respondent completed such divestiture and the date the divestiture was accomplished.

Decision and Order

VIII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent;
- B. Any proposed acquisition, merger, or consolidation of Respondent; or
- C. Any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondent, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession, or under the control, of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at its expense; and
- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

Decision and Order

X.

IT IS FURTHER ORDERED that this Order shall terminate on September 30, 2026.

By the Commission.

NON-PUBLIC APPENDIX I

Asset Purchase Agreement by and between ON Semiconductor Trading SARL, ON Management C.V., Semiconductor Components Industries, LLC, Littelfuse, Inc., Littelfuse Netherland C.V., and ON Semiconductor Corporation

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

NON-PUBLIC APPENDIX II

Agreement and Plan of Merger by and among ON Semiconductor Corporation, Falcon Operations Sub, Inc., and Fairchild Semiconductor International, Inc., dated November 18, 2015.

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Analysis to Aid Public Comment

**APPENDIX III
Monitor Agreement**

**NON-PUBLIC APPENDIX IV
Monitor Compensation**

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

1. INTRODUCTION

The Federal Trade Commission (“Commission”) has accepted from ON Semiconductor Corporation (“ON”), subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) designed to remedy the anticompetitive effects that would likely result from ON’s proposed acquisition of Fairchild Semiconductor International, Inc. (“Fairchild”).

On November 18, 2015, ON announced that it had entered into a definitive agreement involving an all-cash tender offer to acquire all of the outstanding shares of common stock of Fairchild for approximately \$2.4 billion (“Acquisition”). The proposed Acquisition would combine the two largest suppliers of insulated-gate bipolar transistors (IGBTs) used in automotive ignition systems (“Ignition IGBTs”) worldwide. The Commission’s Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C.

Analysis to Aid Public Comment

§ 45, by substantially lessening competition in the worldwide market for Ignition IGBTs.

Under the terms of the proposed Decision and Order (“Order”) contained in the Consent Agreement, ON is required to divest its Ignition IGBT business to Littelfuse, Inc. (“Littelfuse”) no later than 10 days from the close of the Acquisition. The divestiture package includes design files and intellectual property associated with the manufacture and sale of Ignition IGBTs, customer and distributor relationships with respect to Ignition IGBTs, and technology transfers and transitional services such as manufacturing support. In short, the Consent Agreement provides Littelfuse with everything it needs to compete effectively in the Ignition IGBT market.

The Commission has placed the Consent Agreement on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement and the comments received, and decide whether it should withdraw from the Consent Agreement, modify it, or make the Order final.

2. THE PARTIES

Headquartered in Phoenix, Arizona, ON is a semiconductor developer and manufacturer providing a highly diversified portfolio of semiconductor products, including power and signal management, image sensing, and other standard and custom devices, for a variety of end-use applications, including communications, computing, consumer, industrial, and automotive. ON designs, manufactures, and sells Ignition IGBTs, among other products, in its Automotive Product Division.

Fairchild, headquartered in Sunnyvale, California, develops and manufactures a wide variety of low to high voltage power semiconductor products and devices as well as certain non-power semiconductor devices, which are used in a variety of end-use applications, including automotive, consumer, computing, and industrial applications. Fairchild designs, manufactures, and sells Ignition IGBTs in its Automotive Business Unit.

Analysis to Aid Public Comment

3. THE RELEVANT PRODUCT AND MARKET STRUCTURE

The relevant product market in which to assess the competitive effects of the proposed Acquisition is no broader than Ignition IGBTs. IGBTs are a type of semiconductor that transmits, converts, and switches electrical power. Ignition IGBTs are a type of IGBT specifically designed and calibrated for automotive ignition systems in gasoline engine vehicles. They function as switches that control the electrical current that passes through the ignition coil. ON and Fairchild sell Ignition IGBTs to Tier 1 automotive suppliers, who then incorporate them into the ignition systems that they sell to automotive manufacturers. Currently, there is no functional substitute for Ignition IGBTs.

The relevant geographic market for Ignition IGBTs is worldwide. The two major Ignition IGBT suppliers—ON and Fairchild— manufacture the products in facilities around the world, and ship them to customer locations worldwide. There are no regulatory barriers, tariffs, or technical specifications to impede worldwide trade, and transportation costs are low.

The Ignition IGBT market is characterized by a limited number of suppliers. ON and Fairchild are by far the two largest suppliers of Ignition IGBTs. Fairchild is the market leader and ON is the second-largest supplier. Their combined share of the Ignition IGBT market would exceed 60%. The parties' next closest competitor has a significantly smaller share of the market. Other market participants are even smaller and do not constrain the parties. There are also several other suppliers located in Japan, but they primarily supply Japanese automotive manufacturers. Due to burdensome qualification requirements for customers outside of Japan, it would take several years before these suppliers could be qualified to supply the parties' customers with Ignition IGBTs.

The proposed ON/Fairchild combination would cause a highly concentrated market for Ignition IGBTs to become even more concentrated, increasing the Herfindahl-Hirschman Index ("HHI") by more than 1500. This increase in concentration far exceeds the thresholds set out in the *Horizontal Merger Guidelines* for raising

Analysis to Aid Public Comment

a presumption that the Acquisition would create or enhance market power.

4. EFFECTS OF THE ACQUISITION

Absent a divestiture, the proposed Acquisition is likely to cause competitive harm in the Ignition IGBT market. ON and Fairchild compete directly against each other for Ignition IGBT sales, and customers benefit from that competition in terms of both pricing and product innovation. Customers describe ON and Fairchild as each other's closest competitor. Likewise, ON and Fairchild view each other the same way. By eliminating the competition between ON and Fairchild, the proposed Acquisition likely would lead to unilateral effects in the form of higher prices and reduced innovation.

5. ENTRY

Entry into the Ignition IGBT market is not likely to deter or counteract any anti-competitive effects of the proposed Acquisition. Given the niche nature of the Ignition IGBT market, declining demand, and the lengthy time it would take to qualify new products with customers, entry is unlikely and would not be timely. Market participants confirmed that it would take at least three to four years before a new entrant could become a viable supplier. Existing IGBT manufacturers, moreover, are not rapid entrants. The process of designing an IGBT for ignition systems and qualifying it with customers would take years.

6. THE PROPOSED CONSENT AGREEMENT

The Consent Agreement restores the competition lost from the proposed Acquisition by requiring ON to divest its Ignition IGBT business to Littelfuse, a publicly traded company based in Chicago, Illinois. The proposed divestiture includes everything needed for Littelfuse to compete effectively in the worldwide market for Ignition IGBTs.

Under the Order, ON is required to divest its Ignition IGBT business to Littelfuse no later than 10 days from the close of the Acquisition. The divestiture package consists of the following

Analysis to Aid Public Comment

assets: design files, patents and technologies for Ignition IGBTs; licenses to manufacturing process technology; a process to facilitate the transfer of customer and distributor relationships with respect to Ignition IGBTs; technology transfers and transitional services including manufacturing support; and, if Littelfuse requests, secondment of ON personnel to support the transfer from ON to Littelfuse of the technology and know-how for production of Ignition IGBTs. No physical assets are being divested because a third party will manufacture Ignition IGBTs for Littelfuse.

The Order requires that, at the request of Littelfuse and in a manner approved by the Commission, ON must provide transitional manufacturing for a period of up to three years with a possible option to extend the period by up to two years. Similarly, the Order also requires ON to provide support services such as logistical and administrative support for up to three years with a possible option to extend the period for up to two years. In addition, the Order includes other standard terms designed to ensure the viability of the divested business.

A Monitor will monitor ON's compliance with the obligations set forth in the Order. If ON does not fully comply with the divestiture and requirements of the Order, the Commission may appoint a Divestiture Trustee to divest the Ignition IGBT business and perform ON's other obligations consistent with the Order.

The divestiture of ON's Ignition IGBT business to Littelfuse will preserve competition that would otherwise have been lost as a result of the Acquisition. Potential customers have confirmed that the divested assets include everything necessary to compete effectively as a viable business. Similarly, potential customers have confirmed that Littelfuse would be a competitive option as a supplier.

7. OPPORTUNITY FOR PUBLIC COMMENT

The purpose of this analysis is to facilitate public comment on the Consent Agreement to aid the Commission in determining whether it should make the Consent Agreement final. This

Analysis to Aid Public Comment

analysis is not an official interpretation of the proposed Consent Agreement and does not modify its terms in any way.

Complaint

IN THE MATTER OF

**KONINKLIJKE AHOLD, N.V.
AND
DELHAIZE GROUP, NV/SA**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4588; File No. 151 0175**Complaint, July 22, 2016 – Decision, October 14, 2016*

This consent order addresses the \$28 billion merger of equals by Koninklijke Ahold N.V. and Delhaize Group NV/SA. The complaint alleges that the Merger, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by removing an actual, direct, and substantial supermarket competitor in each of the 46 local geographic markets. The consent order requires Respondents to divest 81 supermarkets and related assets in 46 local geographic markets in seven states to seven Commission-approved buyers.

Participants

For the *Commission*: Paul Frangie, Jill M. Frumin, Matthew McDonald, Nancy Park, Neal Perlman, and Joshua Smith.

For the *Respondents*: Sara Razi, Simpson Thacher & Bartlett; Julie North, Christine Varney, and Jesse Weiss, Cravath, Swaine, & Moore.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Koninklijke Ahold, N.V. (“Ahold”), a corporation subject to the jurisdiction of the Commission, agreed to merge with Respondent Delhaize Group, NV/SA (“Delhaize”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the

Complaint

Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Ahold is a corporation organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its office and principal place of business located at Provincialeweg 11, 1506 MA Zaandam, the Netherlands. Koninklijke Ahold N.V.'s principal U.S. subsidiary, Ahold U.S.A., Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Maryland, with its offices and principal place of business located at 1385 Hancock Street, Quincy, Massachusetts 02169.

2. Respondent Ahold owns and operates a number of supermarket chains in ten states in the United States, including supermarkets operating under the Giant, Martin's, and Stop & Shop banners.

3. Respondent Delhaize is a corporation organized, existing, and doing business under and by virtue of the laws of Belgium, with its office and principal place of business located at Square Marie Curie 40, 1070 Brussels, Belgium, and its registered office at Ossenghemstraat 53, 1080, Brussels, Belgium. Delhaize Group NV/SA's principal U.S. subsidiary, Delhaize America, LLC., is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of North Carolina, with its offices and principal place of business at 2110 Executive Drive, Salisbury, North Carolina 28147.

4. Respondent Delhaize owns and operates a number of supermarket chains in 17 states in the United States, including supermarkets operating under the Food Lion and Hannaford banners.

5. Respondents Ahold and Delhaize own and operate supermarkets in each of the geographic markets relevant to this Complaint and compete and promote their businesses in these areas.

Complaint

II. JURISDICTION

6. Respondents, and each of their relevant operating subsidiaries and parent entities, are, and at all times relevant herein have been, engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. § 12, and Section 4 of the FTC Act, 15 U.S.C. § 44.

III. THE MERGER

7. Pursuant to an Agreement and Plan of Merger dated as of June 24, 2015, Ahold and Delhaize intend to combine their businesses through a merger of equals that will result in a combined entity valued at approximately \$28 billion (“the Merger”).

IV. THE RELEVANT PRODUCT MARKET

8. The relevant line of commerce in which to analyze the Merger is the retail sale of food and other grocery products in supermarkets.

9. For purposes of this Complaint, the term “supermarket” means any full-line retail grocery store that enables customers to purchase substantially all of their weekly food and grocery shopping requirements in a single shopping visit with substantial offerings in each of the following product categories: bread and baked goods; dairy products; refrigerated food and beverage products; frozen food and beverage products; fresh and prepared meats and poultry; fresh fruits and vegetables; shelf-stable food and beverage products, including canned, jarred, bottled, boxed, and other types of packaged products; staple foodstuffs, which may include salt, sugar, flour, sauces, spices, coffee, tea, and other staples; other grocery products, including nonfood items such as soaps, detergents, paper goods, other household products, and health and beauty aids; pharmaceutical products and pharmacy services (where provided); and, to the extent permitted by law, wine, beer, and/or distilled spirits.

10. Supermarkets provide a distinct set of products and services and offer consumers convenient one-stop shopping for

Complaint

food and grocery products. Supermarkets typically carry more than 10,000 different items, typically referred to as stock-keeping units (SKUs), as well as a deep inventory of those items. In order to accommodate the large number of food and non-food products necessary for one-stop shopping, supermarkets are large stores that typically have at least 10,000 square feet of selling space.

11. Supermarkets compete primarily with other supermarkets that provide one-stop shopping opportunities for food and grocery products. Supermarkets base their food and grocery prices primarily on the prices of food and grocery products sold at other nearby competing supermarkets. Supermarkets do not regularly conduct price checks of food and grocery products sold at other types of retail stores—including convenience stores, specialty food stores, limited assortment stores, hard-discounters, and club stores—and do not typically set or change their food or grocery prices in response to prices at these types of stores.

12. Although retail stores other than supermarkets may also sell food and grocery products, these types of stores do not, individually or collectively, provide sufficient competition to effectively constrain prices at supermarkets. These retail stores do not offer a supermarket's distinct set of products and services that provides consumers with the convenience of one-stop shopping for food and grocery products. The vast majority of consumers shopping for food and grocery products at supermarkets are not likely to start shopping at other types of stores, or significantly increase grocery purchases at other types of stores, in response to a small but significant nontransitory price increase by supermarkets.

V. THE RELEVANT GEOGRAPHIC MARKETS

13. Customers shopping at supermarkets are motivated by convenience and, as a result, competition for supermarkets is local in nature. Generally, the overwhelming majority of consumers' grocery shopping occurs at stores located very close to where they live.

14. Respondents currently operate supermarkets under the Giant, Martin's, Stop & Shop, Food Lion, and Hannaford banners

Complaint

within approximately one-tenth of a mile to ten miles of each other in each of the relevant geographic markets, though the majority of overlapping banners raising concerns are within six miles or less of each other. The primary trade areas of Respondents' banners in each of the relevant geographic markets overlap significantly.

15. The 46 geographic markets in which to assess the competitive effects of the Merger are localized areas in (1) Lewes & Rehoboth Beach, Delaware; (2) Millsboro, Delaware; (3) Millville, Delaware; (4) Accokeek, Maryland; (5) Bowie, Maryland; (6) California, Maryland; (7) Columbia, Maryland; (8) Cumberland & Frostburg, Maryland; (9) Easton, Maryland; (10) Edgewater, Maryland; (11) Gaithersburg, Maryland; (12) Hagerstown (north), Maryland; (13) Hagerstown (south), Maryland; (14) La Plata, Maryland; (15) Lusby, Maryland; (16) Owings Mills, Maryland; (17) Prince Frederick, Maryland; (18) Reisterstown, Maryland; (19) Salisbury, Maryland; (20) Sykesville, Maryland; (21) Upper Marlboro, Maryland; (22) Gardner, Massachusetts; (23) Kingston, Massachusetts; (24) Mansfield & South Easton, Massachusetts; (25) Milford, Massachusetts; (26) Norwell, Massachusetts; (27) Norwood & Walpole, Massachusetts; (28) Quincy, Massachusetts; (29) Saugus, Massachusetts; (30) Mahopac & Carmel, New York; (31) New Paltz & Modena, New York; (32) Poughkeepsie & Lagrangeville, New York; (33) Rhinebeck & Red Hook, New York; (34) Wappingers Falls, New York; (35) Chambersburg, Pennsylvania; (36) Waynesboro, Pennsylvania; (37) York, Pennsylvania; (38) Culpeper, Virginia; (39) Fredericksburg, Virginia; (40) Front Royal, Virginia; (41) Purcellville, Virginia; (42) Richmond, Virginia; (43) Stafford, Virginia; (44) Stephens City, Virginia; (45) Winchester, Virginia; and (46) Martinsburg, West Virginia. A hypothetical monopolist controlling all supermarkets in any one of these areas could profitably raise prices by a small but significant nontransitory amount in that area.

VI. MARKET CONCENTRATION

16. Under the 2010 Department of Justice and Federal Trade Commission Horizontal Merger Guidelines ("Merger Guidelines") and relevant case law, the Merger is presumptively

Complaint

unlawful in the markets for the retail sale of food and other grocery products in supermarkets in all but one of the 46 geographic markets listed in Paragraph 15. Under the Merger Guidelines' standard measure of market concentration, the Herfindahl-Hirschman Index ("HHI"), an acquisition is presumed to create or enhance market power or facilitate its exercise if it increases the HHI by more than 200 points and results in a post-acquisition HHI that exceeds 2,500 points. The Merger would result in market concentration levels in excess of these thresholds in all but one of these 46 geographic markets.

17. Post-merger HHI levels in the relevant geographic markets would range from 2,268 to 10,000, and the Merger would result in HHI increases ranging from 243 to 4977. Exhibit A presents market concentration levels for each of the relevant geographic markets.

18. As seen in Exhibit A, the Merger would reduce the number of meaningful supermarket competitors from two to one in three relevant geographic markets, three to two in 14 relevant geographic markets, four to three in 18 relevant geographic markets, five to four in ten relevant geographic markets, and seven to six in one relevant geographic market.

VII. ENTRY CONDITIONS

19. Entry into the relevant markets would not be timely, likely, or sufficient in magnitude to prevent or deter the likely anticompetitive effects of the Merger. Significant entry barriers include the time and costs associated with conducting necessary market research, selecting an appropriate location for a supermarket, obtaining necessary permits and approvals, constructing a new supermarket or converting an existing structure to a supermarket, and generating sufficient sales to have a meaningful impact on the market.

VIII. EFFECTS OF THE MERGER

20. The Merger, if consummated, is likely to substantially lessen competition for the retail sale of food and other grocery

Complaint

products in supermarkets in the relevant geographic markets identified in Paragraph 15 in the following ways, among others:

- a. by eliminating direct and substantial competition between Respondents Ahold and Delhaize;
- b. by increasing the likelihood that Respondent Ahold will unilaterally exercise market power; and
- c. by increasing the likelihood of, or facilitating, coordinated interaction between the remaining participants.

21. The ultimate effect of the Merger would be to increase the likelihood that the prices of food or groceries will increase, and that the quality and selection of food, groceries, or services will decrease, in the relevant geographic markets.

IX. VIOLATIONS CHARGED

22. The agreement described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and the Merger, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-second day of July, 2016, issues its complaint against said Respondents.

By the Commission.

Complaint

Exhibit A

Area Number (See Para. 16 of Complaint)	City	State	Merger Result	HHI (pre)	HHI (post)	Delta
1	Lewes/Rehoboth Beach	DE	4 to 3	2947	5369	2421
2	Millsboro	DE	3 to 2	3794	6440	2646
3	Millville	DE	4 to 3	4065	5762	1697
4	Gardner	MA	4 to 3	2517	3723	1207
5	Kingston	MA	5 to 4	3140	4459	1318
6	Mansfield/S. Easton	MA	4 to 3	2834	4307	1472
7	Milford	MA	5 to 4	2298	2780	482
8	Norwell	MA	4 to 3	4052	5840	1789
9	Norwood/Walpole ¹	MA	7 to 6	2025	2268	243
10	Quincy	MA	4 to 3	3854	5092	1239
11	Saugus	MA	5 to 4	2140	2819	679
12	Accokeek	MD	2 to 1	5430	10,000	4570
13	Bowie	MD	4 to 3	3288	3750	462
14	California	MD	4 to 3	3043	4121	1078
15	Columbia	MD	5 to 4	3093	3679	586
16	Cumberland & Frostburg	MD	3 to 2	4032	5157	1125
17	Easton	MD	4 to 3	2803	3578	775
18	Edgewater	MD	3 to 2	3920	5261	1341
19	Gaithersburg	MD	5 to 4	4203	5193	989
20	Hagerstown (South)	MD	4 to 3	3910	4525	615
21	Hagerstown (North)	MD	4 to 3	4043	4323	281
22	La Plata	MD	3 to 2	3935	5007	1072
23	Lusby	MD	2 to 1	5108	10,000	4892

¹ Based on a calculation giving full weight to a third-party supermarket with a large draw area, the Merger results in a post-acquisition HHI that does not meet the threshold for a highly concentrated market in the Norwood/Walpole, Massachusetts, market, even though the change in concentration is more than double the level that raises significant competitive concerns. Under calculations giving less than full weight to that supermarket, the Merger results in a highly concentrated market that meets the presumption for enhanced market power. Ultimately, an analysis of all the evidence indicates that the Merger is likely to substantially lessen competition in this market.

Order to Maintain Assets

24	Owings Mills	MD	4 to 3	3325	4017	692
25	Prince Frederick	MD	3 to 2	3734	5242	1508
26	Reisterstown	MD	4 to 3	3423	4169	746
27	Salisbury	MD	3 to 2	3976	5029	1053
28	Sykesville	MD	5 to 4	3012	3732	720
29	Upper Marlboro	MD	3 to 2	3645	5328	1683
30	Mahopac/Carmel	NY	5 to 4	2940	4352	1412
31	New Paltz/Modena	NY	3 to 2	3690	6601	2911
32	Poughkeepsie/Lagrangeville	NY	4 to 3	3269	5786	2517
33	Rhinebeck/Red Hook	NY	2 to 1	5023	10,000	4977
34	Wappingers Falls	NY	3 to 2	2646	4256	1610
35	Chambersburg	PA	5 to 4	3277	4232	955
36	Waynesboro	PA	3 to 2	5030	5537	506
37	York	PA	4 to 3	3710	4135	424
38	Culpeper	VA	4 to 3	3329	4371	1042
39	Fredericksburg	VA	5 to 4	2696	3560	864
40	Front Royal	VA	3 to 2	3638	5095	1456
41	Purcellville	VA	3 to 2	3679	5321	1642
42	Richmond Metro Area	VA	5 to 4	2198	2857	659
43	Stafford	VA	4 to 3	3333	4038	705
44	Stephens City	VA	3 to 2	4045	5018	973
45	Winchester	VA	3 to 2	3662	5094	1433
46	Martinsburg	WV	4 to 3	2759	3568	809

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed merger between Respondents Koninklijke Ahold N.V. (“Ahold”) and Delhaize Group NV/SA (“Delhaize”), and Respondents having been

Order to Maintain Assets

furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts as set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place the Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent Koninklijke Ahold N.V. is a corporation organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its office and principal place of business located at Provincialeweg 11, 1506 MA Zaandam, the Netherlands. Koninklijke Ahold N.V.’s principal U.S. subsidiary, Ahold U.S.A., Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Maryland, with its offices and principal place of business located at 1385 Hancock Street, Quincy, Massachusetts 02169.

Order to Maintain Assets

2. Respondent Delhaize Group NV/SA is a public limited company (société anonyme/naamloze vennootschap) organized, existing, and doing business under and by virtue of the laws of Belgium, with its office and principal place of business located at Square Marie Curie 40, 1070 Brussels, Belgium, and its registered office at Ossenghemstraat 53, 1080, Brussels, Belgium. Delhaize Group NV/SA's principal U.S. subsidiary, Delhaize America, LLC, is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of North Carolina, with its offices and principal place of business at 2110 Executive Drive, Salisbury, North Carolina 28147.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

I.

IT IS ORDERED that as used in this Order to Maintain Assets, the definitions used in the Consent Agreement and the Decision and Order shall apply. For purposes of this Order to Maintain Assets, the Assets To Be Divested under the Decision and Order include the Schedule C Additional Assets. In addition, "Supermarket To Be Maintained" means any Supermarket business identified as part of the Assets To Be Divested under the Decision and Order.

II.

IT IS FURTHER ORDERED that:

- A. Respondents shall maintain the viability, marketability, and competitiveness of the Assets To Be Divested, and shall not cause the wasting or deterioration of the Assets To Be Divested. Respondents shall not cause the Assets To Be Divested to be operated in a manner inconsistent with applicable laws, nor shall they sell, transfer, encumber, or

Order to Maintain Assets

otherwise impair the viability, marketability, or competitiveness of the Assets To Be Divested. Respondents shall conduct or cause to be conducted the business of the Assets To Be Divested in the regular and ordinary course and in accordance with past practice (including regular repair and maintenance efforts) and shall use best efforts to preserve the existing relationships with suppliers, customers, employees, and others having business relations with the Assets To Be Divested in the ordinary course of business and in accordance with past practice.

- B. Respondents shall not terminate the operation of any Supermarket To Be Maintained. Respondents shall continue to maintain the inventory of each Supermarket To Be Maintained at levels and selections consistent with those maintained by Respondents at such Supermarket in the ordinary course of business consistent with past practice. Respondents shall use best efforts to keep the organization and properties of each Supermarket To Be Maintained intact, including current business operations, physical facilities, working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with the Supermarket To Be Maintained, and shall not transfer store managers from any Supermarket To Be Maintained to any store that is not part of the Assets To Be Divested. Included in the above obligations, Respondents shall, without limitation:
1. Maintain all operations and departments, and not reduce hours, at each Supermarket To Be Maintained;
 2. Not transfer inventory from any Supermarket To Be Maintained, other than in the ordinary course of business consistent with past practice;
 3. Make any payment required to be paid under any contract or lease when due, and otherwise pay all liabilities and satisfy all obligations associated with

Order to Maintain Assets

each Supermarket To Be Maintained, in each case in a manner consistent with past practice;

4. Maintain the books and records of each Supermarket To Be Maintained;
5. Not display any signs or conduct any advertising (e.g., direct mailing, point-of-purchase coupons) that indicates that any Respondent is moving its operations at a Supermarket To Be Maintained to another location, or that indicates a Supermarket To Be Maintained will close;
6. Not conduct any “going out of business,” “close-out,” “liquidation,” or similar sales or promotions at or relating to any Supermarket To Be Maintained; and
7. Not change or modify in any material respect the existing pricing or advertising practices, programs, and policies for each Supermarket To Be Maintained, other than changes in the ordinary course of business consistent with past practice for Supermarkets of the Respondents not being closed, relocated, or sold.

Provided, however, that Respondents shall not be in violation of this Paragraph II. if Respondents take actions (i) as explicitly permitted or required by any Divestiture Agreement, or (ii) that have been requested or agreed-to by an Acquirer, in writing, and approved in advance by the Monitor (in consultation with Commission staff), in all cases to facilitate the Acquirer’s acquisition of Assets To Be Divested and consistent with the purposes of the Order.

Order to Maintain Assets

III.**IT IS FURTHER ORDERED** that:

- A. Brad Wise shall serve as the Monitor pursuant to the agreement executed by the Monitor and Respondents, and attached as Appendix VIII (“Monitor Agreement”) and Non-Public Appendix VIII-1 (“Monitor Compensation”) to the Decision and Order. The Monitor is appointed to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s);
- B. No later than (1) day after the date the Merger is consummated, Respondents shall, pursuant to the Monitor Agreement, confer on the Monitor all rights, powers, and authorities necessary to permit the Monitor to monitor Respondents’ compliance with the terms of this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s), in a manner consistent with the purposes of the orders.
- C. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor Respondents’ compliance with the divestiture and related requirements of this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s), and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the orders and in consultation with the Commission.
 - 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

Order to Maintain Assets

3. The Monitor shall serve until the later of (a) one year from the date the Merger is consummated or (b) all divestiture obligations under Paragraphs II and IV of the Decision and Order have been satisfied.
- D. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with their obligations under this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s).
 - E. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s).
 - F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have the authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
 - G. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that

Order to Maintain Assets

such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor. For purposes of this Paragraph III.G., the term “Monitor” shall include all persons retained by the Monitor pursuant to Paragraph III.F. of this Order to Maintain Assets.

- H. Respondents shall report to the Monitor in accordance with the requirements of this Order to Maintain Assets or the Decision and Order, and as otherwise provided in the Monitor Agreement approved by the Commission. The Monitor shall evaluate the reports submitted by the Respondents with respect to the performance of Respondents’ obligations under this Order to Maintain Assets and the Decision and Order. Within thirty (30) days from the date the Monitor receives the first such report, and every thirty (30) days thereafter, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the orders.
- I. Respondents may require the Monitor and each of the Monitor’s consultants, accountants, and other representatives and assistants to sign a customary confidentiality agreement. *Provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may require, among other things, the Monitor and each of the Monitor’s consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor’s duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:

Order to Maintain Assets

1. The Commission shall select the substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after the notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
 2. Not later than ten (10) days after the appointment of the substitute Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all rights and powers necessary to permit the Monitor to monitor Respondents' compliance with the relevant terms of this Order to Maintain Assets, the Decision and Order, and the Remedial Agreement(s) in a manner consistent with the purposes of the orders and in consultation with the Commission.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order to Maintain Assets.
- M. The Monitor appointed pursuant to this Order to Maintain Assets may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondents;

Order to Maintain Assets

- B. Any proposed acquisition, merger, or consolidation of Respondents; or
- C. Any other change in the Respondents, including but not limited to assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order to Maintain Assets.

V.

IT IS FURTHER ORDERED that within thirty (30) days after this Order to Maintain Assets is issued, and every thirty (30) days thereafter until this Order to Maintain Assets terminates, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with all provisions of this Order to Maintain Assets. Respondents shall submit at the same time a copy of their reports concerning compliance with this Order to Maintain Assets to the Monitor. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order to Maintain Assets.

VI.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities, and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Respondents relating to compliance with this Order to Maintain Assets, which copying services shall be provided by Respondents at the request of the

Order to Maintain Assets

authorized representative(s) of the Commission and at the expense of Respondents; and

- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate at the earlier of:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. With respect to each Supermarket To Be Maintained, the day after Respondents' (or a Divestiture Trustee's) completion of the divestiture of Assets To Be Divested related to such Supermarket, as described in and required by the Decision and Order (or, in the case of the Schedule C Additional Assets, the completion of the divestiture of the Schedule C Assets to Publix).

Provided, however, that if the Commission, pursuant to Paragraph II.B. of the Decision and Order, requires the Respondents to rescind any or all of the divestitures contemplated by any Divestiture Agreement, then, upon rescission, the requirements of this Order to Maintain Assets shall again be in effect with respect to the relevant Assets To Be Divested until the day after Respondents' (or a Divestiture Trustee's) completion of the divestiture(s) of the relevant Assets To Be Divested, as described in and required by the Decision and Order.

By the Commission.

Decision and Order

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed merger between Respondents Koninklijke Ahold N.V. (“Ahold”) and Delhaize Group NV/SA (“Delhaize”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

Decision and Order

1. Respondent Koninklijke Ahold N.V. is a corporation organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its office and principal place of business located at Provincialeweg 11, 1506 MA Zaandam, the Netherlands. Koninklijke Ahold N.V.'s principal U.S. subsidiary, Ahold U.S.A., Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Maryland, with its offices and principal place of business located at 1385 Hancock Street, Quincy, Massachusetts 02169.
2. Respondent Delhaize Group NV/SA is a public limited company (société anonyme/naamloze vennootschap) organized, existing, and doing business under and by virtue of the laws of Belgium, with its office and principal place of business located at Square Marie Curie 40, 1070 Brussels, Belgium, and its registered office at Ossenghemstraat 53, 1080, Brussels, Belgium. Delhaize Group NV/SA's principal U.S. subsidiary, Delhaize America, LLC, is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of North Carolina, with its offices and principal place of business at 2110 Executive Drive, Salisbury, North Carolina 28147.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. "Ahold" means Respondent Koninklijke Ahold N.V, its directors, officers, employees, agents,

Decision and Order

representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Ahold (including, but not limited to, Ahold U.S.A.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- B. “Delhaize” means Respondent Delhaize Group NV/SA, its directors, officers, employees, agents, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Delhaize (including, but not limited to, Delhaize America, LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means Ahold and Delhaize, individually and collectively.
- D. “Acquirer” means any entity approved by the Commission to acquire any or all of the Assets To Be Divested pursuant to this Order.
- E. “Merger” means the proposed merger of Ahold and Delhaize, pursuant to the Merger Agreement.
- F. “Merger Agreement” means the Merger Agreement by and between Delhaize Group NV/SA and Koninklijke Ahold N.V. dated as of June 24, 2015.
- G. “Assets To Be Divested” means the Supermarkets identified on Schedule A, Schedule B, Schedule C, Schedule D, Schedule E, Schedule F, and Schedule G of this Order, or any portion thereof, and all rights, title, and interest in and to all assets, tangible and intangible, relating to, used in, and/or reserved for use in, the Supermarket business operated at each of those locations, including but not limited to all properties, leases, leasehold interests, equipment and fixtures, books and records, government approvals and permits (to the extent transferable), telephone and fax

Decision and Order

numbers, and goodwill. Assets To Be Divested includes any of Respondents' other businesses or assets associated with, or operated in conjunction with, the Supermarket locations listed on Schedules A – G of this Order, including any fuel centers (including any convenience store and/or car wash associated with such fuel center), pharmacies, liquor stores, beverage centers, gaming or slot machine parlors, store cafes, or other related business(es) that customers reasonably associate with the Supermarket business operated at each such location. At each Acquirer's option, the Assets To Be Divested shall also include any or all inventory as of the Divestiture Date.

Provided, however, that the Assets To Be Divested shall not include those assets consisting of or pertaining to any of the Respondents' trademarks, trade dress, service marks, or trade names, *except* with respect to any purchased inventory (including private label inventory) or as may be allowed pursuant to any Remedial Agreement(s).

Provided, further, that in cases in which books or records included in the Assets To Be Divested contain information (a) that relates both to the Assets To Be Divested and to other retained businesses of Respondents or (b) such that Respondents have a legal obligation to retain the original copies, then Respondents shall be required to provide only copies or relevant excerpts of the materials containing such information. In instances where such copies are provided to an Acquirer, the Respondents shall provide to such Acquirer access to original materials under circumstances where copies of materials are insufficient for regulatory or evidentiary purposes.

Provided, further, that if Publix is the Acquirer of the Schedule C Assets, then the Schedule C Assets may exclude certain associated assets of individual stores, as explicitly excluded in the Publix Divestiture Agreement.

Decision and Order

Provided, further, that if Publix is not the Acquirer of the Schedule C Assets, then the Commission may, in its sole discretion, include any or all of the Schedule C Additional Assets as part of the Assets To Be Divested.

- H. “Albertsons” means New Albertson’s Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Ohio, with its offices and principal place of business located at 250 Parkcenter Boulevard, Boise, Idaho 83706.
- I. “Albertsons Divestiture Agreement” means the Asset Purchase Agreement dated as of July 8, 2016, by and between Respondent Ahold and Albertsons, attached as non-public Appendix I, for the divestiture of the Schedule A Assets.
- J. “Big Y” means Big Y Foods, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Massachusetts, with its offices and principal place of business located at 2145 Roosevelt Avenue, Springfield, Massachusetts 01104.
- K. “Big Y Divestiture Agreement” means the Asset Purchase Agreement dated as of July 7, 2016, by and between Respondent Delhaize and Big Y, attached as non-public Appendix II, for the divestiture of the Schedule B Assets.
- L. “Direct Costs” means cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide services under this Order or any Transition Services Agreement. “Direct Cost” to an Acquirer for its use of any of Respondents’ employees’ labor shall not exceed the then-current average wage rate for such employee, including benefits.

Decision and Order

- M. “Divestiture Agreement” means any agreement between Respondents and an Acquirer (or a Divestiture Trustee appointed pursuant to Paragraph IV of this Order and an Acquirer) and all amendments, exhibits, attachments, agreements, and schedules thereto, related to any of the Assets To Be Divested that have been approved by the Commission to accomplish the requirements of this Order. The term “Divestiture Agreement” includes, as appropriate, the Albertsons Divestiture Agreement, the Big Y Divestiture Agreement, the Publix Divestiture Agreement, the Saubels Divestiture Agreement, the Supervalu Divestiture Agreement, the Tops Divestiture Agreement, and the Weis Divestiture Agreement.
- N. “Divestiture Date” means a closing date of any of the respective divestitures required by this Order.
- O. “Divestiture Trustee” means any person or entity appointed by the Commission pursuant to Paragraph IV of this Order to act as a trustee in this matter.
- P. “Proposed Acquirer” means any proposed acquirer of any of the Assets To Be Divested submitted to the Commission for its approval under this Order; “Proposed Acquirer” includes, as appropriate, Albertsons, Big Y, Publix, Saubels, Supervalu, Tops, and Weis.
- Q. “Publix” means Publix Super Markets, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Florida, with its offices and principal place of business located at 3300 Publix Corporate Parkway, Lakeland, Florida 33811, and including Publix North Carolina, L.P.,
- R. “Publix Divestiture Agreement” means the Asset Purchase Agreement dated as of July 7, 2016, by and between Respondent Ahold and Publix, attached as non-public Appendix III, for the divestiture of the Schedule C Assets.

Decision and Order

- S. “Remedial Agreement(s)” means the following:
1. Any Divestiture Agreement; and
 2. Any other agreement between Respondents and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer), including any Transition Services Agreement, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Assets To Be Divested, that have been approved by the Commission to accomplish the requirements of this Order.
- T. “Relevant Areas” means: Sussex County in Delaware; Allegany, Anne Arundel, Baltimore, Calvert, Carroll, Charles, Howard, Montgomery, Prince George’s, St. Mary’s, Talbot, Washington, and Wicomico Counties in Maryland; Bristol, Essex, Norfolk, Plymouth, and Worcester Counties in Massachusetts; Franklin, and York Counties in Pennsylvania; Dutchess, Putnam, and Ulster Counties in New York; Chesterfield, Clarke, Colonial Heights City, Culpeper, Frederick, Fredericksburg City, Hanover, Henrico, Loudoun, Richmond City, Spotsylvania, Stafford, Winchester City, and Warren Counties in Virginia; and Berkeley County in West Virginia.
- U. “Saubels” means Saubels Market, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its offices and principal place of business located at 65 East Forrest Avenue, Shrewsbury, Pennsylvania 17361.
- V. “Saubels Divestiture Agreement” means the Asset Purchase Agreement dated as of July 7, 2016, by and between Respondent Delhaize and Saubels, attached as non-public Appendix IV, for the divestiture of the Schedule D Assets.

Decision and Order

- W. “Schedule A Assets” means the Assets To Be Divested identified on Schedule A of this Order.
- X. “Schedule B Assets” means the Assets To Be Divested identified on Schedule B of this Order.
- Y. “Schedule C Assets” means the Assets To Be Divested identified on Schedule C of this Order.
- Z. “Schedule C Additional Assets” means the additional Supermarket businesses, identified as such on Schedule C of this Order.

Provided, however, that Martin’s Store No. 6492 shall be removed from the list of Schedule C Additional Assets on April 1, 2017, if the Commission has notified Respondents, in advance of that date and in writing, that the sale of that store will not be required pursuant to Paragraph II.B.1 and/or IV.A. of this Order.

- AA. “Schedule D Assets” means the Assets To Be Divested identified on Schedule D of this Order.
- BB. “Schedule E Assets” means the Assets To Be Divested identified on Schedule E of this Order.
- CC. “Schedule F Assets” means the Assets To Be Divested identified on Schedule F of this Order.
- DD. “Schedule G Assets” means the Assets To Be Divested identified on Schedule G of this Order.
- EE. “Supermarket” means any full-line retail grocery store that enables customers to purchase substantially all of their weekly food and grocery shopping requirements in a single shopping visit with substantial offerings in each of the following product categories: bread and baked goods; dairy products; refrigerated food and beverage products; frozen food and beverage products; fresh and prepared meats and poultry; fresh fruits and

Decision and Order

vegetables; shelf-stable food and beverage products, including canned, jarred, bottled, boxed, and other types of packaged products; staple foodstuffs, which may include salt, sugar, flour, sauces, spices, coffee, tea, and other staples; other grocery products, including nonfood items such as soaps, detergents, paper goods, other household products, and health and beauty aids; pharmaceutical products and pharmacy services (where provided); and, to the extent permitted by law, wine, beer, and/or distilled spirits.

- FF. “Supervalu” means Supervalu Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 11840 Valley View Road, Eden Prairie, Minnesota 55344, and including its direct and indirect wholly-owned subsidiaries, Shop ‘N Save East, LLC and Shop ‘N Save East Prop, LLC.
- GG. “Supervalu Divestiture Agreement” means the Asset Purchase Agreement dated as of July 7, 2016, by and between Respondent Delhaize and Supervalu, attached as non-public Appendix V, for the divestiture of the Schedule E Assets.
- HH. “Third Party Consents” means all consents from any person other than the Respondents, including all landlords, that are necessary to effect the complete transfer to the Acquirer(s) of the Assets To Be Divested.
- II. “Tops” means Tops Markets, LLC, a New York limited liability company that is organized, existing, and doing business under and by virtue of the laws of the State of New York with its offices and principal place of business located at 6363 Main Street, Williamsville, New York 14221 and a mailing address c/o PO Box 1027, Buffalo, NY 14240-1027.

Decision and Order

- JJ. “Tops Divestiture Agreement” means the two Asset Purchase Agreements dated as of July 7, 2016, by and between Respondents and Tops, attached as non-public Appendix VI, for the divestiture of the Schedule F Assets.
- KK. “Transition Services” means services (or training for an Acquirer to provide services for itself) related to payroll, employee benefits, accounting, IT systems, back-office and front-office systems (including inventory and price management), distribution, warehousing, use of trademarks or trade names for transitional purposes, and other transitional support as may be required by an Acquirer to transfer and operate the divested assets in a manner consistent with the purposes of this Order.
- LL. “Transition Services Agreement” means an agreement that receives the prior approval of the Commission between one or more Respondents and an Acquirer of any of the assets divested under this Order to provide, at the option of each Acquirer, any services (or training for an Acquirer to provide services for itself) necessary to transfer the divested assets to the Acquirer in a manner consistent with the purposes of this Order.
- MM. “Weis” means Weis Markets, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of the State of Pennsylvania, with its offices and principal place of business located at 1000 S. Second Street, P.O. Box 471, Sunbury, Pennsylvania 17801.
- NN. “Weis Divestiture Agreement” means the Asset Purchase Agreement dated as of July 7, 2016, by and between Respondent Delhaize and Weis, attached as non-public Appendix VII, for the divestiture of the Schedule G Assets.

Decision and Order

II.**IT IS FURTHER ORDERED** that:

- A. Respondents shall divest the Assets To Be Divested, absolutely and in good faith, as follows:
1. Within 60 days of the date the Merger is consummated, the Schedule A Assets shall be divested as ongoing Supermarket businesses to Albertsons pursuant to and in accordance with the Albertsons Divestiture Agreement;
 2. Within 90 days of the date the Merger is consummated, the Schedule B Assets shall be divested as ongoing Supermarket businesses to Big Y pursuant to and in accordance with the Big Y Divestiture Agreement;
 3. The Schedule C Assets shall be divested to Publix, pursuant to and in accordance with the Publix Divestiture Agreement, on the following schedule:
 - a. Within 180 days of the date the Merger is consummated, the Schedule C, Group I Stores shall be divested to Publix;
 - b. Within 240 days of the date the Merger is consummated, the Schedule C, Group II Stores shall be divested to Publix; and
 - c. Within 360 days of the date the Merger is consummated, the Schedule C, Group III Stores shall be divested to Publix;
 4. Within 60 days of the date the Merger is consummated, the Schedule D Assets shall be divested as an ongoing Supermarket business to Saubels pursuant to and in accordance with the Saubels Divestiture Agreement;

Decision and Order

5. Within 105 days of the date the Merger is consummated, the Schedule E Assets shall be divested as ongoing Supermarket businesses to Supervalu pursuant to and in accordance with the Supervalu Divestiture Agreement;
 6. Within 60 days of the date the Merger is consummated, the Schedule F Assets shall be divested as ongoing Supermarket businesses to Tops pursuant to and in accordance with the Tops Divestiture Agreement;
 7. The Schedule G Assets shall be divested as ongoing Supermarket businesses to Weis, pursuant to and in accordance with the Weis Divestiture Agreement, on the following schedule:
 - a. Within 90 days of the date the Merger is consummated, at least 15 of the Schedule G, Phase I Locations shall be divested to Weis; and
 - b. Within 230 days of the date the Merger is consummated, the remaining Schedule G, Phase I Locations and all of the Schedule G, Phase II Locations shall be divested to Weis.
- B. *Provided, that*, if prior to the date this Order becomes final, Respondents have divested the Assets To Be Divested pursuant to Paragraph II.A and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:
1. Any Proposed Acquirer identified in Paragraph II.A is not an acceptable Acquirer, then Respondents shall, within five days of notification by the Commission, rescind such transaction with that Proposed Acquirer, and shall divest such assets (and, in the case of the Schedule C Assets, including any of the Schedule C Additional Assets, as determined by the Commission in its sole

Decision and Order

discretion) as ongoing Supermarket businesses, absolutely and in good faith, at no minimum price, to an Acquirer and in a manner that receives the prior approval of the Commission, within 90 days of the date the Commission notifies Respondents that such Proposed Acquirer is not an acceptable Acquirer; or

2. The manner in which any divestiture identified in Paragraph II.A was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee pursuant to Paragraph IV of this Order, to effect such modifications to the manner of divesting those assets to such Acquirer (including, but not limited to, entering into additional agreements or arrangements, or modifying the relevant Divestiture Agreement) as may be necessary to satisfy the requirements of this Order.
- C. Respondents shall obtain at their sole expense all required Third Party Consents relating to the divestiture of all Assets To Be Divested prior to the applicable Divestiture Date.
- D. All Remedial Agreements approved by the Commission:
1. Shall be deemed incorporated by reference into this Order, and any failure by Respondents to comply with the terms of any such Remedial Agreement(s) shall constitute a violation of this Order; and
 2. Shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of any Acquirer or to reduce any obligation of Respondents under such agreement. If any term of any Remedial Agreement(s) varies from the terms

Decision and Order

of this Order (“Order Term”), then to the extent that Respondents cannot fully comply with both terms, the Order Term shall determine Respondents’ obligations under this Order.

- E. At the option of each Acquirer of any Assets To Be Divested, and subject to the prior approval of the Commission, Respondents shall enter into a Transition Services Agreement for a term extending up to 180 days following the Divestiture Date. The services subject to the Transition Services Agreement shall be provided at no more than Respondents’ Direct Costs and may include, but are not limited to, payroll, employee benefits, accounting, IT systems, distribution, warehousing, use of trademarks or trade names for transitional purposes, and other logistical and administrative support.
- F. Pending divestiture of any of the Assets To Be Divested, Respondents shall:
1. Take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the Assets To Be Divested, to minimize any risk of loss of competitive potential for the Assets To Be Divested, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Assets To Be Divested, except for ordinary wear and tear; and
 2. Not sell, transfer, encumber, or otherwise impair the Assets To Be Divested (other than in the manner prescribed in this Decision and Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Assets To Be Divested.

Provided, however, that Respondents shall not be in violation of this Paragraph II.F. if Respondents take actions (i) as explicitly permitted or required by any Divestiture Agreement, or (ii) that have been requested

Decision and Order

or agreed-to by an Acquirer, in writing, and approved in advance by the Monitor (in consultation with Commission staff), in all cases to facilitate the Acquirer's acquisition of Assets To Be Divested and consistent with the purposes of the Order.

- G. The purpose of the divestitures is to ensure the continuation of the Assets To Be Divested as ongoing, viable enterprises engaged in the Supermarket business and to remedy the lessening of competition resulting from the Merger as alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that, with respect to each Divestiture Agreement, Respondents shall:

- A. No later than ten (10) days after a request from a Proposed Acquirer, provide the Proposed Acquirer with the following information for each employee of the Assets To Be Divested, as requested by the Proposed Acquirer, and to the extent permitted by law:
1. Name, job title or position, date of hire, and effective service date;
 2. Specific description of the employee's responsibilities;
 3. The base salary or current wages;
 4. Most recent bonus paid, aggregate annual compensation for Respondents' last fiscal year, and current target or guaranteed bonus, if any;
 5. Employment status (*i.e.*, active or on leave or disability; full-time or part-time);
 6. Any other material terms and conditions of employment in regard to such employee that are

Decision and Order

not otherwise generally available to similarly situated employees; and

7. At the Proposed Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the employee.
- B. Within a reasonable time after a request from a Proposed Acquirer, provide to the Proposed Acquirer an opportunity to meet personally and outside the presence or hearing of any employee or agent of any Respondent, with any one, or all, of the employees of the Assets To Be Divested, and to make offers of employment to any one, or more, of the employees of the Assets To Be Divested.
 - C. Not interfere, directly or indirectly, with the hiring or employing by the Proposed Acquirer of any employee of the Assets To Be Divested, not offer any incentive to such employees to decline employment with the Proposed Acquirer, and not otherwise interfere with the recruitment or employment of any employee by the Proposed Acquirer.
 - D. Remove any impediments within the control of Respondents that may deter employees of the Assets To Be Divested from accepting employment with the Proposed Acquirer, including, but not limited to, removal of any non-compete or confidentiality provisions of employment, or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by the Proposed Acquirer, and shall not make any counteroffer to an employee who has an outstanding offer of employment from the Proposed Acquirer or has accepted an offer of employment from the Proposed Acquirer.
 - E. Provide all employees with reasonable financial incentives to continue in their positions until the Divestiture Date. Such incentives shall include, but are not limited to, a continuation, until the Divestiture

Decision and Order

Date, of all employee benefits, including the funding of regularly scheduled raises and bonuses, and the vesting as of the Divestiture Date of any unvested qualified 401(k) plan account balances (to the extent permitted by law, and for those employees covered by a 401(k) plan), offered by Respondents.

- F. Not, for a period of one (1) year following the Divestiture Date, directly or indirectly, solicit, or otherwise attempt to induce any of the employees who have accepted offers of employment with the Acquirer to terminate his or her employment with the Acquirer; *provided, however*, that Respondents may:
1. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at employees of the Assets To Be Divested; or
 2. Hire employees of the Assets To Be Divested who apply for employment with Respondents, as long as such employees were not solicited by Respondents in violation of this Paragraph; *provided further, however*, that this Paragraph shall not prohibit Respondents from making offers of employment to, or employing, any such employees if the Acquirer has notified Respondents in writing that the Acquirer does not intend to make an offer of employment to that employee, or where such an offer has been made and the employee has declined the offer, or where the employee's employment has been terminated by the Acquirer.

IV.

IT IS FURTHER ORDERED that:

- A. If Respondents have not divested all of the Assets To Be Divested in the time and manner required by Paragraph II of this Order, the Commission may

Decision and Order

appoint a Divestiture Trustee to divest the remaining Assets To Be Divested (including, in the case of the Schedule C Assets, the Schedule C Additional Assets) in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondents to comply with this Order.

- B. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

Decision and Order

2. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, contract, deliver, or otherwise convey the relevant assets or rights that are required to be assigned, granted, licensed, divested, transferred, contracted, delivered, or otherwise conveyed by this Order.
3. Within ten (10) days after appointment of the Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestitures or transfers required by the Order.
4. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph IV.B.3. to accomplish the divestiture(s), which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
5. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities relating to the assets that are required to be assigned, granted, licensed, divested, transferred, contracted, delivered, or otherwise conveyed by this Order or to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture

Decision and Order

Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

6. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously at no minimum price. The divestiture(s) shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity for any of the relevant Assets To Be Divested, and if the Commission determines to approve more than one such acquiring entity for such assets, the Divestiture Trustee shall divest such assets to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such entity within five (5) days of receiving notification of the Commission's approval.
7. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The

Decision and Order

Divestiture Trustee shall account for all monies derived from the divestiture(s) and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for his or her services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets required to be divested by this Order.

8. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
9. If the Commission determines that the Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph IV.
10. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

Decision and Order

11. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
12. The Divestiture Trustee shall report in writing to Respondents and to the Commission every thirty (30) days concerning the Divestiture Trustee's efforts to accomplish the divestiture(s).
13. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
14. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, representatives, and assistants to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties and responsibilities.

V.**IT IS FURTHER ORDERED** that:

- A. Brad Wise shall serve as the Monitor pursuant to the agreement executed by the Monitor and Respondents, and attached as Appendix VIII ("Monitor Agreement") and Non-Public Appendix VIII-1 ("Monitor Compensation"). The Monitor is appointed to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreement(s);

Decision and Order

- B. No later than one (1) day after the date the Merger is consummated, Respondents shall, pursuant to the Monitor Agreement, confer on the Monitor all rights, powers, and authorities necessary to permit the Monitor to monitor Respondents' compliance with the terms of this Order, the Order to Maintain Assets, and the Remedial Agreement(s), in a manner consistent with the purposes of the orders.
- C. Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and related requirements of this Order, the Order to Maintain Assets, and the Remedial Agreement(s), and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the orders and in consultation with the Commission.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
 3. The Monitor shall serve until the later of (a) one year from the date this Order is issued or (b) all divestiture obligations under Paragraphs II and IV of this Order have been satisfied.
- D. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under this Order, the Order to Maintain Assets, and the Remedial Agreement(s).

Decision and Order

- E. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order, the Order to Maintain Assets, and the Remedial Agreement(s).
- F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have the authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor. For purposes of this Paragraph V.G., the term "Monitor" shall include all persons retained by the Monitor pursuant to Paragraph V.F. of this Order.
- H. Respondents shall report to the Monitor in accordance with the requirements of this Order or the Order to Maintain Assets, and as otherwise provided in the Monitor Agreement approved by the Commission. The Monitor shall evaluate the reports submitted by the Respondents with respect to the performance of Respondents' obligations under this Order and the Order to Maintain Assets. Within thirty (30) days from the date the Monitor receives the first such

Decision and Order

report, and every thirty (30) days thereafter, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the orders.

- I. Respondents may require the Monitor and each of the Monitor's consultants, accountants, and other representatives and assistants to sign a customary confidentiality agreement. *Provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may require, among other things, the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:
 1. The Commission shall select the substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after the notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
 2. Not later than ten (10) days after the appointment of the substitute Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all rights and powers necessary to permit the Monitor to monitor Respondents' compliance

Decision and Order

with the relevant terms of this Order, the Order to Maintain Assets, and the Remedial Agreement(s) in a manner consistent with the purposes of orders and in consultation with the Commission.

- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.
- M. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

VI.

IT IS FURTHER ORDERED that if Supervalu purchases the Schedule E Assets pursuant to Paragraph II.A.5, Supervalu shall not sell or otherwise convey, directly or indirectly, any of the Schedule E Assets, except to an Acquirer approved by the Commission and only in a manner that receives the prior approval of the Commission. *Provided, however*, that prior approval of the Commission is not required if Supervalu sells or conveys, directly or indirectly, any or all of its interests in the Schedule E Assets to Donstekim Enterprises, LLC pursuant to and in accordance with the Shop 'N Save East, LLC Joint Venture Term Sheet attached to this Order as non-public Appendix IX. Supervalu shall comply with this Paragraph until three (3) years after the date this Order is issued.

VII.

IT IS FURTHER ORDERED that:

- A. For a period of ten (10) years commencing on the date this Order is issued, Respondents shall not, directly or indirectly, through subsidiaries, partnerships or otherwise, without providing advance written notification to the Commission:

Decision and Order

1. Acquire any ownership or leasehold interest in any facility that has operated as a Supermarket within six (6) months prior to the date of such proposed acquisition in any of the Relevant Areas.
2. Acquire any stock, share capital, equity, or other interest in any entity that owns any interest in or operates any Supermarket, or owned any interest in or operated any Supermarket within six (6) months prior to such proposed acquisition, in any of the Relevant Areas.

Provided, however, that advance written notification shall not apply to the construction of new facilities or the acquisition or leasing of a facility that has not operated as a Supermarket within six (6) months prior to Respondents' offer to purchase or lease such facility.

- B. Said notification under this Paragraph shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended, and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of Respondents and not of any other party to the transaction. Respondents shall provide the notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not consummate the transaction until thirty (30) days after substantially complying with such request. Early termination of the waiting periods in this Paragraph may be requested and, where

Decision and Order

appropriate, granted by letter from the Bureau of Competition. *Provided, however,* that prior notification shall not be required by this Paragraph for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

VIII.**IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the date this Order is issued and every thirty (30) days thereafter until the Respondents have fully complied with the provisions of Paragraphs II and IV of this Order, Respondents shall submit to the Commission verified written reports setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their reports concerning compliance with this Order to the Monitor. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order, including a description of all substantive contacts or negotiations for the divestitures and the identity of all parties contacted. Respondents shall include in their reports copies of all material written communications to and from such parties, all non-privileged internal memoranda, reports, and recommendations concerning completing the obligations; and
- B. One (1) year from the date this Order is issued, annually for the next nine (9) years on the anniversary of the date this Order is issued, and at other times as the Commission may require, Respondents shall file verified written reports with the Commission setting forth in detail the manner and form in which they have complied and are complying with this Order.

Decision and Order

IX.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondents;
- B. Any proposed acquisition, merger, or consolidation of Respondents; or
- C. Any other change in the Respondents, including but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

X.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and upon five (5) days' notice to Respondents made to their principal United States office, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents relating to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and
- B. To interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

Decision and Order

XI.

IT IS FURTHER ORDERED that this Order shall terminate on October 14, 2026.

By the Commission.

Schedule A Assets

1. Giant Store No. 351, located at 751 S Salisbury Boulevard, Salisbury, Maryland (Wicomico County).

Schedule B Assets

1. Hannaford Store No. 8008, located at 182 Summer Street, Kingston, Massachusetts (Plymouth County).
2. Hannaford Store No. 8018, located at 475 Hancock Street, Quincy, Massachusetts (Norfolk County).
3. Hannaford Store No. 8020, located at 10 Washington Street, Norwell, Massachusetts (Plymouth County).
4. Hannaford Store No. 8021, located at 7 Medway Road, Milford, Massachusetts (Worcester County).
5. Hannaford Store No. 8022, located at 434 Walpole Street, Norwood, Massachusetts (Norfolk County).

Decision and Order

6. Hannaford Store No. 8286, located at 357 Broadway, Saugus, Massachusetts (Essex County).

7. Hannaford Store No. 8382, located at 25 Robert Drive, Easton, Massachusetts (Bristol County).

Schedule C Assets**Closing Group 1**

1. Martin's Store No. 6499, located at 4591 S. Laburnum Avenue, Richmond, Virginia (Henrico County).

2. Martin's Store No. 6434, located at 2250 John Rolfe Parkway, Henrico, Virginia (Henrico County).

3. Martin's Store No. 6433, located at 10250 Staples Mill Road, Glen Allen, Virginia (Henrico County).

Closing Group 2

4. Martin's Store No. 6421, located at 3460 Pump Road, Henrico, Virginia (Henrico County).

5. Martin's Store No. 6435, located at 10150 Brook Road, Glen Allen, Virginia (Henrico County).

6. Martin's Store No. 6438, located at 13700 Hull Street Road, Midlothian, Virginia (Chesterfield County).

7. Martin's Store No. 6494, located at 3107 Boulevard, Colonial Heights, Virginia (Colonial Heights City).

Decision and Order

Closing Group 3

8. Martin's Store No. 6429, located at 3522 West Cary Street, Richmond, Virginia (Richmond City).

9. Martin's Store No. 6439, located at 7035 Three Chopt Road, Richmond, Virginia (Henrico County).

10. Martin's Store No. 6498, located at 9645 West Broad Street, Glen Allen, Virginia (Henrico County).

Schedule C Additional Assets

1. Martin's Store No. 6491, located at 12601 Jefferson Davis Highway, Chester, Virginia (Chesterfield County).

2. Martin's Store No. 6492, located at 10001 Hull Street Road, Richmond, Virginia (Chesterfield County).

3. Martin's Store No. 6428, located at 7045 Forest Hill Avenue, Richmond, Virginia (Richmond City).

4. Martin's Store No. 6588, located at 200 Charter Colony Parkway, Midlothian, Virginia (Chesterfield County).

5. Martin's Store No. 6489, located at 253 N Washington Highway, Ashland, Virginia (Hanover County).

6. Martin's Store No. 6436, located at 5700 Brook Road, Richmond, Virginia (Henrico County).

Schedule D Assets

1. Food Lion Store No. 1241, located at 3611 E. Market Street, York, Pennsylvania (York County).

Decision and Order

Schedule E Assets

1. Food Lion Store No. 362, located at 707 Fort Collier Road, Winchester, Virginia (Winchester City).
2. Food Lion Store No. 366, located at 2600 Valley Avenue, Winchester, Virginia (Winchester City).
3. Food Lion Store No. 626, located at 761 East Wilson Boulevard, Hagerstown, Maryland (Washington County).
4. Food Lion Store No. 733, located 249 Sunnyside Plaza Circle, Winchester, Virginia (Frederick County).
5. Food Lion Store No. 745, located at 609 K East Main Street, Purcellville, Virginia (Loudoun County).
6. Food Lion Store No. 994, located at 4170 Philadelphia Avenue, Chambersburg, Pennsylvania (Franklin County).
7. Food Lion Store No. 1059, located at 260 Remount Road, Front Royal, Virginia (Warren County).
8. Food Lion Store No. 1147, located at 18717 North Pointe Drive, Hagerstown, Maryland (Washington County).
9. Food Lion Store No. 1164, located at 409 North McNeil Road, Berryville, Virginia (Clarke County).
10. Food Lion Store No. 1180, located at 17718 Virginia Avenue, Hagerstown, Maryland (Washington County).
11. Food Lion Store No. 1189, located at 1140 Winchester Avenue, Martinsburg, West Virginia (Berkeley County).
12. Food Lion Store No. 1281, located at 190 Delco Plaza, Winchester, Virginia (Frederick County).
13. Food Lion Store No. 1489, located at 380 Fairfax Pike, Stephens City, Virginia (Frederick County).

Decision and Order

14. Food Lion Store No. 1527, located at 875 Lincoln Way West, Chambersburg, Pennsylvania (Franklin County).

15. Food Lion Store No. 1663, located at 11105 Buchanan Trail, Waynesboro, Pennsylvania (Franklin County).

16. Food Lion Store No. 1683, located at 18360 College Road, Hagerstown, Maryland (Washington County).

17. Food Lion Store No. 2568, located at 1317 Old Courthouse Square, Martinsburg, West Virginia (Berkeley County).

18. Food Lion Store No. 2668, located at 159 Grocery Avenue, Winchester, Virginia (Frederick County).

Schedule F Assets

1. Stop & Shop Store No. 536, located at 6726 Route 9, Rhinebeck, New York (Dutchess County).

2. Stop & Shop Store No. 515, located at 271 Main Street, New Paltz, New York (Ulster County).

3. Stop & Shop Store No. 598, located at 1357 Route 9, Wappingers Falls, New York (Dutchess County).

4. Stop & Shop Store No. 434, located at 372 Timpany Boulevard, Gardner, Massachusetts (Worcester County).

5. Hannaford Store No. 8325, located at 1936 U.S. Route 6, Carmel, New York (Putnam County).

6. Hannaford Store No. 8368, located at 16 Jon J Wagner Way, LaGrange, New York (Dutchess County).

Decision and Order

Schedule G Assets**Phase I Locations**

1. Food Lion Store No. 488, located at 19287 Miller Road, Unit 14, Rehoboth Beach, Delaware (Sussex County).
2. Food Lion Store No. 784, located at 45315 Alton Lane, California, Maryland (St. Mary's County).
3. Food Lion Store No. 786, located at 10 Village Center Road, Reisterstown, Maryland (Baltimore County).
4. Food Lion Store No. 960, located at 24832 John J Williams Highway, Millsboro, Delaware (Sussex County).
5. Food Lion Store No. 1168, located at 100 Drury Drive, La Plata, Maryland (Charles County).
6. Food Lion Store No. 1187, located at 17600 Old National SW Pike, Frostburg, Maryland (Allegany County).
7. Food Lion Store No. 1210, located at 19 St. Mary's Square, Lexington Park, Maryland (St. Mary's County).
8. Food Lion Store No. 1289, located at 219 Marlboro Avenue, Easton, Maryland (Talbot County).
9. Food Lion Store No. 1315, located at 3261 Solomons Island Road, Edgewater, Maryland (Anne Arundel County).
10. Food Lion Store No. 1321, located at 215 Atlantic Avenue, Millville, Delaware (Sussex County).
11. Food Lion Store No. 1324, located at 6375 Monroe Avenue, Sykesville, Maryland (Carroll County).
12. Food Lion Store No. 1345, located at 16567 S. Frederick Road, Gaithersburg, Maryland (Montgomery County).

Decision and Order

13. Food Lion Store No. 1356, located at 15789 Livingston Road, Accokeek, Maryland (Prince George's County).
14. Food Lion Store No. 1387, located at 12100 Central Avenue, Bowie, Maryland (Prince George's County).
15. Food Lion Store No. 1443, located at 13300 H G Trueman Road, Solomons, Maryland (Calvert County).
16. Food Lion Store No. 1477, located at 883 Russell Avenue, Gaithersburg, Maryland (Montgomery County).
17. Food Lion Store No. 1526, located at 750 Prince Frederick Boulevard, Prince Frederick, Maryland (Calvert County).
18. Food Lion Store No. 1529, located at 6551 Waterloo Road, Elkridge, Maryland (Howard County).
19. Food Lion Store No. 1535, located at 5715 Crain Highway, Upper Marlboro, Maryland (Prince George's County).
20. Food Lion Store No. 1549, located at 15300 McMullen Highway SW, Cumberland, Maryland (Allegany County).
21. Food Lion Store No. 2515, located at 20995 Point Lookout Road, Callaway, Maryland (St. Mary's County).
22. Food Lion Store No. 2535, located at 9251 Lakeside Boulevard, Owings Mills, Maryland (Baltimore County).
23. Food Lion Store No. 2565, located at 17232 N Village Main Boulevard, Lewes, Delaware (Sussex County).
24. Food Lion Store No. 2598, located at 5896 Robert Oliver Place, Columbia, Maryland (Howard County).
25. Food Lion Store No. 2606, located at 210 H G Trueman Rd, Lusby, Maryland (Calvert County).

Decision and Order

Phase II Locations

26. Food Lion Store No. 250, located at 505 Meadowbrook Shopping Center, Culpeper, Virginia (Culpeper County).

27. Food Lion Store No. 358, located at 282 Deacon Road ,Suite 106, Fredericksburg, Virginia (Stafford County).

28. Food Lion Store No. 419, located at 10611 Courthouse Road, Fredericksburg, Virginia (Spotsylvania County).

29. Food Lion Store No. 450, located at 4153 Plank Road, Fredericksburg, Virginia (Spotsylvania County).

30. Food Lion Store No. 578, located at 905 Garrisonville Road, Stafford, Virginia (Stafford County).

31. Food Lion Store No. 1043, located at 515 Jefferson Davis Highway, Fredericksburg, Virginia (Fredericksburg City).

32. Food Lion Store No. 1166, located at 2612 Jefferson Davis Highway, Stafford, Virginia (Stafford County).

33. Food Lion Store No. 1177, located at 9801 Courthouse Road, Spotsylvania, Virginia (Spotsylvania County).

34. Food Lion Store No. 1235, located at 10601 Spotsylvania Avenue, Fredericksburg, Virginia (Spotsylvania County).

35. Food Lion Store No. 1243, located at 736 Warrenton Road, Fredericksburg, Virginia (Stafford County).

36. Food Lion Store No. 1567, located at 540 Culpeper Town Mall, Culpeper, Virginia (Culpeper County).

37. Food Lion Store No. 1579, located at 7100 Salem Fields Boulevard, Fredericksburg, Virginia (Spotsylvania County).

38. Food Lion Store No. 2583, located at 10871 Tidewater Trail, Fredericksburg, Virginia (Spotsylvania County).

Decision and Order

APPENDIX I

Albertsons Divestiture Agreement

**[Redacted From the Public Record Version, But
Incorporated By Reference]**

APPENDIX II

Big Y Divestiture Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

APPENDIX III

Publix Divestiture Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Decision and Order

APPENDIX IV

Saubels Divestiture Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

APPENDIX V

Supervalu Divestiture Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

APPENDIX VI

Tops Divestiture Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Decision and Order

APPENDIX VII

Weis Divestiture Agreement

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

APPENDIX VIII

Monitor Agreement

APPENDIX VIII-1

Monitor Compensation

[Redacted From the Public Record Version]

APPENDIX IX

Shop 'N Save East, LLC Joint Venture Term Sheet

**[Redacted From the Public Record Version, But Incorporated
By Reference]**

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT****I. INTRODUCTION AND BACKGROUND**

The Federal Trade Commission (“Commission”) has accepted for public comment, subject to final approval, an Agreement Containing Consent Order (“Consent Order”) from Koninklijke Ahold N.V. (“Ahold”) and Delhaize Group NV/SA (“Delhaize”) (collectively, the “Respondents”). Pursuant to an Agreement and Plan of Merger dated June 24, 2015, Ahold and Delhaize will combine their businesses through a merger of equals, resulting in a combined entity valued at approximately \$28 billion (“the Merger”). The purpose of the proposed Consent Order is to remedy the anticompetitive effects that otherwise would result from the Merger. Under the terms of the proposed Consent Order, Respondents are required to divest 81 supermarkets and related assets in 46 local geographic markets (collectively, the “relevant markets”) in seven states to seven Commission-approved buyers. The divestitures must be completed within a time-period ranging from 60 to 360 days following the date of the Merger. The Commission and Respondents have agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture store in the normal course of business through the date the store is ultimately divested to a buyer.

The proposed Consent Order has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission again will review the proposed Consent Order and any comments received, and decide whether it should withdraw the Consent Order, modify the Consent Order, or make the Consent Order final.

The Commission’s Complaint alleges that the Merger, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by removing an actual, direct, and substantial supermarket competitor in each of the 46 local geographic markets. The elimination of this competition would result in significant competitive harm;

Analysis to Aid Public Comment

specifically, the Merger will allow the merged firm to increase prices above competitive levels, unilaterally or through coordinated interaction among the remaining market participants. Similarly, absent a remedy, there is significant risk that the merged firm may decrease quality and service aspects of its stores below competitive levels. The proposed Consent Order would remedy the alleged violations by requiring divestitures to replace competition that otherwise would be lost in the relevant markets because of the Merger.

II. THE RESPONDENTS

Respondent Ahold is a Dutch company that operates in the United States through its principal U.S. subsidiary Ahold U.S.A., Inc. As of June 24, 2015, Ahold operated 760 supermarkets in the United States under the Stop & Shop, Giant, and Martin's banners. Ahold's stores are located in Connecticut, Delaware, the District of Columbia, Maryland, Massachusetts, New Jersey, New York, Pennsylvania, Rhode Island, Virginia, and West Virginia.

Delhaize is a Belgian company that operates in the United States through its principal U.S. subsidiary Delhaize America, LLC. As of June 24, 2015, Delhaize operated 1,291 supermarkets in the United States under the Food Lion and Hannaford banners, dispersed throughout Delaware, Georgia, Kentucky, Maine, Maryland, Massachusetts, New Hampshire, New York, North Carolina, Pennsylvania, South Carolina, Tennessee, Vermont, and West Virginia.

III. RETAIL SALE OF FOOD AND OTHER GROCERY PRODUCTS IN SUPERMARKETS

The Merger presents substantial antitrust concerns for the retail sale of food and other grocery products in supermarkets. Supermarkets are traditional full-line retail grocery stores that sell food and non-food products that customers regularly consume at home—including, but not limited to, fresh produce and meat, dairy products, frozen foods, beverages, bakery goods, dry groceries, household products, detergents, and health and beauty products. Supermarkets also provide service options that enhance the shopping experience, including deli, butcher, seafood, bakery,

Analysis to Aid Public Comment

and floral counters. This broad set of products and services provides consumers with a “one-stop shopping” experience by enabling them to shop in a single store for all of their food and grocery needs. The ability to offer consumers one-stop shopping is the critical difference between supermarkets and other food retailers.

The relevant product market includes supermarkets within “hypermarkets” such as Walmart Supercenters. Hypermarkets also sell an array of products not found in traditional supermarkets. Like conventional supermarkets, however, hypermarkets contain bakeries, delis, dairy, produce, fresh meat, and sufficient product offerings to enable customers to purchase all of their weekly grocery requirements in a single shopping visit.

Other types of retailers, such as hard discounters, limited assortment stores, natural and organic markets, ethnic specialty stores, and club stores, also sell food and grocery items. These types of retailers are not in the relevant product market because they offer a more limited range of products and services than supermarkets and because they appeal to a distinct customer type. Shoppers typically do not view these other food and grocery retailers as adequate substitutes for supermarkets.¹ Consistent with prior Commission precedent, the Commission has excluded these other types of retailers from the relevant product market.²

¹ That is, supermarket shoppers would be unlikely to switch to one of these other types of retailers in response to a small but significant nontransitory increase in price or “SSNIP” by a hypothetical supermarket monopolist. *See* U.S. DOJ and FTC Horizontal Merger Guidelines § 4.1.1 (2010).

² *See, e.g.*, Cerberus Institutional Partners, L.P./Safeway, Inc., Docket C-4504 (Jul. 2, 2015); Bi-Lo Holdings, LLC/Delhaize America, LLC, Docket C-4440 (Feb. 25, 2014); AB Acquisition, LLC, Docket C-4424 (Dec. 23, 2013); Koninklijke Ahold N.V./Safeway Inc., Docket C-4367 (Aug. 17, 2012); Shaw’s/Star Markets, Docket C-3934 (Jun. 28, 1999); Kroger/Fred Meyer, Docket C-3917 (Jan. 10, 2000); Albertson’s/American Stores, Docket C-3986 (Jun. 22, 1999); Ahold/Giant, Docket C-3861 (Apr. 5, 1999); Albertson’s/Buttrey, Docket C-3838 (Dec. 8, 1998); Jitney-Jungle Stores of America, Inc., Docket C-3784 (Jan. 30, 1998). *But see* Wal-Mart/Supermercados Amigo, Docket C-4066 (Nov. 21, 2002) (the Commission’s complaint alleged that in Puerto Rico, club stores should be included in a product market that included supermarkets because club stores in

Analysis to Aid Public Comment

The relevant geographic markets in which to analyze the effects of the Merger are areas that range from one-tenth of a mile to a ten-mile radius around each of the Respondents' supermarkets, though the majority of Respondents' overlapping supermarkets raising concerns are within six miles or less of each other.³ The length of the radius depends on factors such as population density, traffic patterns, and other specific characteristics of each market. Where the Respondents' supermarkets are located in rural areas, the relevant geographic areas are larger than areas where the Respondents' supermarkets are located in more densely populated cities. A hypothetical monopolist of the retail sale of food and grocery products in supermarkets in each relevant area could profitably impose a small but significant nontransitory increase in price.

The 46 geographic markets in which to analyze the effects of the Merger are local areas in and around:

(1) Lewes & Rehoboth Beach, Delaware; (2) Millsboro, Delaware; (3) Millville, Delaware; (4) Accokeek, Maryland; (5) Bowie, Maryland; (6) California, Maryland; (7) Columbia, Maryland; (8) Cumberland & Frostburg, Maryland; (9) Easton, Maryland; (10) Edgewater, Maryland; (11) Gaithersburg, Maryland; (12) Hagerstown (north), Maryland; (13) Hagerstown (south), Maryland; (14) La Plata, Maryland; (15) Lusby, Maryland; (16) Owings Mills, Maryland; (17) Prince Frederick, Maryland; (18) Reisterstown, Maryland; (19) Salisbury, Maryland; (20) Sykesville, Maryland; (21) Upper Marlboro, Maryland; (22) Gardner, Massachusetts; (23) Kingston, Massachusetts; (24) Mansfield & South Easton, Massachusetts; (25) Milford, Massachusetts; (26) Norwell, Massachusetts; (27) Norwood & Walpole, Massachusetts; (28) Quincy, Massachusetts; (29) Saugus, Massachusetts; (30) Mahopac &

Puerto Rico enabled consumers to purchase substantially all of their weekly food and grocery requirements in a single shopping visit).

³ For purpose of the Complaint and remedial orders, Richmond, Virginia, is considered one geographic market because of the particular facts in this case, including the extensive overlaps between the Respondents' supermarkets in Richmond and because identifying narrower relevant geographic markets in Richmond would not have changed the analysis.

Analysis to Aid Public Comment

Carmel, New York; (31) New Paltz & Modena, New York; (32) Poughkeepsie & Lagrangeville, New York; (33) Rhinebeck & Red Hook, New York; (34) Wappingers Falls, New York; (35) Chambersburg, Pennsylvania; (36) Waynesboro, Pennsylvania; (37) York, Pennsylvania; (38) Culpeper, Virginia; (39) Fredericksburg, Virginia; (40) Front Royal, Virginia; (41) Purcellville, Virginia; (42) Richmond, Virginia; (43) Stafford, Virginia; (44) Stephens City, Virginia; (45) Winchester, Virginia; and (46) Martinsburg, West Virginia.

Under the 2010 Department of Justice and Federal Trade Commission Horizontal Merger Guidelines, an acquisition that results in an HHI in excess of 2,500 and increases the HHI by more than 200 significantly increases concentration in a highly concentrated market and therefore is presumed anticompetitive. With the exception of one market,⁴ each of the relevant geographic markets identified above meets the Horizontal Merger Guidelines presumption. Based on the market shares of the parties and other market participants, the post-Merger HHI levels in the relevant markets vary from 2,268 to 10,000, and the HHI deltas vary from 243 to 5,000.

The relevant markets are also highly concentrated in terms of the number of remaining market participants post-Merger. Of the 46 geographic markets, the Merger will result in a merger-to-monopoly in three markets and a merger-to-duopoly in 14 markets. In the remaining markets, the Merger will reduce the number of market participants from four to three in 18 markets, from five to four in ten markets, and from seven to six in one market.⁵

⁴ Based on a calculation giving full weight to a third-party supermarket with a large draw area, the Merger results in a post-Merger HHI that does not meet the threshold for a highly concentrated market in the Norwood/Walpole, Massachusetts, market, even though the change in concentration is more than double the level that raises significant competitive concerns. Under calculations giving less than full weight to that supermarket, the Merger results in a highly concentrated market that meets the presumption for enhanced market power. Ultimately, an analysis of all the evidence indicates that the Merger is likely to substantially lessen competition in this market.

⁵ See Exhibit A.

Analysis to Aid Public Comment

The anticompetitive implications of such significant increases in market concentration are reinforced by substantial evidence demonstrating that Ahold and Delhaize are close and vigorous competitors in terms of price, format, service, product offerings, promotional activity, and location in each of the relevant geographic markets. Absent relief, the Merger would eliminate significant head-to-head competition between Ahold and Delhaize and would increase the ability and incentive of Ahold to raise prices unilaterally post-Merger. The Merger would also decrease incentives to compete on non-price factors, such as service levels, convenience, and quality. Lastly, the high levels of concentration also increase the likelihood of competitive harm through coordinated interaction.

New entry or expansion in the relevant markets is unlikely to deter or counteract the anticompetitive effects of the Merger. Even if a prospective entrant existed, the entrant must secure an economically-viable location, obtain the necessary permits and governmental approvals, build its retail establishment or renovate an existing building, and open to customers before it could begin operating and serve as a relevant competitive constraint. As a result, new entry sufficient to achieve a significant market impact and act as a competitive constraint is unlikely to occur in a timely manner.

IV. THE PROPOSED CONSENT ORDER

The proposed remedy, which requires the divestiture of either Ahold or Delhaize supermarkets in each relevant market to seven Commission-approved upfront buyers (the “proposed buyers”) will restore fully the competition that otherwise would be eliminated in these markets as a result of the Merger. Specifically, Respondents have agreed to divest:

- 1 store in Maryland to New Albertson’s Inc. (“Albertsons”);
- 7 stores in Massachusetts to Big Y Foods, Inc. (“Big Y”);
- 10 stores in Virginia to Publix North Carolina, LP (“Publix”);
- 1 store in Pennsylvania to Saubel’s Market, Inc. (“Saubels”);

Analysis to Aid Public Comment

- 18 stores in Maryland, Pennsylvania, Virginia, and West Virginia to Shop ‘N Save East, LLC (“Supervalu”);
- 6 stores in Massachusetts and New York to Tops Markets, LLC (“Tops”); and
- 38 stores in Delaware, Maryland, and Virginia to Weis Markets Inc. (“Weis”).

The proposed buyers appear to be highly suitable purchasers that are well positioned to enter the relevant geographic markets through the divested stores and prevent the increase in market concentration and likely competitive harm that otherwise would have resulted from the Merger. The supermarkets currently owned by the proposed buyers are all located outside the relevant geographic markets in which they are purchasing divested stores.

Albertsons is a large supermarket chain operating over 2,200 stores around the country. Albertsons will purchase the Salisbury, Maryland, store. Big Y is a regional supermarket operator with 61 stores in Connecticut and Massachusetts. Big Y will purchase seven divested stores in Massachusetts. Publix is a large supermarket chain with approximately 1,100 supermarkets in Alabama, Florida, Georgia, North Carolina, South Carolina, and Tennessee. Publix will purchase ten divested stores in Richmond, Virginia. Saubels is a small supermarket chain with three stores in Pennsylvania and Maryland. Saubels will purchase the York, Pennsylvania, store. Tops operates 165 supermarkets in New York, Pennsylvania, and Vermont. Tops will purchase five divested stores in New York and one divested store in Massachusetts. Supervalu is a wholesale food distributor that operates corporate-owned stores. Supervalu will purchase 18 divested stores in Maryland, Pennsylvania, Virginia, and West Virginia. Because Supervalu has in the past sold or assigned its rights in corporate-owned stores to independent operators, the Order requires Supervalu to seek prior approval for any such transfer of the divested stores for a period of three years. Weis is a regional supermarket operating 163 stores in Maryland, New Jersey, New York, Pennsylvania, and West Virginia. Weis will purchase 38 divested stores in Delaware, Maryland, and Virginia.

The proposed Consent Order requires Respondents to divest:
(a) the Salisbury, Maryland, asset to Albertsons within 60 days of

Analysis to Aid Public Comment

the date of Merger; (b) the Massachusetts (except Gardner) assets to Big Y within 90 days from the date of the Merger; (c) the Richmond, Virginia, assets to Publix in three groupings (the first within 180 days of the date of Merger, the second within 240 days, and the third within 360 days); (d) the York, Pennsylvania, asset to Saubels within 60 days of the date of Merger; (e) the Chambersburg and Waynesboro, Pennsylvania, assets, the Hagerstown, Maryland, assets, certain of the Virginia assets, and the West Virginia assets to Supervalu within 105 days of the date of the Merger; (f) the New York and Gardner, Massachusetts, assets to Tops within 60 days of the date of the Merger; and (g) the Delaware, Maryland (except Hagerstown and Salisbury), and certain of the Virginia assets to Weis in two phases (the first within 90 days of the date of the Merger, and the second within 230 days).

The variation in divestiture date deadlines is a function of the number of stores being acquired by each proposed buyer, as those acquiring a larger number of stores have requested and need a longer acquisition and transition period than those acquiring a smaller number of stores. In the case of Publix, the divestiture schedule is extended in order to give Publix sufficient time prior to the divestitures to secure permits and approvals needed for remodeling and construction work for the store locations it is acquiring. Publix is planning to make significant improvements to the acquired stores, including rebuilding several of them, in order to conform them to a typical Publix store. In addition, the extended divestiture schedule will reduce the time periods these stores will need to be closed before being reopened as Publix stores. The proposed Consent Order and the Order to Maintain Assets require Respondents to continue operating and maintaining the divestiture stores in the normal course of business until the date that each store is sold to the proposed buyer. If, at the time before the proposed Consent Order is made final, the Commission determines that any of the proposed buyers are not acceptable buyers, Respondents must rescind the divestiture(s) and divest the assets to a different buyer that receives the Commission's prior approval.⁶

⁶ In the case of the Richmond, Virginia, the Consent Order also provides the Commission the option to add six additional Richmond-area Ahold stores to

Analysis to Aid Public Comment

The proposed Consent Order contains additional provisions designed to ensure the adequacy of the proposed relief. For example, Respondents have agreed to an Order to Maintain Assets that will be issued at the time the proposed Consent Order is accepted for public comment. The Order to Maintain Assets requires Ahold and Delhaize to operate and maintain each divestiture store in the normal course of business through the date the store is ultimately divested to a buyer. Since the divestiture schedule with certain stores runs for an extended period of time (potentially up to 360 days following the Merger date), the proposed Consent Order appoints Brad Wise⁷ as a Monitor to oversee the Respondents' compliance with the requirements of the proposed Consent Order and Order to Maintain Assets. Brad Wise has the experience and skills to be an effective Monitor, no identifiable conflicts, and sufficient time to dedicate to this matter through its conclusion. Lastly, for a period of ten years, Ahold is required to give the Commission prior notice of plans to acquire any interest in a supermarket that has operated or is operating in the counties included in the relevant markets.

The sole purpose of this Analysis is to facilitate public comment on the proposed Consent Order. This Analysis does not constitute an official interpretation of the proposed Consent Order, nor does it modify its terms in any way.

the Richmond divestiture package, as may be needed, to secure an approvable alternative buyer for the Richmond assets.

⁷ Mr. Wise is a retired, long-time industry executive, having most recently served as President of Hannaford until his retirement in 2015. Mr. Wise currently works at pro-voke, a business consulting firm.

Analysis to Aid Public Comment

Exhibit A

Area Number	City	State	Merger Result	HHI (pre)	HHI (post)	Delta	Divested Store(s)
1	Lewes & Rehoboth Beach	DE	4 to 3	2,947	5,369	2,421	D2565 & D488
2	Millsboro	DE	3 to 2	3,794	6,440	2,646	D960
3	Millville	DE	4 to 3	4,065	5,762	1,697	D1321
4	Gardner	MA	4 to 3	2,517	3,723	1,207	A434
5	Kingston	MA	5 to 4	3,140	4,459	1,318	D8008
6	Mansfield & South Easton	MA	4 to 3	2,834	4,307	1,472	D8382
7	Milford	MA	5 to 4	2,298	2,780	482	D8021
8	Norwell	MA	4 to 3	4,052	5,840	1,789	D8020
9	Norwood & Walpole	MA	7 to 6	2,025	2,268	243	D8022
10	Quincy	MA	4 to 3	3,854	5,092	1,239	D8018
11	Saugus	MA	5 to 4	2,140	2,819	679	D8286
12	Accokeek	MD	2 to 1	5,430	10,000	4,570	D1356
13	Bowie	MD	4 to 3	3,288	3,750	462	D1387
14	California	MD	4 to 3	3,043	4,121	1078	D784, D1210 & D2515
15	Columbia	MD	5 to 4	3,093	3,679	586	D2598 & D1529
16	Cumberland & Frostburg	MD	3 to 2	4,032	5,157	1,125	D1549 & D1187
17	Easton	MD	4 to 3	2,803	3,578	775	D1289
18	Edgewater	MD	3 to 2	3,920	5,261	1,341	D1315
19	Gaithersburg	MD	5 to 4	4,203	5,193	989	D1345 & D1477
20	Hagerstown (South)	MD	4 to 3	3,910	4,525	615	D626, D1683 & D1180
21	Hagerstown (North)	MD	4 to 3	4,043	4,323	281	D1147
22	La Plata	MD	3 to 2	3,935	5,007	1,072	D1168
23	Lusby	MD	2 to 1	5,108	10,000	4,892	D1443 & D2606
24	Owings Mills	MD	4 to 3	3,325	4,017	692	D2535
25	Prince Frederick	MD	3 to 2	3,734	5,242	1,508	D1526

Analysis to Aid Public Comment

Area Number	City	State	Merger Result	HHI (pre)	HHI (post)	Delta	Divested Store(s)
26	Reisterstown	MD	4 to 3	3,423	4,169	746	D786
27	Salisbury	MD	3 to 2	3,976	5,029	1,053	A351
28	Sykesville	MD	5 to 4	3,012	3,732	720	D1324
29	Upper Marlboro	MD	3 to 2	3,645	5,328	1,683	D1535
30	Mahopac & Carmel	NY	5 to 4	2,940	4,352	1,412	D8325
31	New Paltz, Modena & Highland	NY	3 to 2	3,690	6,601	2,911	A515
32	Poughkeepsie & Lagrangeville	NY	4 to 3	3,269	5,786	2,517	D8368
33	Rhinebeck & Red Hook	NY	2 to 1	5,023	10,000	4,977	A536
34	Wappingers Falls	NY	3 to 2	2,646	4,256	1,610	A598
35	Chambersburg	PA	5 to 4	3,277	4,232	955	D1527 & D994
36	Waynesboro	PA	3 to 2	5,030	5,537	506	D1663
37	York	PA	4 to 3	3,710	4,135	424	D1241
38	Culpepper	VA	4 to 3	3,329	4,371	1,042	D250 & D1567
39	Fredericksburg	VA	5 to 4	2,696	3,560	864	D358, D419, D450, D1043, D1177, D1235, D1243, D1579 & D2583
40	Front Royal	VA	3 to 2	3,638	5,095	1,456	D1059
41	Purcellville	VA	3 to 2	3,679	5,321	1,642	D745
42	Richmond	VA	5 to 4	2,198	2,857	659	A6421, A6434, A6433, A6498, A6429, A6439, A6435, A6499, A6438 & A6494
43	Stafford	VA	4 to 3	3,333	4,038	705	D578 & D1166
44	Stephens City	VA	3 to 2	4,045	5,018	973	D1489
45	Winchester	VA	3 to 2	3,662	5,094	1,433	D366, D362, D733, D1281, D2668 & D1164
46	Martinsburg	WV	4 to 3	2,759	3,568	809	D1189 & D2568

Complaint

IN THE MATTER OF

**THE PENN STATE HERSHEY MEDICAL
CENTER
AND
PINNACLEHEALTH SYSTEM**COMPLAINT AND FINAL ORDER IN REGARD TO ALLEGED
VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION
ACT AND SECTION 7 OF THE CLAYTON ACT

*Docket No. 9368; File No. 141 0191
Complaint, December 7, 2015 – Order, October 23, 2016*

This case addresses the merger of certain assets of The Penn State Hershey Medical Center and PinnacleHealth System. The complaint alleges that a merger agreement between the Respondents to combine Penn State Hershey Medical Center and Pinnacle Health System violated Section 5 of the Federal Trade Commission Act, and, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by significantly reducing competition in the market for general acute care inpatient services in the Harrisburg, Pennsylvania, area. The order dismisses the Complaint without prejudice on the ground that the Respondents have ended their efforts to pursue the proposed merger and the Hart-Scott-Rodino filing for the proposed merger has expired.

Participants

For the *Commission*: Ryan Harsch, Jared P. Nagley, Jonathan Platt, Gerald Stein, GERALYN J. TRUJILLO, Nancy Turnblacer, and Theodore Zang.

For the *Respondents*: Ken Field and Toby Singer, Jones Day.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (“FTC Act”), and by virtue of the authority vested in it by the Act, the Federal Trade Commission (“Commission”), having reason to believe that the Penn State Hershey Medical Center (“Hershey”) and PinnacleHealth System (“Pinnacle”) (collectively the “Respondents”), having executed a letter of intent to enter into a merger agreement (the “Merger”), in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, which, if

Complaint

consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

I.**NATURE OF THE CASE**

1. Hershey and Pinnacle, the two largest health systems in the greater Harrisburg, Pennsylvania area, intend to merge. If allowed to proceed, the Merger would create a dominant provider of general acute care (“GAC”) inpatient hospital services in the Harrisburg area. The Merger is likely to substantially lessen competition for healthcare services in Harrisburg, Pennsylvania, and its surrounding communities, leading to increased healthcare costs and reduced quality of care for over 500,000 local residents and patients.

2. Today, Hershey owns and operates one GAC hospital in the Harrisburg area, while Pinnacle operates three GAC hospitals. Hershey and Pinnacle operate the only three hospitals located in Dauphin County. Both Hershey and Pinnacle are high-quality health systems that, with limited exceptions, offer an overlapping range of GAC inpatient hospital services (“GAC services”), including primary, secondary, tertiary, and quaternary services.

3. Hershey and Pinnacle are close competitors for GAC services in the Harrisburg area. Hershey and Pinnacle vigorously compete on price, quality of care, and services provided, both for inclusion in commercial health plan networks and to attract patients from one another. The rivalry between Hershey and Pinnacle has benefited local patients with lower healthcare costs and increased quality of care. The Merger would eliminate this significant head-to-head competition between Hershey and Pinnacle and its related benefits.

Complaint

4. The Merger would substantially lessen competition in the market for GAC services sold to commercial health plans in an area roughly equivalent to a four-county region comprised of the Harrisburg Metropolitan Statistical Area (Dauphin, Cumberland, and Perry Counties) plus Lebanon County (the “Harrisburg Area”).

5. The only significant competitor of the Respondents in the Harrisburg Area is Holy Spirit Hospital (“Holy Spirit”), which is a smaller community hospital located in eastern Cumberland County that offers a more limited range of services than Hershey or Pinnacle. There are two other hospitals located on the outskirts of the Harrisburg Area. They are even smaller community hospitals that offer a more limited range of services than Holy Spirit and a much more limited range of services than the Respondents. Neither of these hospitals meaningfully constrains Hershey or Pinnacle.

6. Post-Merger, the combined entity will account for approximately 64% of all GAC services in the Harrisburg Area. Using the Herfindahl-Hirschman Index (“HHI”) to measure market concentration, the post-Merger HHI would be approximately 4,500 with an increase of approximately 2,000 points. This high market share and corresponding high concentration level render the Merger presumptively unlawful under the relevant case law and likely to increase market power—by a wide margin—under the 2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (“Merger Guidelines”).

7. The Merger would substantially increase the combined entity’s bargaining leverage in negotiations with commercial health plans. The combined entity would be able to exercise market power by raising prices and reducing quality and services, ultimately harming Harrisburg Area residents and patients.

8. Entry or expansion by other providers of the relevant services is unlikely to occur, much less in a manner that is timely, likely or sufficient to deter or mitigate the loss of price and non-price competition in the near future.

Complaint

9. Finally, the Respondents' efficiency claims are overstated, speculative, unverifiable, not merger-specific, or result from an anticompetitive reduction in output, quality, or services, and are largely non-cognizable. Any cognizable efficiency claims are insufficient to offset the substantial competitive harm the Merger is likely to cause.

II.**BACKGROUND****A.****Jurisdiction**

10. The Respondents, and each of their relevant operating entities and parent entities are, and at all relevant times have been, engaged in commerce or in activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

11. The Merger constitutes a transaction subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

B.**The Respondents**

12. Respondent Hershey is a not-for-profit healthcare system headquartered in Hershey, Pennsylvania in Dauphin County. The system includes the Milton S. Hershey Medical Center ("Hershey Medical Center"), a GAC academic medical center affiliated with the Penn State College of Medicine, and the Penn State Hershey Children's Hospital (located on the Hershey Medical Center campus and the only children's hospital in the Harrisburg Area).

13. The Hershey Medical Center has 551 licensed beds (125 of which are located at the Children's Hospital). It employs approximately 804 physicians. Hershey offers a full range of GAC services, from primary care to quaternary services. It offers quaternary services such as heart transplants and operates a state-

Complaint

designated Level I Trauma Center for pediatrics and adults. In fiscal year 2014, on a system-wide basis, Hershey generated approximately \$1.4 billion in revenue and had approximately 29,000 inpatient discharges.

14. Respondent Pinnacle is a not-for-profit healthcare system headquartered in Harrisburg, Pennsylvania. Pinnacle operates three GAC hospitals in the Harrisburg Area. Pinnacle's Harrisburg Hospital and Community General Osteopathic Hospital are located in Dauphin County and Pinnacle's West Shore Hospital, which opened in May 2014, is located in eastern Cumberland County.

15. Pinnacle's combined system has 662 licensed beds, which are divided among its three GAC hospitals. Pinnacle offers a full range of GAC services, from primary care to quaternary services, excluding only a limited number of quaternary services. Harrisburg Hospital, which is Pinnacle's flagship teaching hospital, has a Level III neonatal intensive care unit and performs high-level services such as kidney transplants. Pinnacle's CardioVascular Institute is considered one of the leading cardiology programs in Pennsylvania. In 2014, Pinnacle generated approximately \$850 million in revenue and had more than 35,000 inpatient discharges.

C.

The Proposed Merger

16. In June 2014, Hershey and Pinnacle signed a letter of intent pursuant to which they agreed to explore the possibility of combining their assets. In March 2015, the Respondents' boards approved moving forward with the transaction. Although the final merger documents have not yet been signed, pursuant to the letter of intent, the transaction would be structured as a membership substitution by which the new entity would become the sole member of both Hershey and Pinnacle, and Hershey and Pinnacle will have equal representation on the new entity's board of directors.

Complaint

III.**THE RELEVANT SERVICE MARKET**

17. The relevant service market in which to analyze the effects of the Merger is GAC inpatient hospital services sold to commercial health plans and their members. This service market encompasses a broad cluster of medical and surgical diagnostic and treatment services offered by both Hershey and Pinnacle that require an overnight hospital stay.

18. Although the Merger's likely effect on competition could be analyzed separately for each of the hundreds of affected medical procedures and treatments, it is appropriate to evaluate the Merger's likely effects across this cluster of services because the services are offered to Harrisburg Area patients under similar competitive conditions, by similar market participants. There are no practical substitutes for this cluster of GAC services.

IV.**THE RELEVANT GEOGRAPHIC MARKET**

19. The relevant geographic market in which to analyze the effects of the Merger is the Harrisburg Area, which is an area roughly equivalent to the Harrisburg Metropolitan Statistical Area (Dauphin, Cumberland, and Perry Counties) and Lebanon County.

20. The appropriate geographic market in which to analyze the Merger is the area in which consumers can practicably find alternative providers of the service. The test from the Merger Guidelines used to determine the boundaries of the geographic market is whether a hypothetical monopolist of the relevant services within that geographic area could profitably negotiate a small but significant and non-transitory increase in price (here, reimbursement rates for GAC services). If so, the boundaries of that geographic area are an appropriate geographic market.

21. In general, patients choose to seek care close to their homes or workplaces for their own convenience and that of their families because it takes less time to travel to a hospital that is

Complaint

nearby and it is easier to arrange for transportation and visitation. Residents of the Harrisburg Area strongly prefer to, and do, obtain GAC services locally. Moreover, residents of the Harrisburg Area who require emergency hospital services seek such services within the Harrisburg Area. They would not travel outside of the Harrisburg Area for such emergency services without jeopardizing their health and well-being.

22. Evidence from multiple sources shows that an overwhelming percentage of commercially insured residents of the Harrisburg Area seek GAC services within the Harrisburg Area.

23. Hospitals outside the Harrisburg Area, such as those in York and Lancaster Counties, [REDACTED] are not, meaningful competitors of Hershey, Pinnacle, or other hospitals in the Harrisburg Area for the provision of GAC services to residents of the Harrisburg Area because they draw very few patients from the Harrisburg Area.

24. Health plans that offer health care networks in the Harrisburg Area do not consider hospitals outside of the Harrisburg Area to be viable substitutes for Harrisburg Area hospitals. Very few of their members leave the Harrisburg Area to obtain GAC services, even for tertiary and quaternary care.

25. Because residents of the Harrisburg Area strongly prefer to obtain GAC services in the Harrisburg Area, a health plan that did not have Harrisburg Area hospitals in its network would be very difficult to successfully market a network to employers and consumers in the area. Accordingly, a health plan would not exclude from its network a hypothetical monopolist of hospital services in the Harrisburg Area in response to a small but significant price increase.

Complaint

V.

**MARKET STRUCTURE AND THE MERGER'S
PRESUMPTIVE ILLEGALITY**

26. Hershey currently accounts for approximately 26% of the relevant market. Pinnacle currently accounts for approximately 38% of the market. A combined Hershey/Pinnacle would own by far the largest GAC hospital system within the Harrisburg Area. Defendants' post-Merger market share would be overwhelming at approximately 64% of the relevant market.

27. Of the three other hospitals that provide GAC services to residents in the Harrisburg Area, only one – Holy Spirit Hospital – is of any competitive significance. Holy Spirit currently accounts for approximately 15% of the relevant market. The remaining two hospitals are Carlisle Regional Medical Center (in central Cumberland County), which accounts for approximately 5% of the market, and WellSpan Good Samaritan Hospital (in central Lebanon County), which accounts for approximately 6% of the market. These two hospitals are small community hospitals with limited service offerings and little appeal to residents of the Harrisburg Area. They do not compete to any significant degree with the Respondents. No other hospital accounts for more than 3% of the relevant market. Accordingly, the proposed Merger would reduce the number of meaningful competitors in the Harrisburg Area from three to two.

28. Under the relevant case law, including U.S. Supreme Court precedent and recent litigated hospital merger cases, the Merger is presumptively unlawful by a wide margin, as it would significantly increase concentration in an already highly concentrated market.

29. The Herfindahl-Hirschman Index (“HHI”) is used to measure market concentration under the Merger Guidelines. A merger or acquisition is presumed likely to create or enhance market power under the Merger Guidelines, and thus, is presumed illegal under relevant case law, when the post-merger HHI exceeds 2,500 points and the merger or acquisition increases the HHI by more than 200 points.

Complaint

30. Here, the market concentration levels far exceed those HHI thresholds. The post-Merger HHI in the GAC services market will be over 4,400, an increase of approximately 2,000 points. The approximate HHI figures and market shares for the GAC services market in the Harrisburg Area are summarized in the table below.

GENERAL ACUTE CARE INPATIENT HOSPITAL SERVICES		
Hospital System	Pre-Merger Market Share	Post-Merger Market Share
Penn State Hershey Medical Center	26%	64%
PinnacleHealth System	38%	
Holy Spirit Health System – A Geisinger Affiliate (Cumberland County)	15%	15%
WellSpan Good Samaritan Hospital (Lebanon County)	6%	6%
Carlisle Regional Medical Center (Cumberland County)	5%	5%
Other (<3% share each)	10%	10%
HHI	2,500	4,500
Change in HHI	+2,000	

Complaint

VI.**ANTICOMPETITIVE EFFECTS****A.****Hospital Competition Yields Lower Prices and Higher Quality**

31. Competition between hospitals occurs in two distinct but related dimensions. First, hospitals compete to be selected as in-network providers for commercial health plans' members. Second, hospitals compete with each other on the basis of non-price features (*e.g.*, quality, amenities, etc.) to attract patients, including health plan members, to their facilities.

32. In the first dimension of hospital competition, hospitals compete to be included in health plan networks. To become an in-network provider, a hospital negotiates with a health plan and, if mutually agreeable terms can be reached, enters into a contract. Reimbursement rates (*i.e.*, prices), which the hospital charges to a health plan for services rendered to a health plan's members, are the primary contractual terms negotiated.

33. In-network status benefits the hospital by giving it preferential access to the health plan's members. Health plan members typically pay far less to access in-network hospitals than out-of-network hospitals. Thus, all else being equal, an in-network hospital will attract more patients from a particular health plan than an out-of-network hospital. This dynamic motivates hospitals to offer lower rates to health plans to win inclusion in their networks.

34. From the health plan's perspective, having hospitals in-network is beneficial because it enables the health plan to create a healthcare provider network in a particular geographic area that is attractive to current and prospective members, typically local employers and their employees.

35. A critical determinant of the relative bargaining positions of a hospital and a health plan during negotiations is whether other, nearby comparable hospitals are available to the health plan

Complaint

and its members as alternatives in the event of a negotiating impasse. The presence of alternative hospitals limits a hospital's bargaining leverage and thus constrains its ability to obtain higher reimbursement rates from health plans. The more attractive these alternative hospitals are to a health plan's members in a local area, the greater the constraint on that hospital's bargaining leverage. Where there are few or no meaningful alternatives, a hospital will have greater bargaining leverage to demand and obtain higher reimbursement rates.

36. A merger between hospitals that are close substitutes from the perspective of health plans and their members therefore tends to produce increased bargaining leverage for the merged entity and, as a result, higher negotiated rates, because it eliminates a competitive alternative for health plans.

37. Increases in the reimbursement rates negotiated between a hospital and a health plan significantly impact the health plan's members. "Self-insured" employers rely on a health plan for access to its provider network and negotiated rates. These employers pay the cost of their employees' health care claims directly and thus bear the full and immediate burden of any rate increases in the healthcare services used by their employees. "Fully-insured" employers pay premiums to health plans—and employees pay premiums, co-pays, co-insurance and/or deductibles—in exchange for the health plan assuming financial responsibility for paying hospital costs generated by the employees' use of hospital services. When hospital rates increase, health plans pass on these increases to their fully-insured customers in the form of higher premiums, co-pays, co-insurance and/or deductibles.

38. In the second dimension of hospital competition, hospitals compete to attract patients to their facilities by offering higher quality care, amenities, convenience, and patient satisfaction than their competitors. This competition can be significant because health plan members often have a choice of in-network hospitals where they face similar out-of-pocket costs. Hospitals also compete on these non-price dimensions to attract patients covered by Medicare and Medicaid, as well as other patients without commercial insurance. A merger of competing hospitals

Complaint

eliminates that non-price competition and reduces their incentive to improve and maintain quality.

B.**The Merger Would Eliminate Close Competition between Hershey and Pinnacle**

39. Hershey and Pinnacle are vigorous competitors in the relevant market due to the similarity in services that they both offer and their geographic proximity. The Merger would eliminate direct and substantial competition between the Respondents and create a dominant health system that could increase reimbursement rates and/or reduce service levels for GAC inpatient services. Close competition in the relevant market is evident from a wide variety of evidence, including econometric analysis of the Respondents' patient draw data, ordinary-course documents, testimony, and information from health plans.

40. A standard economic analysis of the closeness of competition known as diversion analysis, which is based on data about where patients receive hospital services, confirms that Hershey and Pinnacle are very close competitors. More specifically, Pinnacle is the only significant competitor of Hershey and Hershey is the only significant competitor of Pinnacle other than Holy Spirit Hospital. Diversion analyses show that if Hershey were no longer available, over 40% of its patients would seek GAC services at Pinnacle. Similarly, if Pinnacle were no longer available to patients, over 30% of its patients would seek GAC services at Hershey. The diversions between the Respondents are higher than those present in recent hospital merger cases where courts have found that the transaction at issue would substantially lessen competition and, therefore, violated the Clayton Act.

41. Hershey and Pinnacle offer a wide range of overlapping GAC inpatient service lines, from primary to higher-end tertiary and quaternary care, with the limited exceptions of major organ transplants and high-end trauma care, which are provided by Hershey but not by Pinnacle. Data show that the services offered by each of the Respondents substantially overlap with one

Complaint

another. Diagnosis-related groups (“DRGs”) are categories of diagnoses used by Medicare and health plans to set reimbursement rates. 98% of Hershey’s patients are in DRGs that are offered by Pinnacle. Similarly, 97% of Pinnacle’s patients are in DRGs offered by Hershey.

42. According to the Respondents’ documents, Pinnacle and Hershey “aggressively compete with one another in many areas” and view each other as close competitors. For example, in 2011, Hershey hired a consulting firm to conduct a detailed service line analysis, which concluded that Pinnacle was Hershey’s most significant, and often the “dominant,” local competitor in numerous key services lines, including neurosciences, heart and vascular, orthopaedics, obstetrics and gynecology (“OB/GYN”), spine, and pediatrics. The analysis also states that within the local market, Hershey had increased its market share in orthopedic services by “taking away market share from Pinnacle.” The same analysis also notes that Hershey is the “dominant player” in pediatrics while Pinnacle is the “second dominant player.”

[REDACTED]

43. In addition, Pinnacle has been expanding its service offerings and [REDACTED] that would further enhance its competition with Hershey.

44. Pinnacle’s ordinary course documents and business plans

[REDACTED]

While Holy Spirit competes in the Harrisburg Area, Pinnacle’s documents reveal that [REDACTED]

[REDACTED]

Complaint

[REDACTED]

45. Similarly, Hershey's internal documents reveal that Hershey identifies Pinnacle as being one of its principal competitors. Hershey focuses significant attention on Pinnacle's strategy, while focusing its own competitive strategies on capturing market share from Pinnacle.

46. The Respondents are also close competitors because of their geographic proximity. Competition between Hershey and Pinnacle is particularly intense in Dauphin County, where Hershey and Pinnacle operate the only GAC hospitals and the only emergency departments (where the Respondents draw approximately half of their inpatient admissions), and both draw more patients from Dauphin County than any other county. Post-Merger, the Respondents will operate the only two emergency rooms in Dauphin County and two of only three emergency rooms within 25 miles of downtown Harrisburg.

47. Competition between Hershey and Pinnacle also extends into Cumberland and Lebanon Counties. Hershey has expanded its primary care services in Cumberland County to drive referrals to Hershey Medical Center following Pinnacle's opening of West Shore Hospital in Cumberland County in 2014. Pinnacle has expanded its primary care services in Lebanon County, near Hershey Medical Center, in order to compete with Hershey and drive referrals to Pinnacle hospitals. Both Pinnacle and Hershey have both expanded their oncology services in Cumberland County.

[REDACTED]

Hershey and Pinnacle are large health systems that compete closely against one another by offering very similar services and high levels of quality. [REDACTED]

[REDACTED]

Complaint

C.

The Merger Would Eliminate Price Competition and Increase the Merged Entity's Bargaining Leverage

49. Because the Merger would eliminate direct competition between Pinnacle and Hershey, a combined Hershey/Pinnacle would have increased bargaining leverage, allowing it to raise rates for GAC inpatient services in the Harrisburg Area. This increased leverage could manifest itself in multiple ways including through an increase in rates across the entire combined hospital system or by raising Pinnacle's rates [REDACTED]. Such leverage could negatively affect agreements with traditional fee-for-service arrangements and/or new reimbursement models such as risk sharing, by, for example, allocating more risk to the health plan and less risk to a combined Hershey/Pinnacle.

50. Currently, health plans in the Harrisburg Area can negotiate lower rates by threatening to exclude Hershey or Pinnacle from their networks because the other hospital serves as a close alternative for patients living in the Harrisburg Area. [REDACTED]

51. If Hershey and Pinnacle were to merge, health plans could no longer threaten to exclude the combined Hershey/Pinnacle from their networks or otherwise use competition between Hershey and Pinnacle to negotiate better reimbursement rates. In fact, one of Pinnacle's [REDACTED]

52. Moreover, [REDACTED] a provider network that lacked the combined Hershey/Pinnacle would be very difficult, if not impossible, to market to Harrisburg Area residents. [REDACTED]

Complaint

[REDACTED]

53. Numerous health plans have expressed concern that the proposed Merger will eliminate competition and result in price increases. For example, a representative of [REDACTED] health plan in the Harrisburg Area, sent an email to the Respondents which stated that [REDACTED]

[REDACTED]

54. [REDACTED], the Harrisburg Area currently benefits from competition between Hershey and Pinnacle and [REDACTED]

[REDACTED]

55. Post-Merger, the transaction would eliminate this beneficial competition and create a dominant health system in the Harrisburg Area. Accordingly, if allowed to proceed, the Merger would substantially increase the combined entity's bargaining leverage in negotiations and result in higher rates.

D.**The Merger Eliminates Vital Quality Competition**

56. In addition to price competition, Hershey and Pinnacle compete extensively on non-price dimensions, including expansion of services, quality of care, and the use of state-of-the-

Complaint

art facilities and technology. Patients in the Harrisburg Area have benefitted from this competition.

57. In order to further compete with Hershey, Pinnacle has expanded its tertiary services in recent years. For example, Pinnacle has expanded and modernized its facilities, and introduced new advanced service lines [REDACTED], all to the benefit of Harrisburg Area residents. Pinnacle recently renovated Harrisburg Hospital and its other hospitals to modernize, increase the number of private rooms, and add clinical space. Pinnacle has also expanded its service line offerings and implemented numerous operational improvements and best practices to improve its quality metrics and patient satisfaction. These improvements were driven by Pinnacle's desire to improve the patient experience and attract additional patients to Pinnacle and away from Hershey.

58. Competition between Pinnacle and Hershey is particularly evident in their efforts to improve and expand their respective oncology services. Pinnacle's strategic plan for its new state-of-the-art Ortenzio Cancer Center in Cumberland County states that

[REDACTED]

An internal Hershey document about Pinnacle's Cancer Center notes [REDACTED]

[REDACTED]

59. Pinnacle also has improved the quality of care at its hospitals to attract more patients from the Harrisburg Area. Pinnacle's internal documents show that it implemented operational improvements and best practices in order to improve its quality metrics and patient satisfaction.

60. Hershey has begun to [REDACTED] expand its network of primary care practices and to construct a new outpatient ambulatory facility to increase access for patients in the Harrisburg Area and to compete with Pinnacle. It expanded

Complaint

outpatient services in Cumberland County to drive referrals to Hershey Medical Center and [REDACTED]

61. Hershey's documents also show its recognition that it needs to reduce costs and improve its quality and efficiency to remain competitive with Pinnacle and other competitors. It is "working to improve operational and cost performance" with specific initiatives on "quality & safety" and "cost efficiency."

62. The Merger would eliminate this beneficial competition between Hershey and Pinnacle on these vital non-price factors, thereby reducing incentives to improve quality, implement new medical technologies, and expand services in the Harrisburg Area. In addition, the Respondents intend, post-Merger, to move low acuity cases from Hershey to Pinnacle and high acuity cases from Pinnacle to Hershey. Such plans will further reduce the combined Hershey/Pinnacle's incentive to continue to invest in tertiary services at Pinnacle, and reduce costs and improve efficiency at Hershey. Losing these important benefits would affect all patients in the Harrisburg Area.

E.**Respondents' Recent [REDACTED] Agreements With [REDACTED]
[REDACTED] Would Not Prevent Competitive Harm**

63. The Respondents have [REDACTED]

[REDACTED] The [REDACTED] agreements were designed to forestall opposition to the Merger.

[REDACTED] Accordingly, these [REDACTED] agreements are strong evidence that the payors believe that the Merger would result in anticompetitive increases in reimbursement rates to health plans imposed by the combined Hershey/Pinnacle. However, these [REDACTED]

Complaint

agreements do not alleviate the anticompetitive effects of the Merger.

64. First, the [REDACTED] agreements are limited to only [REDACTED]. The Respondents have not entered into similar agreements with other [REDACTED] in the Harrisburg Area. Accordingly, the combined Hershey/Pinnacle would be able to use its enhanced bargaining leverage to demand higher prices or better terms, without any constraints, when negotiating with these other health plans.

65. Second, the [REDACTED] agreements foreclose the possibility that, absent the Merger, competition could lead to rates that increase less quickly or even decrease. Similarly, they do not address that the change in bargaining dynamics due to the merged entity's increased leverage would also apply to different types of agreements, such as risk-sharing arrangements, [REDACTED]

Under such newer reimbursement arrangements, the health plan and the provider must negotiate over the level of risk that each party bears. Here, the combined entity could use its increased bargaining leverage post-Merger to the detriment of health plans (and ultimately their members) when negotiating risk-sharing or value-based agreements.

66. Third, the [REDACTED] agreements do nothing to preserve the service and quality competition between Pinnacle and Hershey that has benefitted Harrisburg Area residents and patients and that the Merger would eliminate.

67. Finally [REDACTED] When they terminate, the Respondents will no longer be subject to any purported commitment to maintain the [REDACTED]. Accordingly, the combined Hershey/Pinnacle would be able to use its enhanced bargaining leverage to demand higher prices or better terms from the [REDACTED] without any constraints, when negotiating both traditional fee-for-service contracts as well as contracts with newer reimbursement models.

Complaint

VII.**ENTRY BARRIERS**

68. Neither entry by new healthcare providers into the relevant service market nor expansion by existing market participants will deter or counteract the Merger's likely serious competitive harm in the relevant service market.

69. New hospital entry in the Harrisburg Area would not be likely, timely, or sufficient to offset the Merger's harmful effects. Construction and operation of a new GAC inpatient hospital involves high costs and serious financial risk. The construction of a new hospital also would take much more than two years from the initial planning stage to opening, as evidenced by the significant time and expense involved in the building of Pinnacle's West Shore Hospital and Hershey's Children's Hospital.

70. Even if new hospital entry did occur, it likely would not be sufficient to offset the Merger's harm because a new hospital could not achieve the scale required to offer the broad cluster of GAC services comparable to those offered by the Respondents. Hershey and Pinnacle are both large, high-quality health systems, which offer a full range of GAC services and employ a significant number of physicians. Their service capabilities, strong reputations, and significant share of the relevant market present significant barriers to entry and would be extremely challenging for a new entrant to replicate in a manner sufficient to counteract the likely anticompetitive effects of the Merger.

71. [REDACTED]

[REDACTED] In fact, the Respondents are the only healthcare providers that have constructed new hospitals in the relevant area (one each) in over a decade.

Complaint

VIII.**EFFICIENCIES**

72. No court ever has found, without being reversed, that efficiencies rescue an otherwise illegal transaction. Here, in order to rebut the presumption that the Merger is unlawful, Respondents would need to present evidence that extraordinary merger-specific efficiencies, which will be passed on to consumers, outweigh the Merger's likely significant harm to competition in the Harrisburg Area. However, Respondents' efficiency claims are overstated, speculative, unverifiable, not merger-specific, or result from an anticompetitive reduction in output, quality, or services, and are largely non-cognizable. Overall, Respondents' efficiency claims, to the extent they are cognizable, are insufficient to offset the substantial competitive harm the Merger is likely to cause.

73. Respondents have claimed that Hershey is at capacity and the Merger will allow the Respondents to transfer patients suffering from less severe illnesses from Hershey to Pinnacle, which has the capacity to treat them. Respondents further claim that this will allow Hershey to avoid constructing a new inpatient bed tower to alleviate its capacity issues.

74. However, Hershey could alleviate its capacity constraints in a timely manner without the Merger. Moreover, the Respondents' alleged efficiency plans would result in competitive harm. Respondents' plans would force patients to go to a different hospital than the one they originally chose. Respondents' plans would also reduce output, capacity, and service compared to the but-for world without the Merger, thereby denying patients the benefits of new inpatient rooms at Hershey. Accordingly, these claims are not cognizable under the law.

75. The Respondents have also claimed that the Merger may achieve other operational efficiencies. However, these efficiency claims are speculative, overstated, and have not been substantiated by the Respondents.

Complaint

IX.**VIOLATION****COUNT I – ILLEGAL AGREEMENT**

76. The allegations of Paragraphs 1 through 75 above are incorporated by reference as though fully set forth.

77. The merger agreement constitutes an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

COUNT II – ILLEGAL MERGER

78. The allegations of Paragraphs 1 through 75 above are incorporated by reference as though fully set forth.

79. The Merger, if consummated, may substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the seventeenth day of May, 2016, at 10 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in

Complaint

which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the Respondents' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each Respondent, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

Complaint

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Merger challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and Section 7 of the Clayton Act, as amended, the Commission may order such relief against the Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. A prohibition against any transaction between Hershey and Pinnacle that combines their businesses in the relevant markets, except as may be approved by the Commission.
2. If the Merger is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant markets, with the ability to offer such products and services as Hershey and Pinnacle were offering and planning to offer prior to the Merger.
3. A requirement that, for a period of time, Hershey and Pinnacle provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other company operating in the relevant markets.
4. A requirement to file periodic compliance reports with the Commission.
5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to restore Pinnacle and Hershey as viable, independent competitors in the relevant markets.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this seventh day of December, 2015.

Final Order

By the Commission.

ORDER DISMISSING COMPLAINT

On December 7, 2015, the Commission issued an administrative complaint alleging that a merger agreement between the Respondents to combine Penn State Hershey Medical Center and Pinnacle Health System violated Section 5 of the Federal Trade Commission Act, and, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act. Complaint Counsel and Respondents now jointly seek dismissal of the Complaint, on the ground that the Respondents have ended their efforts to pursue the proposed merger and the Hart-Scott-Rodino filing for the proposed merger has expired.

The Commission has determined to dismiss the Complaint without prejudice in light of the foregoing. Respondents would not be able to effectuate the proposed merger without a new HSR filing. Dismissal of the Complaint would therefore be in accordance with the public interest.¹ Accordingly,

IT IS ORDERED THAT the Complaint in this matter be, and it hereby is, dismissed without prejudice.

By the Commission.

¹ See, e.g., *Superior Plus Corp.*, Docket No. 9371, Order Dismissing Complaint (August 2, 2016), available at <https://www.ftc.gov/system/files/documents/cases/160803superiorcanexuscmpt.pdf>; *Staples Inc.*, Docket No. 9367, Order Dismissing Complaint (May 18, 2016), available at <https://www.ftc.gov/system/files/documents/cases/160519staplesrorder.pdf>.

Complaint

IN THE MATTER OF

WARNER BROS. HOME ENTERTAINMENT INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4595; File No. 152 3034**Complaint, November 17, 2016 – Decision, November 17, 2016*

This consent order addresses Warner Bros. Home Entertainment Inc.'s use of social media influencers to advertise the video game, *Middle Earth: Shadow of Mordor*. The complaint alleges that Warner Bros., through its ad agency, Plaid Social Labs, LLC, hired individuals who had earned reputations as video game enthusiasts on YouTube ("YouTube influencers") for hundreds of dollars to tens of thousands of dollars to post positive videos promoting *Shadow of Mordor* on YouTube, which did not necessarily reflect the independent experiences of the individual YouTube influencers. The complaint further alleges that, in numerous instances, YouTube influencers did not disclose or adequately disclose that Warner Bros., through Plaid Social, offered compensation to the influencers in exchange for creating and uploading gameplay videos as part of a *Shadow of Mordor* advertising campaign. The consent order prohibits Warner Bros., in connection with the advertising of any home entertainment product or service, from misrepresenting in any influencer campaign that an influencer or endorser of such product or service is an independent user or ordinary consumer of the product or service.

Participants

For the *Commission*: Linda K. Badger, Matthew D. Gold, and Evan Rose.

For the *Respondents*: Kelly DeMarchis, Leonard Gordon, and Stuart Ingis, Venable LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that Warner Bros. Home Entertainment Inc., a corporation ("respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Warner Bros. Home Entertainment Inc. ("WBHE") is a Delaware corporation with its principal office or

Complaint

place of business at 4000 Warner Blvd., Burbank, California 91522. Warner Bros. Interactive Entertainment (“WBIE”) is a division of WBHE.

2. The acts and practices of respondent, as alleged herein, have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

3. Respondent produces and distributes home entertainment content to consumers. Respondent, through its division, WBIE, has manufactured, advertised, labeled, offered for sale, sold, and distributed interactive entertainment for consumers, including but not limited to the video game title, *Middle Earth: Shadow of Mordor* (“*Shadow of Mordor*”). WBIE is a major worldwide publisher and distributor of video game titles.

4. In 2014, respondent hired an advertising agency, Plaid Social Labs, LLC (“Plaid Social”), to coordinate a “YouTube Influencer Campaign” for its soon-to-be-released video game, *Shadow of Mordor*. Through the YouTube Influencer Campaign, respondent intended to maximize consumer awareness of the game when it became available for sale and to persuade consumers to purchase it.

5. Respondent, through Plaid Social, hired individuals who had earned reputations as video game enthusiasts on YouTube (“YouTube influencers”) to post positive videos promoting *Shadow of Mordor* on YouTube. These YouTube influencers were given free access to a pre-release version of *Shadow of Mordor* and cash payments often ranging from hundreds of dollars to tens of thousands of dollars, provided that the videos they created about *Shadow of Mordor* met certain requirements defined by respondent. These requirements were communicated to the YouTube influencers through Plaid Social.

6. In respondent’s contract with Plaid Social, any work performed on behalf of respondent is respondent’s property, or “work made for hire,” and respondent is the “the sole owner of all rights in and to the [w]ork of every kind and character whatsoever in perpetuity and throughout the universe.” Similarly, the influencers agreed that respondent “will be deemed the author and

Complaint

exclusive owner” of any work arranged for by Plaid Social on behalf of the respondent.

7. Respondent, through Plaid Social, required that each influencer’s video meet the following requirements:

- Video will feature gameplay of the [*Shadow of Mordor* video game]
- Video will have a strong verbal call-to-action to click the link in the description box for the viewer to go to the [game’s] website to learn more about the [game], to learn how they can register, and to learn how to play the game.
-
- Video will promote positive sentiment about the [game].
- Video will not show bugs or glitches that may exist.
-
- Video will not communicate negative sentiment about WBIE, its affiliates or the [game].
- One Facebook post or one Tweet by Influencer in support of Video.

Consequently, these videos are sponsored advertisements, and do not necessarily reflect the independent experiences of the individual YouTube Influencers.

8. Respondent also required that the YouTube influencers be instructed to place specified information in the written text or “description box” that typically appears underneath the portion of the web page where a consumer can view a YouTube video. For example:

- Description box will contain information about the [game] above the fold.
-
- Description box will include FTC disclaimer disclosing that the post is sponsored.

Complaint

9. As described in Paragraph 8, respondent, through Plaid Social, instructed the YouTube influencers to provide a written disclosure that their videos had been sponsored (“FTC disclaimer”), and to place this disclosure in the description box appearing below the YouTube videos. Respondent did not require that the YouTube influencers be instructed to place a sponsorship disclosure clearly and conspicuously in the video itself. Nor did respondent require that the YouTube influencers be instructed to place the sponsorship disclosure “above the fold” in the description box, or visible without consumers having to scroll down or click on a link, as it had for other information about *Shadow of Mordor*. (See, e.g., Exhibit A-1) Accordingly, the vast majority of YouTube influencers did not include any sponsorship disclosure in their videos and only placed their sponsorship disclosures “below the fold” in the description box below the video. Therefore, consumers have to click on a “Show More” button in the description box and potentially scroll down before they can see the sponsorship disclosure. (See, e.g., Exhibits A-1, A-2; Exhibits B-1, B-2) As a result, consumers who watched these YouTube videos were unlikely to learn that the videos were paid promotions.

10. Respondent, through Plaid Social, required the YouTube influencers to promote their videos on Twitter or Facebook. When the influencers posted these videos for consumers to view on Twitter or Facebook, however, consumers were even less likely to see the required sponsorship disclosures because such posts did not include the Show More button. (See, e.g., Exhibit C).

11. On at least two occasions, the YouTube influencers disclosed only that they had been given early access to the game, and did not adequately disclose that they had also been paid to post the video. (See, e.g., Exhibit D-1, D-2) For example, one influencer’s disclosure states: “This has been one of my favorite sponsored games, so thanks that I could play it for free!!” (See Exhibit D-1) This statement implies that the only compensation this YouTube influencer received was free access to the *Shadow of Mordor* video game. In fact, this YouTube influencer also received monetary compensation of thousands of dollars in return

Complaint

for his positive gameplay video and social media postings about *Shadow of Mordor*.

12. By contract, influencers' videos were subject to pre-approval by respondent and/or Plaid Social to ensure that they conformed with respondent's requirements. On at least one occasion, respondent reviewed and approved an influencer video with an inadequate sponsorship disclosure before it was made public. On this occasion, respondent did not require the influencer or Plaid Social to move the sponsorship disclosure.

13. Prior to and immediately after the public release of *Shadow of Mordor* on September 30, 2014, the YouTube influencers commissioned for the *Shadow of Mordor* YouTube Influencer Campaign posted approximately thirty gameplay videos on YouTube. These videos were viewed over 5.5 million times by consumers, and were publicly available for over a year.

Count I
False Claim of Independent Reviews

14. Through the means described in Paragraphs 4 through 13, respondent has represented, directly or indirectly, expressly or by implication, that gameplay videos of *Shadow of Mordor* produced and disseminated in connection with the YouTube Influencer Campaign reflect the independent opinions or experiences of impartial video game enthusiasts.

15. In truth and in fact, these gameplay videos of *Shadow of Mordor* do not reflect the independent opinions or experiences of impartial video game enthusiasts. The YouTube influencers were paid by respondent to create the videos as part of respondent's advertising campaign to promote sales of the game. Therefore, the representation set forth in Paragraph 14 was, and is, false and misleading.

Complaint

Count II**Deceptive Failure to Disclose Material Connection Between Endorsers and Seller**

16. Through the means described in Paragraphs 4 through 13, respondent has represented, directly or indirectly, expressly or by implication, that favorable gameplay videos for *Shadow of Mordor* reflect the opinions or experiences of individuals who had played *Shadow of Mordor*. In numerous instances, respondent has failed to disclose or disclose adequately that these individuals received compensation, including both a free game and monetary payment, to produce and disseminate the videos. This fact would be material to consumers in their decision to purchase *Shadow of Mordor*. The failure to disclose or disclose adequately this fact, in light of the representations made, was, and is, a deceptive practice.

Violations of Section 5

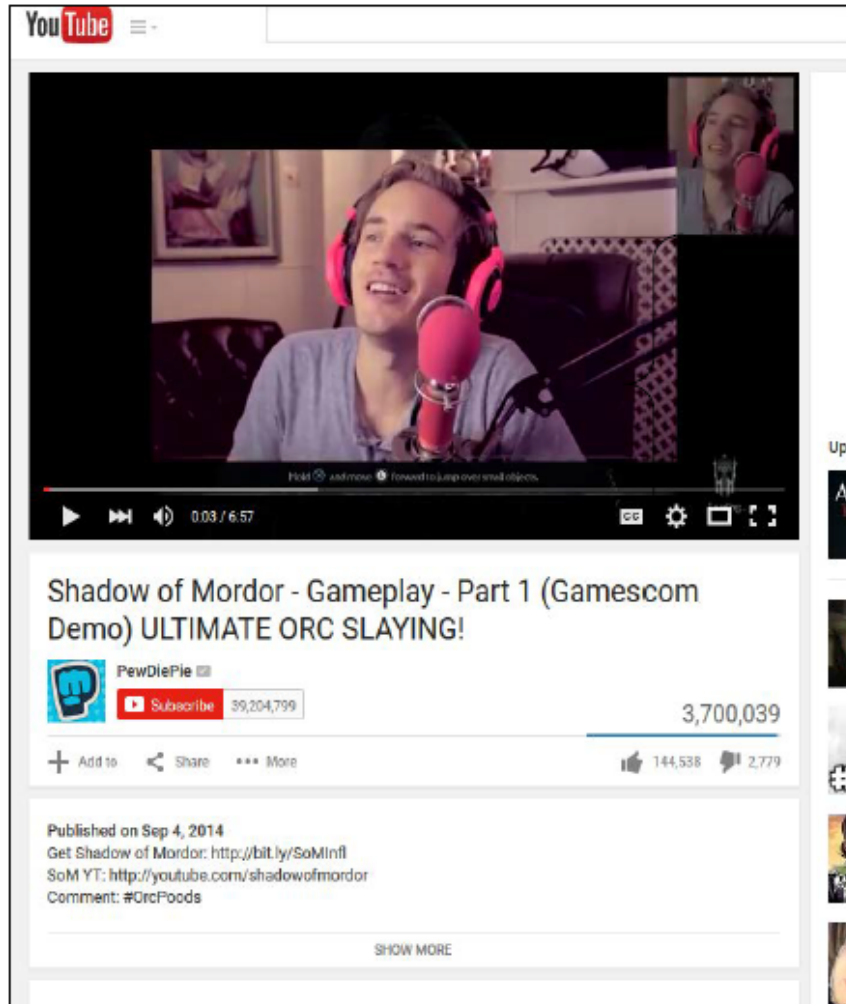
17. The acts and practices of respondent as alleged in this Complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission on this seventeenth day of November, 2016, has issued this Complaint against respondent.

By the Commission.

Complaint

Exhibit A



YouTube Description Box Before “Show More” Link Clicked,
Sponsorship Disclosure Not Visible

EXHIBIT A-1

Complaint

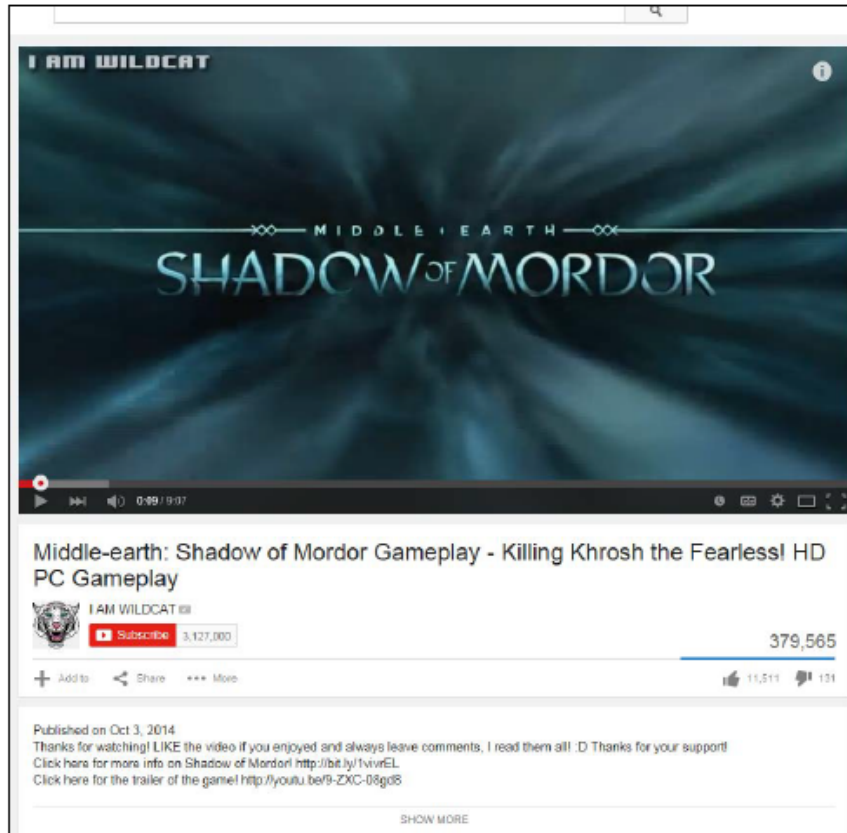


YouTube Description Box After "Show More" Link Clicked, Sponsorship Disclosure Visible

EXHIBIT A-2

Complaint

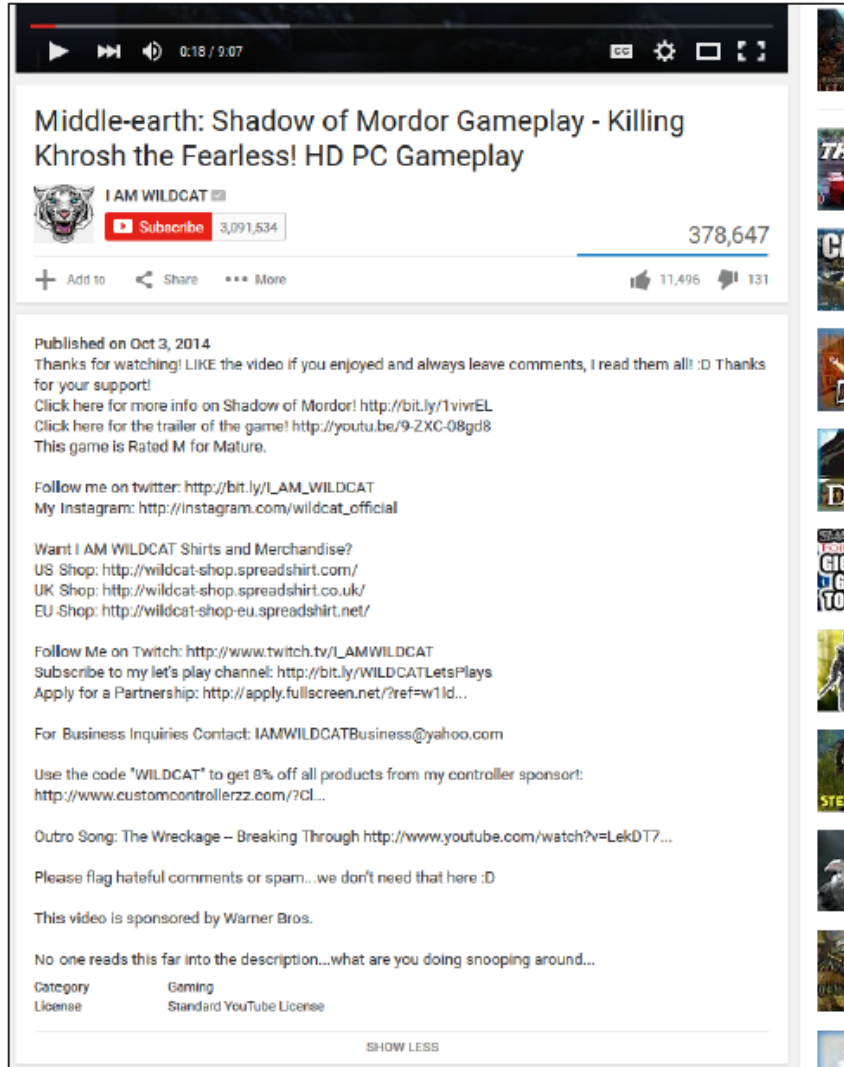
Exhibit B



**YouTube Description Box Before “Show More” Link Clicked,
Sponsorship Disclosure Not Visible**

EXHIBIT B-1

Complaint

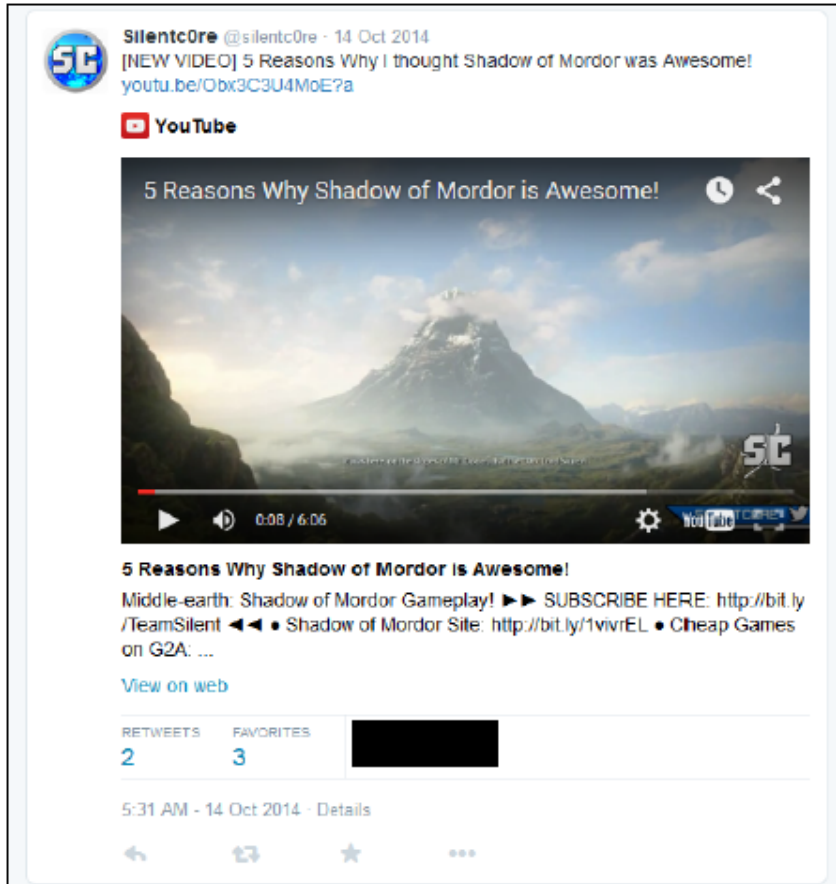


YouTube Description Box After "Show More" Link Clicked, Sponsorship Disclosure Visible

EXHIBIT B-2

Complaint

Exhibit C

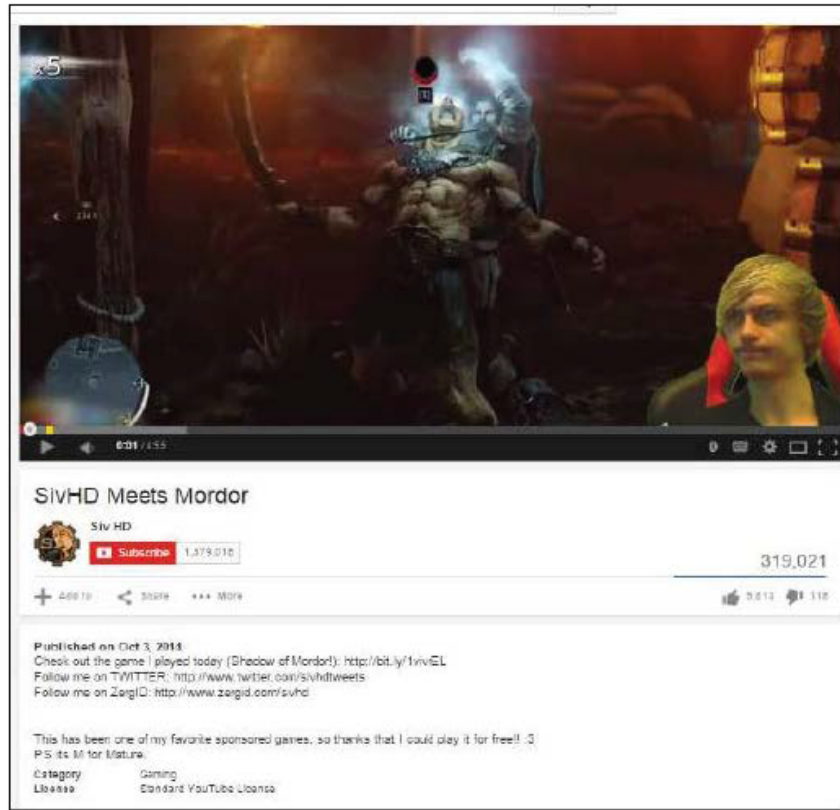


Twitter Post,
Limited Text from YouTube Description Box Visible

EXHIBIT C

Complaint

Exhibit D



“This has been one of my favorite sponsored games, so thanks that I could play it for free!!”

EXHIBIT D-1

Complaint

The screenshot shows a YouTube video player interface. At the top, the channel name 'SILENTORE' is visible in a blue banner. The video title is '5 Reasons Why Shadow of Mordor is Awesome!'. The channel's profile picture is a blue circle with 'SE' in white. Below the profile picture is a 'Subscribe' button with '170,738' subscribers and a view count of '3,963'. The video description includes the following text:

Published on Oct 14, 2014
 Middle-earth: Shadow of Mordor Gameplay!
 ► SUBSCRIBE HERE: <http://bit.ly/TeamSilent> ◀◀
 • Shadow of Mordor Site: <http://bit.ly/1vvr6L>

• Cheap Games on G2A: <http://g2a.com/inSilentOre>
 • Follow me on Twitter! <http://twitter.com/silentOre>

Thanks for watching, have an awesome day! :D

- Twitter: <http://goo.gl/1Pq7u>
- Facebook: <http://on.fb.me/OiG6Jf>
- Twitch: <http://www.twitch.tv/silentOre>
- Google+: <http://plus.google.com/+silentOre>
- Instagram: <http://instagram.com/inSilentOre>
- 2nd Channel: <http://youtube.com/silentOre2nd>

Copyright Free Music: <http://www.youtube.com/activtymusic>

• Music used:
 SoJero & Comoraset - Astronaut
<https://soundcloud.com/sojeronmusic>
<https://soundcloud.com/comoraset>
 Link to song: <https://www.youtube.com/watch?v=Misc...>

• What is Shadow of Mordor?
 In Middle-earth: Shadow of Mordor, you take on the role of Talion, a valiant ranger whose family is slain the night Sauron and his army return to Mordor, moments before his own life is taken. Resurrected by a spirit of vengeance and empowered with Wraith abilities, Talion ventures into Mordor and vows to destroy those who have wronged him. Through the course of Talion's personal vendetta, you will uncover the truth of the split that compels you, learn the origins of the Rings of Power and ultimately confront your true nemesis.
 Thanks to Warner Brothers for sponsoring my access! ESRB Rating M.

Category: Gaming
 License: Standard YouTube License

“Thanks to Warner Brothers for sponsoring my access!”

EXHIBIT D-2

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of a complaint which the Western Region-San Francisco proposed to present to the Commission for its consideration and which, if issued, would charge the respondent with violations of the Federal Trade Commission Act; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“consent agreement”), which includes: a statement by respondent that it neither admits nor denies any of the allegations in the draft complaint except as specifically stated in the consent agreement, and, only for purposes of this action, admits the facts necessary to establish jurisdiction; and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Warner Bros. Home Entertainment Inc. is a Delaware corporation with its principal office or place of business at 4000 Warner Blvd., Burbank, California 91522.

Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “Respondent” means Warner Bros. Home Entertainment Inc., its successors and assigns, and its officers, agents, representatives, and employees.
- B. “Clearly and Conspicuously” means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
 1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means.
 2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
 3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume,

Decision and Order

speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

4. In any communication using an interactive electronic medium, such as the internet or software, the disclosure must be unavoidable.
 5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.
 6. The disclosure must comply with these requirements in each medium through which it is received, including but not limited to all electronic devices and face-to-face communications.
 7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
 8. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, “ordinary consumers” includes reasonable members of that group.
- C. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. “Endorsement” means any advertising message (including but not limited to verbal statements, demonstrations, or depictions of the name, signature, likeness, or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.

Decision and Order

- E. “Endorser” or “Influencer” means an individual or organization that provides an Endorsement.
- F. “Home Entertainment Product or Service” means any video game product or service for any platform, including but not limited to video game consoles, handheld or mobile devices, and personal computers.
- G. “Influencer Campaign” means any arrangement whereby, in connection with the advertising, promotion, offering for sale, sale, or distribution of any product or service, an Influencer creates, publishes, or otherwise disseminates an Endorsement for which the Influencer is to receive compensation from either Respondent or anyone else that Respondent engages to conduct such campaign.
- H. “Material Connection” means any relationship that materially affects the weight or credibility of any Endorsement and that would not be reasonably expected by consumers.

I.

IT IS ORDERED that Respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any Home Entertainment Product or Service, in or affecting commerce, shall not in any Influencer Campaign misrepresent, in any manner, expressly or by implication, that an Influencer is an independent user or ordinary consumer of the product or service.

II.

IT IS FURTHER ORDERED that Respondent, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any Home Entertainment Product or Service, in or affecting commerce, by means of an Endorsement of such product or service, shall in any

Decision and Order

Influencer Campaign Clearly and Conspicuously disclose a Material Connection, if one exists, between the Influencer and Respondent.

III.

IT IS FURTHER ORDERED that Respondent, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any Home Entertainment Product or Service, in or affecting commerce, shall: (i) in any Influencer Campaign it conducts directly, take steps sufficient to ensure that its Influencer Campaigns comply with Parts I and II of this order; and (ii) require that any entity that Respondent engages to conduct an Influencer Campaign take steps sufficient to ensure that its Influencer Campaigns comply with Parts I and II of this order. Such steps shall include, at a minimum:

- A. Providing each Influencer with a statement of his or her responsibility to disclose Clearly and Conspicuously, in any online video, social media posting, or other communication for which the Influencer is to receive compensation, the Influencer's Material Connection to Respondent. Respondent or the entity conducting the campaign shall obtain from each Influencer a signed and dated acknowledgment that the Influencer has received the statement and expressly agrees to comply with it;
- B. Establishing, implementing, and thereafter maintaining a system to monitor and review the representations and disclosures of Influencers with Material Connections to Respondent to ensure compliance with Parts I and II of this order. The system shall include, at a minimum, monitoring and reviewing the Influencers' online videos, social media postings, or other digital advertisements or communications made as part of the Influencer Campaign;

Decision and Order

- C. Immediately terminating and ceasing payment to any Influencer with a Material Connection to Respondent who Respondent reasonably concludes:
1. Has misrepresented, in any manner, his or her independence and impartiality; or
 2. Has failed to disclose, Clearly and Conspicuously, and in close proximity to the representation, a Material Connection between such Influencer and Respondent.

Provided, however, that Respondent may provide an Influencer with notice of failure to disclose and an opportunity to cure the disclosure prior to terminating the Influencer if Respondent reasonably concludes that the failure to disclose was inadvertent. Respondent shall inform any Influencer to whom it has provided a notice of a failure to disclose a Material Connection that any subsequent failure to disclose will result in immediate termination;

- D. Directing the entity conducting the campaign to immediately terminate and cease payment to any Influencer with a Material Connection to Respondent who the entity conducting the campaign reasonably concludes:
1. Has misrepresented, in any manner, his or her independence and impartiality; or
 2. Has failed to disclose, Clearly and Conspicuously, and in close proximity to the representation, a Material Connection between such Influencer and Respondent.

Provided, however, that Respondent may allow the entity conducting the campaign to provide an Influencer with notice of failure to disclose and an opportunity to cure the disclosure prior to terminating the Influencer if the entity conducting the campaign

Decision and Order

reasonably concludes that the failure to disclose was inadvertent. The entity conducting the campaign shall inform any Influencer to whom it has provided a notice of a failure to disclose a Material Connection that any subsequent failure to disclose will result in immediate termination;

- E. Establishing, implementing, and thereafter maintaining a system for Respondent to monitor any entity that Respondent engages to conduct an Influencer Campaign for adherence to this Part of the order. If Respondent reasonably concludes that the entity engaged to conduct the Influencer Campaign has failed to comply with this Part of the order, Respondent shall immediately suspend payment to the entity, unless and until any noncompliance has been cured. Respondent shall disqualify the entity from conducting future Influencer Campaigns for Respondent upon a repeat incident unless Respondent reasonably concludes that the noncompliance was inadvertent; and
- F. Creating, and thereafter maintaining, reports showing the results of the monitoring required by subparts B and E of this Part of the order.

IV.

IT IS FURTHER ORDERED that Respondent and its successors and assigns shall, for five (5) years after the last date of dissemination of any Endorsement or other representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. Any documents that:
 - 1. Are reasonably necessary to demonstrate full compliance with each provision of this order, including but not limited to documents obtained, created, or generated, or which relate to, the requirements, provisions, or terms of this order,

Decision and Order

and all reports submitted to the Commission pursuant to this order;

2. Contradict, qualify, or call into question Respondent's compliance with this order; or
 3. Comprise or relate to complaints or inquiries, whether received directly, indirectly, or through any third party, concerning any Endorsement made by Respondent, and any responses to those complaints or inquiries; and
- B. All acknowledgments of receipt of this order obtained pursuant to Part V.

V.

IT IS FURTHER ORDERED that, for five (5) years, Respondent and its successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that Respondent and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed

Decision and Order

change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Warner Bros. Home Entertainment Inc.

VII.

IT IS FURTHER ORDERED that Respondent and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

VIII.

This order will terminate on November 17, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Analysis to Aid Public Comment

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal

By the Commission.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing consent order from Warner Bros. Home Entertainment Inc. (“Warner Bros.” or “respondent”). The proposed consent order (“proposed order”) has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

This matter involves respondent’s use of social media influencers to advertise the video game, *Middle Earth: Shadow of Mordor* (“*Shadow of Mordor*”). According to the Commission’s complaint, Warner Bros., through its ad agency, Plaid Social Labs, LLC, hired individuals who had earned reputations as video game enthusiasts on YouTube (“YouTube influencers”) to post positive videos promoting *Shadow of Mordor* on YouTube. The Commission’s complaint alleges that these YouTube influencers were given free access to a pre-release version of *Shadow of Mordor* and cash payments often ranging from hundreds of

Analysis to Aid Public Comment

dollars to tens of thousands of dollars, if the videos they created about *Shadow of Mordor* met certain requirements defined by Warner Bros. Among other things, Warner Bros. required influencer videos to promote a positive sentiment about the game, and not to disclose any bugs or glitches that the game might have. Consequently, these videos were sponsored advertisements, and did not necessarily reflect the independent experiences of the individual YouTube influencers.

The complaint also alleges that while Warner Bros. instructed the YouTube influencers to provide a disclosure that their videos had been sponsored, it specified that the disclosure be written, and placed in the description box appearing below the YouTube videos. Warner Bros. did not require the YouTube influencers to place a sponsorship disclosure clearly and conspicuously in the video itself. Nor did Warner Bros. require that the YouTube influencers be instructed to place the sponsorship disclosure “above the fold” in the description box, or visible without consumers having to scroll down or click on a link, as it had for other promotional information about *Shadow of Mordor*. (See, e.g., Exhibit A-1) As a result, most YouTube influencers did not include any sponsorship disclosures in their videos, and only placed their sponsorship disclosures “below the fold” in the description box below the video. Therefore, consumers had to click on a “Show More” button in the description box and potentially scroll down before they could see the sponsorship disclosure. As a result, consumers who watched these YouTube videos were unlikely to learn that the videos were paid promotions for Warner Bros.

The Commission’s complaint further alleges that when YouTube influencers posted their *Shadow of Mordor* videos for viewing on Facebook or Twitter, consumers were even less likely to see these sponsorship disclosures because such posts did not include the “Show More” button. In addition, the complaint states that on at least two occasions, the influencers disclosed only that they had been given early access to the game, and did not adequately disclose that they had also been paid to post the video.

According to the complaint, in numerous instances, YouTube influencers did not disclose or adequately disclose that Warner

Analysis to Aid Public Comment

Bros., through Plaid Social, offered compensation to the influencers in exchange for creating and uploading gameplay videos as part of a *Shadow of Mordor* advertising campaign. The Commission's complaint alleges that these videos were false and misleading because they did not reflect the independent opinions or experiences of impartial video game enthusiasts. The complaint further alleges that the videos were deceptive because they failed to disclose or disclose adequately that the influencers who posted the videos were compensated in connection with their endorsements.

The proposed order includes injunctive relief to address these alleged violations and requires Warner Bros. to follow certain monitoring and compliance procedures related to its use of influencer campaigns.

Part I of the proposed order prohibits Warner Bros., in connection with the advertising of any home entertainment product or service, from misrepresenting in any influencer campaign that an influencer or endorser of such product or service is an independent user or ordinary consumer of the product or service.

Part II of the proposed order requires Warner Bros., in connection with the advertising of any home entertainment product or service by means of an endorsement, in any influencer campaign, to disclose clearly and conspicuously a material connection, if one exists, between the influencer or endorser and Warner Bros.

Part III of the proposed order sets out certain monitoring and compliance obligations to ensure that Warner Bros., or any entity it engages to conduct an influencer campaign, comply with Parts I and II of the proposed order. These obligations include: Obtaining signed acknowledgements from such influencers that they will disclose their material connection to Warner Bros.; monitoring the influencers' representations and disclosures; maintaining records of monitoring efforts; and, under certain circumstances, terminating and ceasing payment to influencers who misrepresent their independence, or fail to properly disclose any material connection to Warner Bros. Part III specifically

Analysis to Aid Public Comment

provides that if Warner Bros. engages an entity to conduct an influencer campaign, Warner Bros. must take steps to ensure that the entity complies with this Part, and to monitor its compliance. If the entity fails to comply with this Part, Warner Bros. must cease payment to the entity until it cures any noncompliance. Furthermore, Warner Bros. is required to disqualify the entity from conducting future influencer campaigns upon a repeat incident, unless it reasonably concludes that the entity's failure to comply was inadvertent.

Part IV of the proposed order contains recordkeeping requirements for relevant documents.

Parts V through VII of the proposed order require the company to: Provide copies of the order to certain personnel having responsibilities with respect to the subject matter of the order; notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part VIII of the proposed order provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order's terms in any way.

Complaint

IN THE MATTER OF

CALIFORNIA NATUREL, INC.COMPLAINT, OPINION OF THE COMMISSION AND ORDER IN
REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE
FEDERAL TRADE COMMISSION ACT*Docket No. 9370; File No. 152 3267*
Complaint, April 11, 2016 – Order, December 5, 2016

This case addresses California Naturel, Inc.'s marketing of its sunscreen product. The complaint alleges that California Naturel falsely advertises its Sunscreen SPF 30 product as an "all natural" sunscreen when in fact it contains the synthetic ingredient dimethicone, in violation of Sections 5 and 12 of the Federal Trade Commission Act. Complaint Counsel filed a Motion for Summary Decision. The Commission granted the Motion and issued an Order to cease and desist.

Participants

For the *Commission*: Robert M. Frisby, Gregory Madden, and John Andrew Singer.

For the *Respondent*: John Bernard Duler, President, *pro se*.

COMPLAINT

The Federal Trade Commission, having reason to believe that California Naturel, Inc., a corporation, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent California Naturel is a Delaware corporation with its principal office or place of business at 480 Gate 5 Road – Suite 114, Sausalito, California 94965.
2. Respondent has advertised, labeled, offered for sale, sold, and distributed products to consumers, including Sunscreen SPF 30. This sunscreen product is a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

Complaint

3. The acts and practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent advertises Sunscreen SPF 30 on the Internet. This product retails for \$35.

5. Respondent has disseminated or has caused to be disseminated advertisements for Sunscreen SPF 30, including but not necessarily limited to the attached Exhibits A-B. These materials contain the following statements:

- a. California Naturel’s “Sunscreen SPF 30” webpage states:

This soft, luxurious and non-oily all natural sunscreen is formulated with Glacial Oceanic Minerals and Zinc Oxide to protect the skin from both UVA and UVB rays. It is enriched with antioxidants from botanical sources such as Shea Butter, Pomegranate Extract and Marigold Flower Extract to increase skin hydration and protection from environmental damage.

Exhibit A, Internet webpage www.californianaturel.com/sunscreen-spf-30 (August 2015).

- b. The text under the heading “Our Ingredients” on California Naturel’s “Ingredients” webpage states:

California Naturel uses only the purest, most luxurious and effective ingredients found in nature. All of our formulas are naturally scented and free of parabens and harsh synthetic chemicals. Our ingredients have been thoughtfully selected for their highly interactive properties, subtle scents, pleasurable textures and effectiveness on skin.”

Exhibit B, Internet webpage www.californianaturel.com/ingredients#filter=.f-ss (August 2015).

Complaint

Count I
False Claim

6. In connection with the advertising, labeling, promotion, offering for sale, or sale of Sunscreen SPF 30, Respondent has represented, directly or indirectly, expressly or by implication, that the product is an “all natural” sunscreen.

7. In fact, Sunscreen SPF 30 is not “all natural” because it contains or contained a synthetic ingredient Dimethicone. Therefore, the “all natural” representations set forth in Paragraph 6 are false or misleading.

Violations of Sections 5(a) and 12

8. The acts and practices of Respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

NOTICE

You are notified that on December 12, 2016, at 10:00 a.m., at the Federal Trade Commission offices, 600 Pennsylvania Avenue, NW, Room 532-H, Washington, DC 20580, an Administrative Law Judge of the Federal Trade Commission will hold a hearing on the charges set forth in this Complaint. At that time and place, you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this Complaint.

You are notified that you are afforded the opportunity to file with the Federal Trade Commission (“Commission”) an answer to this Complaint on or before the 14th day after service of the Complaint upon you. An answer in which the allegations of the Complaint are contested must contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the Complaint or, if you are without knowledge thereof, a statement to that effect.

Complaint

Allegations of the Complaint not thus answered will be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the Complaint, the answer should consist of a statement that you admit all of the material facts to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the Complaint and, together with the Complaint, will provide a record basis on which the Commission may issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings of fact and conclusions of law under FTC Rule § 3.46.

Failure to answer timely will be deemed to constitute a waiver of your right to appear and contest the allegations of the Complaint. It will also authorize the Commission, without further notice to you, to find the facts to be as alleged in the Complaint and to enter a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

The Administrative Law Judge will hold an initial prehearing scheduling conference, to be held not later than 10 days after the answer is filed by the Respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, NW, Room 532-H, Washington, DC 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, but in any event no later than 5 days after the answer is filed by the Respondent. Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a Respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

The following is the form of the order which the Commission has reason to believe should issue if the facts are found to be as alleged in the Complaint. If, however, the Commission concludes from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions as to Respondent might be inadequate to fully protect the consuming public, the

Complaint

Commission may order such other relief as it finds necessary and appropriate.

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “respondent” shall mean California Naturel, a corporation, its successors and assigns, and its officers, agents, representatives, and employees.
- B. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not make any representation, expressly or by implication, including through the use of a product name, trademark, or trade name, about:

- A. whether such product is all natural or 100% natural;
- B. the extent to which such product contains any natural or synthetic ingredient or component;
- C. the ingredients or composition of such product; or
- D. the environmental or health benefits of such product,

unless the representation is non-misleading, including that, at the time such representation is made, the respondent possesses and relies upon competent and reliable evidence, which when appropriate based on the expertise of professionals in the relevant area must be competent and reliable scientific evidence, that is

Complaint

sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true. For the purposes of this Provision:

1. “competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results; and
2. “competent and reliable *scientific* evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

II.

IT IS FURTHER ORDERED that respondent California Naturel, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

Complaint

III.

IT IS FURTHER ORDERED that respondent California Naturel, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent must maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

IV.

IT IS FURTHER ORDERED that respondent California Naturel, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re California Naturel, Docket No. 9370.

Complaint

V.

IT IS FURTHER ORDERED that respondent California Naturel, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VI.

IT IS FURTHER ORDERED that the final and effective date of this Order is the 60th day after this Order is served. This Order will terminate 20 years from the date of its issuance (which is stated at the end of this Order, next to the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Provision in this Order that terminates in less than 20 years;
- B. This Order if such complaint is filed after the Order has terminated pursuant to this Provision. If such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

THEREFORE, the Federal Trade Commission, this eleventh day of April, 2016, has issued this Complaint against Respondent.

Complaint

Exhibit B

The screenshot shows the 'Our Ingredients' page of the California Naturel website. At the top left is the California Naturel logo. The navigation menu includes 'OUR STORY', 'PRODUCTS', 'INGREDIENTS', 'BLOG', and 'CONTACT'. A shopping cart icon is visible in the top right. The main heading is 'Our Ingredients', followed by a descriptive paragraph: 'California Naturel uses only the purest, most luxurious and effective ingredients found in nature. All our formulations are naturally scented and free of parabens, sulfates, and harsh synthetic chemicals. Our ingredients have been thoughtfully selected for their highly active properties, subtle scents, preservative benefits and effectiveness in our...' Below this is a row of seven red navigation buttons: 'HOME', 'ABOUT US', 'OUR INGREDIENTS', 'PRODUCTS', 'BLOG', 'CONTACT', and 'SHOP'. The main content area features a grid of 12 ingredients, each with an image and a caption:

- Callispermum maritimum* extract
- Punica granatum* (pomegranate) fruit extract
- Butyrospermum parkii* (shea) butter
- Taraxacum officinale* (sunflower) seed oil
- Salvia* (Sage)
- Chamaemelum nobile* (chamomile) flower extract
- Scrubium gum
- Dimethicone
- Chlorella*
- glucosylated sodium benzoate
- Zinc Oxide
- Chococypolate

At the bottom of the page, there is a sign-up form for exclusive news and promotions, social media icons for Facebook, Twitter, Pinterest, and Instagram, and a footer with navigation links: 'Our Story', 'Shop', 'Products', 'Ingredients', 'Contact', 'Shipping', 'Returns', 'History/Policy', 'Terms & Conditions'. A browser notification for 'California Naturel' is visible in the bottom right corner.

Opinion of the Commission

OPINION OF THE COMMISSION

By Chairwoman Edith Ramirez, for the Commission.

We have before us a motion by Complaint Counsel seeking summary decision against Respondent California Naturel, Inc., a seller and marketer of personal care products. California Naturel markets its sunscreen product as “all natural,” describing the product on its website as containing “only the purest, most luxurious and effective ingredients found in nature.” The company, however, admits that eight percent of its sunscreen formula is dimethicone, a synthetic ingredient. On these simple and undisputed facts, Complaint Counsel seeks a summary finding that California Naturel is falsely advertising its sunscreen. As discussed below, we grant summary decision and issue an order prohibiting California Naturel from misrepresenting the ingredients or composition of its products.

I. Background

On April 11, 2016, the Commission issued an administrative complaint alleging that California Naturel falsely advertises its Sunscreen SPF 30 product as an “all natural” sunscreen when in fact it contains the synthetic ingredient dimethicone, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

On May 6, 2016, California Naturel’s president, John Bernard Duler, submitted an answer to the complaint on the company’s behalf as permitted by Rule 4.1(a)(2)(i) of the Commission’s Rules of Practice, 16 C.F.R. § 4.1(a)(2)(i).¹ In its answer, California Naturel does not dispute that the Commission has jurisdiction over it and over the conduct challenged in the complaint. It does deny that its “all natural” advertising is false or misleading. Among other things, California Naturel asserts in its

¹ California Naturel’s answer does not comply with all of the requirements of Rule 4.2, 16 C.F.R. § 4.2. However, in substance, it responds to the allegations in the complaint, and we therefore accept it as an answer. *Cf. Yakima Fruit & Cold Storage Co.*, 59 F.T.C. 693, 705 (1961) (holding that Commission has discretion to accept review of an initial decision when request for review was in the form of a letter addressed to the Chairman rather than in the form of a brief as required by the Commission’s Rules of Practice).

Opinion of the Commission

answer that, as a result of the FTC's investigation, it now includes a disclaimer on its website that the ingredient dimethicone in its sunscreen is synthetic.

Complaint Counsel filed their motion for summary decision on September 14, 2016. They contend that California Naturel has admitted that its Sunscreen SPF 30 contains eight percent dimethicone, a synthetic substance, and thus effectively admitted that its advertising claims are false. California Naturel disputes that its advertising is false or misleading. It argues that, as of early 2016, it has sufficiently disclosed the ingredients in Sunscreen SPF 30. In particular, it cites what it contends is a readily visible disclosure statement on its website specifying that eight percent of its "all natural" sunscreen formula is dimethicone, a synthetic ingredient.

We review Complaint Counsel's motion for summary decision pursuant to Rule of Practice 3.24, 16 C.F.R. § 3.24, which parallels Federal Rule of Civil Procedure 56 governing summary judgment in the federal courts. Consistent with Rule 56, a party moving for summary decision must show that "there is no genuine issue as to any material fact." *Id.* We may therefore rely on authority applying the federal summary judgment standard. *See, e.g., Fanning v. FTC*, 821 F.3d 164, 170 (1st Cir. 2016) (under FTC rules, summary decision is reviewed "under the same standard as summary judgment before a district court"), *petition for cert. docketed*, (Sept. 27, 2016) (No. 16-397).

As the moving party, Complaint Counsel bears the initial burden of identifying evidence that demonstrates the absence of any genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). When a motion for summary decision is made and supported, the "party opposing the motion may not rest upon the mere allegations or denials of his or her pleading; the response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue of material fact for trial." 16 C.F.R. § 3.24(a)(3); *see also Celotex*, 477 U.S. at 323. We are required to resolve all factual ambiguities and draw all justifiable inferences in the light most favorable to California Naturel, the party opposing the motion.

Opinion of the Commission

Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986). We now turn to an analysis of Complaint Counsel's motion.

II. Analysis

Section 5 of the FTC Act prohibits “unfair or deceptive acts or practices in or affecting commerce.” 15 U.S.C. § 45(a). Section 12 proscribes the dissemination of any “false advertisement,” for food, drugs, devices, services, or cosmetics. *Id.* § 52(a). The deception standard is the same under both provisions. *POM Wonderful LLC*, 2013 WL 268926, at *18. n.5 (F.T.C. Jan. 16, 2013), *aff'd sub nom. POM Wonderful, LLC v. FTC*, 777 F.3d 478 (D.C. Cir. 2015); *see also Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992).

“An advertisement is deceptive if it contains a representation or omission of fact that is likely to mislead a consumer acting reasonably under the circumstances, and that representation or omission is material to a consumer's purchasing decision.” *POM Wonderful*, 2013 WL 268926, at *18; *FTC Policy Statement on Deception*, 103 F.T.C. 174, 175 (1984) (“*Deception Statement*”), appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110 (1984). Determining whether California Naturel has violated the FTC Act thus consists of a three-part inquiry. We must evaluate whether, as a matter of law, California Naturel's advertising conveyed the claim alleged in the complaint, the claim was false or misleading, and the claim was material. *See POM Wonderful*, 2013 WL 268926, at *18; *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285, 297 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010).

We first consider what claims California Naturel has conveyed in marketing its Sunscreen SPF 30. A claim may be either express or implied; express claims are those that directly state the representation at issue. *Kraft, Inc. v. FTC*, 114 F.T.C. 40, 120 (1991). “In determining what claims may reasonably be attributed to an advertisement, the Commission examines the entire advertisement and assesses the overall ‘net impression’ it conveys.” *POM Wonderful*, 2013 WL 268926, at *19 (citing *Deception Statement*, 103 F.T.C. at 178). Extrinsic evidence is unnecessary to establish the impression that consumers would

Opinion of the Commission

take away from an ad if the claim is reasonably clear from the face of the advertisement. *Id.*, at *20.

The net impression conveyed by California Naturel's representations regarding its Sunscreen SPF 30 is clear from a facial analysis. It is undisputed that California Naturel expressly advertises Sunscreen SPF 30 as "all natural." The sunscreen itself bears the description "All Natural." *See* Attachment A.² On its website, California Naturel states with respect to Sunscreen SPF 30:

This soft, luxurious and non-oily all natural sunscreen is formulated with Glacial Oceanic Minerals and Zinc Oxide to protect the skin from both UVA and UVB rays. It is enriched with antioxidants from botanical sources such as Shea Butter, Pomegranate Extract and Marigold Flower Extract to increase skin-hydration and protect it from environmental damage.

In addition, the website describes the sunscreen's ingredients as follows:

California Naturel uses only the purest, most luxurious and effective ingredients found in nature. All of our formulas are naturally scented and free of parabens, sulfates, and harsh synthetic chemicals.

See Declaration of Brittani Garland in support of Motion for Summary Decision (May 31, 2016) ("Garland Decl."), ¶ 3 and screenshots attached as Exhibits A and B to the Complaint.

² California Naturel has urged the Commission to examine its current website, and we have done so. Pursuant to 16 C.F.R. § 3.43(f), we take official notice of the content of California Naturel's website and attach relevant portions as Attachments A and B. *See Sunscreen SPF 30*, CALIFORNIA NATUREL, <http://www.californianaturel.com/sunscreen-spf-30> (last visited Oct. 21, 2016) (Attachment A); *Our Ingredients*, CALIFORNIA NATUREL, <http://www.california-naturel.com/ingredients#filter=f-ss> (last visited Oct. 21, 2016) (Attachment B). The procedures set forth in 16 C.F.R. § 3.55 afford an opportunity to challenge the noticed facts and our inferences therefrom.

Opinion of the Commission

California Naturel does not, nor can it, dispute that it has consistently advertised its sunscreen as an “all natural” product and represented that it uses “only the purest, most luxurious and effective ingredients found in nature.” Instead, it opposes summary decision by pointing to a disclaimer it added to the bottom of the sunscreen webpage in “early 2016” after the FTC began its investigation. Opposition to Motion for Summary Decision (“Opp.”) at 1. The disclaimer states, “The FTC requires us to add the following: ‘Dimethicone, a synthetic ingredient, is 8% of the sunscreen formula, the remaining 92% are natural products.’” *Id.*; see also Answer at 3. California Naturel argues that the disclaimer and other portions of its website adequately disclose that the sunscreen contains the synthetic ingredient dimethicone. Put differently, California Naturel contends that its marketing claims are not false or misleading. We disagree.

As an initial matter, there is no question that prior to early 2016, California Naturel expressly marketed its sunscreen as an “all natural” product and that it did not include the disclaimer on which it now relies. Other than adding the referenced disclaimer, California Naturel has not changed the representations challenged in the complaint. As noted above, in addition to the express and prominent claim on the product that Sunscreen SPF 30 is “all natural,” California Naturel describes the sunscreen on its website as a “soft, luxurious and non-oily *all natural* sunscreen” and states that it “uses *only* the purest, most luxurious and effective ingredients found in nature.” Garland Decl. ¶ 3, and screenshots attached as Exhibits A and B to the Complaint (emphasis added). This plainly conveys to reasonable consumers that every ingredient in the product is natural. The recent addition by California Naturel of a disclaimer on its website does not excuse deception that has already occurred. See, e.g., *Libbey-Owens-Ford Glass Co. v. FTC*, 352 F.2d 415, 418 (6th Cir. 1965).

Nor are we persuaded by California Naturel’s argument that the disclaimer it added renders its marketing claims “transparent.” The sunscreen itself continues to state it is “all natural.”³ And

³ In addition to citing to its new disclaimer, California Naturel represents that it has produced stickers containing the same disclaimer language and placed them on the product packaging. Opp. at 2; Answer at 6. Because no such stickers are visible on the product images depicted in California Naturel’s website, and

Opinion of the Commission

California Naturel continues to prominently display the “all natural” language discussed above on its website. See Attachments A, B. Adding a disclaimer to the bottom of the webpage that is well removed from proximity to the “all natural” claims – and, in fact, not visible at all without scrolling down – does not change the net impression conveyed to consumers that the product is “all natural.” See *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 12 (1st Cir. 2010) (inconspicuous disclaimer that infomercial was paid advertising and that statements were opinion was insufficient to correct “bold and straightforward” claims that supplements could cure or prevent disease); *FTC v. Cyberspace.Com LLC*, 453 F.3d 1196, 1201 (9th Cir. 2006) (finding fine print notices on the back of solicitations insufficient to overcome deceptive nature of front-side communications). Notably, the disclaimer is also well below the website’s “Add to Cart” button so that consumers are invited to purchase the product before they would even see the disclaimer. In guidance on online disclosures, we have urged that disclosures “be provided before the consumer makes the decision to buy, e.g., before clicking on an ‘order now’ button or a link that says ‘add to shopping cart.’” FEDERAL TRADE COMMISSION, .COM DISCLOSURES: HOW TO MAKE EFFECTIVE DISCLOSURES IN DIGITAL ADVERTISING 14 (March 2013).⁴

In her partial dissent, Commissioner Ohlhausen questions the propriety of determining as a matter of summary decision the impact of California Naturel’s 2016 website disclaimer, arguing that such a determination is both unnecessary and improper.⁵

there is no other evidence of how the stickers appear on the sunscreen packaging, we do not consider the stickers as part of our analysis. We note, however, that in light of the prominent and express “all natural” claims on California Naturel’s website and the absence of any indication that consumers would see the stickers before making an online purchase, we are skeptical that a sticker would suffice to address our concerns about the net impression conveyed.

4 The FTC disclosure guidelines are available at <https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-staff-revises-online-advertising-disclosure-guidelines/130312dotcomdisclosures.pdf>.

5 Commissioner Ohlhausen agrees that the “all natural” claims made prior to the addition of the disclaimer were false and misleading. In her view, however, there is a fact question as to whether California Naturel has since clarified its

Opinion of the Commission

While it may not be necessary to rule on the effect of California Naturel's disclaimer on the net impression conveyed to consumers, it is entirely appropriate for the Commission to do so. As noted above, California Naturel cites its new disclaimer as its principal defense against Complaint Counsel's allegations of deception and motion for summary decision, and asks us to examine its updated website to evaluate the effect of the disclaimer on its advertising claims. We have taken official notice of California Naturel's website and determined that there are no disputed facts regarding the placement or font size of the disclaimer.⁶ Just as we engaged in a facial analysis to evaluate the net impression of California Naturel's advertising claims prior to the addition of the disclaimer, we can appropriately perform a facial analysis to determine the effect of the disclaimer. *See, e.g., Daniel Chapter One*, 2009 FTC LEXIS 259, at *24 (F.T.C. Dec. 24, 2009) (conducting facial analysis of a disclaimer's print size, positioning, and scope); *Kraft, Inc.*, 114 F.T.C. 40, 122-28 (1991) (finding disclosures ineffective to dispel the net impression otherwise presented in view of the disclosures' brevity, placement, and complexity).

Courts have similarly not hesitated to find disclaimers ineffective to dispel deceptive claims when the Commission has moved for summary judgment. *See, e.g., Cyberspace.Com*, 453 F.3d at 1201 (finding that "no reasonable factfinder could conclude that the solicitation was not likely to deceive consumers" despite the presence of fine-print disclosures on the back of the marketing material); *Direct Mktg. Concepts*, 624 F.3d at 24 n.9 (concluding from a facial examination that the disclaimer would not cure deceptive infomercials). In fact, declining to address the disclaimer's sufficiency could create the misimpression that the disclaimer cures the deception. As a matter of transparency and efficiency, the Commission should

"all natural" claims through its recently-added disclaimer and new stickers to accompany product packaging. As explained in her partial dissent, she believes that granting summary decision on that point is inappropriate and thus does not join the portion of the opinion holding that the disclaimer is insufficient to qualify California Naturel's "all natural" claims, based on the current record.

⁶ *See supra* note 2.

Opinion of the Commission

make clear that California Naturel's disclaimer does not cure its deceptive "all natural" claims. In our view, sidestepping the issue now only to argue later in a potential contempt action that the Commission's order has been violated would not serve the interests of either the public or California Naturel.

California Naturel also points to a list of ingredients that appears if one scrolls down on its Sunscreen SPF 30 webpage. This list, however, does nothing to dispel the net impression that the sunscreen is "all natural." It first identifies one ingredient, zinc oxide, as the active ingredient, and then lists 31 other ingredients using scientific terminology. Buried in the middle of the list is dimethicone. All of the ingredients are in the same font and font size, and nothing on the face of the list identifies dimethicone as a synthetic ingredient. California Naturel nonetheless asserts that the website is "transparent" because a consumer can click on the word "dimethicone," which takes the consumer to the general "ingredients" webpage. If the cursor is properly positioned, this webpage identifies dimethicone as a "silicone-based polymer." Case law, however, establishes that it is reasonable for a consumer to rely on express claims, and thus that they should not be required to search for and dig out information that contradicts what an advertisement expressly and prominently conveys. Indeed, we expect consumers to rely on express statements such as the "all natural" representation at issue here, and to interpret such statements as meaning what they say. See *FTC v. Skybiz.com, Inc.*, 2001 WL 1673645, at *9 (N.D. Okla. 2001) (reasonable to expect that consumers could rely on express claims); *FTC v. Five-Star Auto Club, Inc.*, 97 F. Supp. 2d 502, 528 (S.D.N.Y. 2000) ("Consumer reliance on express claims is [] presumptively reasonable.") (internal quotation omitted).

As purported evidence of the supposed transparency of its disclaimer and ingredient list, California Naturel points to an article referencing this case by an investigative reporter for the *Wall Street Journal*. California Naturel notes that the article quotes California Naturel's recently-added website disclaimer that "Dimethicone, a synthetic ingredient, is 8% of the sunscreen formula" and asserts that the reporter also saw the ingredient list. Opp. at 1; Answer at 3 (citing Serena Ng, *FTC Charges Five 'Natural' Products Firms Over Claims*, WALL ST. J., (Apr. 13,

Opinion of the Commission

2016), *available at* <http://www.wsj.com/articles/ftc-charges-five-natural-products-firms-over-claims-146050>). However, we look at claims from the viewpoint of the average consumer, and the fact that an investigative reporter researching a story about “all natural” claims located the disclaimer and saw dimethicone on the ingredient list does not alter our conclusion regarding the net impression of the website.⁷ *See Thompson Med. Co., Inc.*, 104 F.T.C. 648, 810 (1984) (focusing the deception inquiry on “average or ordinary members of the adult population”), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986); *Kraft*, 114 F.T.C. at 122.

We therefore find that California Naturel’s advertising conveys that its sunscreen is “all natural,” meaning it contains only ingredients found in nature. *See, e.g., Williams v. Gerber Prods. Co.*, 552 F.3d 934, 939-40 (9th Cir. 2008) (stating, in denying motion to dismiss, that “‘fruit juice and other all natural ingredients’ could easily be interpreted by consumers as a claim that all the ingredients in the product were natural” and rejecting the argument that a list of ingredients on the same box would dispel this impression); *Bohac v. Gen. Mills, Inc.*, 2014 WL 1266848, at *6 (N.D. Cal. Mar. 26, 2014) (in rejecting motion to dismiss, concluding that “all natural” conveys “the affirmative and specific factual representation that the products are made *entirely* of natural ingredients”).

We consider next whether California Naturel’s “all natural” claims are false or misleading. The central question is whether the claim is likely to mislead; Complaint Counsel need not prove actual deception. *See, e.g., Jerk, LLC*, 2015 WL 1518891, at *10 (F.T.C. Mar. 13, 2015). Moreover, “[t]he deception need not be made with intent to deceive; it is enough that the representations or practices were likely to mislead consumers acting reasonably.” *FTC v. Verity Int’l, Ltd.*, 443 F.3d 48, 63 (2d Cir. 2006) (citation omitted). Accordingly, “[a]n advertiser’s good faith does not immunize it from responsibility for its misrepresentations” *Chrysler Corp. v. FTC*, 561 F.2d 357, 363 n.5 (D.C. Cir. 1977).

⁷ California Naturel’s unsupported claim that its customers “praise [its] disclosure and transparency,” Answer at 5, is inadmissible hearsay that lacks any indicia of reliability. *See* 16 C.F.R. § 3.43(b).

Opinion of the Commission

In its answer and in opposition to Complaint Counsel's motion, California Naturel admits that its sunscreen formula consists of eight percent dimethicone and that dimethicone is a synthetic material. These two admissions, Complaint Counsel argue, establish that California Naturel's "all natural" claims are false or misleading. We agree.

It is undisputed that California Naturel's sunscreen contains eight percent of a synthetic ingredient. California Naturel nonetheless asserts that its policy is to list all ingredients and thus to be "transparent." However, Complaint Counsel need not demonstrate an intent to deceive. *See, e.g., FTC v. Freecom Commc'ns, Inc.*, 401 F.3d 1192, 1202 (10th Cir. 2005) ("[I]ntent to deceive . . . is not an element of a [Section] 5 violation."). California Naturel also argues that there is no regulatory definition that specifies the percentage of natural ingredients required in order to describe a product as "natural." While true, this argument misses the mark.⁸ California Naturel does not merely claim that its product is "natural"; it expressly asserts that its sunscreen is "all natural" and that it "uses only the purest, most luxurious and effective ingredients found in nature." By California Naturel's own admission, that is not true.

Finally, we consider whether California Naturel's false and misleading claim is material. A "material" misrepresentation is one that is likely to affect a consumer's conduct with respect to the product or service. *Deception Statement*, 103 F.T.C. at 182. "[T]he Commission presumes that express claims are material." *Id.* As noted in the *Deception Statement*, the Commission "may assume that the willingness of a business to promote its products reflects a belief that consumers are interested in the advertising." *Id.* (internal quotations omitted). In turn, a respondent may rebut a presumption of materiality by providing evidence that the claim is not material. *Novartis Corp.*, 127 F.T.C. 580, 686 (1999).

⁸ The Commission's Green Guides do not provide guidance on the term "natural." However, our guidance is clear that "marketers must identify all express and implied claims that the advertisement reasonably conveys" and "ensure that all reasonable interpretations of their claims are truthful . . ." 77 Fed. Reg. 62125 (2012).

Opinion of the Commission

Here, California Naturel's "all natural" representation for Sunscreen SPF 30 is express and therefore presumptively material. California Naturel does not provide any evidence to rebut this presumption. Accordingly, we find that California Naturel's "all natural" claim is false and misleading, and likely to affect a consumer's purchasing decision in violation of Sections 5 and 12 of the FTC Act.

III. Remedy

Having found liability, we now turn to the issue of the remedy. The FTC Act authorizes the Commission to issue an order requiring a respondent to cease and desist the deceptive acts or practices. 15 U.S.C. § 45(b). Importantly, "[t]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past." *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392, 395 (1965). The Commission may "frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in [the] future." *Id.* at 395. We have the authority to issue orders "encompassing all products or all products in a broad category, based on violations involving only a single product or group of products." *ITT Continental Baking Co. v. FTC*, 532 F.2d 207, 223 (2d Cir. 1976); *see also Colgate-Palmolive*, 380 U.S. at 394-95.

We enter the accompanying Final Order to address California Naturel's unlawful conduct. The core substantive provision of the Final Order, Part I, prohibits California Naturel from making the kinds of misrepresentations alleged in the complaint. In particular, California Naturel is prohibited from misrepresenting (a) whether a product is all natural or 100% natural; (b) the extent to which a product contains any natural or synthetic ingredient; (c) the ingredients or composition of a product; and (d) the product's environmental or health benefits. To ensure that representations about ingredients are not misleading, California Naturel must have competent and reliable evidence supporting its claims about the content and ingredients of the product.

"Fencing-in provisions serve to 'close all roads to the prohibited goal, so that (the FTC's) order may not be by-passed with impunity.'" *Litton Indus., Inc. v. FTC*, 676 F.2d 364, 370

Opinion of the Commission

(9th Cir. 1982) (quoting *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952)). When determining whether an order is reasonably related to the unlawful practices so as to extend the order provisions beyond the specific products for which the challenged claims were made, the Commission considers “(1) the seriousness and deliberateness of the violation; (2) the ease with which the violative claim may be transferred to other products; and (3) whether the respondent has a history of prior violations.” *Stouffer Foods Corp.*, 118 F.T.C. 746, 811 (1994); *see also Telebrands Corp v. FTC.*, 457 F.3d 354, 358 (4th Cir. 2006); *Kraft*, 970 F.2d at 326. “The reasonable relationship analysis operates on a sliding scale – any one factor’s importance varies depending on the extent to which the others are found. . . . All three factors need not be present for a reasonable relationship to exist.” *Telebrands*, 457 F.3d at 358-59.

We first consider the seriousness and deliberateness of the violation. California Naturel’s express representations marketing its sunscreen as an “all natural” product despite containing eight percent dimethicone suggest deliberate action. *See Stouffer Foods*, 118 F.T.C. at 812. Even after the company learned of the FTC’s concerns and added language to its website in 2016 disclosing that dimethicone is a synthetic ingredient, California Naturel continued to claim that Sunscreen SPF 30 is “all natural.” *See ECM BioFilms*, 2015 WL 6384951, at *65 (“awareness of concern” and a “calculated choice” of revised marketing that conveyed “essentially the same” claims suggests deliberateness of conduct); *see also Stouffer Foods*, 118 F.T.C. at 813-14 (awareness of inappropriateness of claim and that wording was ‘a delicate matter’ suggests deliberateness of conduct that supports fencing-in). Next, we examine the ease with which California Naturel’s claims may be transferred from its Sunscreen SPF 30 to other products. There is no question that California Naturel could readily assert similar “all natural” claims to advertise other products it markets. *See FTC v. Colgate-Palmolive*, 380 U.S. 374, 394-95 (1965); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392, 394-95 (9th Cir. 1982); *POM Wonderful*, 2013 WL 268926, at *64. Finally, although the limited record in this case does not show that California Naturel has a history of prior violations, the other two factors weigh in favor of restraining the company’s conduct in the future. We therefore conclude that the prohibited

Opinion of the Commission

misrepresentations described in Part I of the Final Order bear a reasonable relationship to California Naturel's violations of the FTC Act.

California Naturel argues that an order is unnecessary in light of the addition of the disclaimer on California Naturel's website and because California Naturel allegedly no longer sells Sunscreen SPF 30. For the reasons discussed above, we find California Naturel's disclaimer inadequate to render its "all natural" claim truthful and non-misleading. Moreover, California Naturel has not provided any evidence to support its assertion that it has stopped selling Sunscreen SPF 30. In any event, even if we accept that these sales have ceased, the Commission has authority to enter an order where "the challenged practices have been voluntarily abandoned or revised." *Am. Home Prods. Corp.*, 98 F.T.C. 136, 406 (1981); *Fedders Corp. v. FTC*, 529 F.2d 1398, 1403 (2d Cir. 1976) ("The fact that [the advertiser] may have discontinued the offending practice before the Commission issued the complaint . . . does not bar a cease-and-desist order, where the public interest otherwise requires it."), *aff'd*, 695 F.2d 681 (3d Cir. 1982); *Libbey-Owens-Ford Glass Co. v. FTC*, 352 F.2d 415, 418 (6th Cir. 1965). An order is appropriate when, as is the case here, a respondent could resume sales of the product in question in the future. *See United States v. Bldg. Inspector of Am., Inc.*, 894 F. Supp. 507, 521 (D. Mass. 1995) (finding injunction appropriate when company had ceased operation but "remains a going concern and could resume at any time").

Finally, Parts II-V of the Final Order impose certain record-keeping, notification, and reporting requirements, and properly serve to facilitate administration of the order. *See FTC v. Direct Mktg. Concepts, Inc.*, 648 F. Supp. 2d 202, 213 (D. Mass. 2009) ("Courts have also included monitoring provisions in final orders in FTC cases to ensure compliance with permanent injunctions."); *FTC v. Think Achievement Corp.*, 144 F. Supp. 2d 1013, 1018 (N.D. Ind. 2000) (ordering record retention, notification of changed employment or residence, access to premises, and monitoring); *FTC v. US Sales Corp.*, 785 F. Supp. 737, 753 (N.D. Ill. 1992) ("The order should also require Defendants to report their addresses and places of employment or business, and any subsequent changes in this information to the F.T.C."). Part VI

Opinion of the Commission


provides that the Final Order will terminate in twenty years. *See US Sales Corp.*, 785 F. Supp. at 754 (recognizing that “a sustained period of monitoring by the F.T.C.” may be needed “to ensure adequate compliance”).

IV. Conclusion

For the reasons explained above, we have concluded as a matter of law that California Naturel’s “all natural” claims are false and misleading and violate Sections 5 and 12 of the FTC Act. Accordingly, we issue the accompanying Final Order.

Opinion of the Commission

Attachment A




[OUR STORY](#)
[PRODUCTS](#)
[INGREDIENTS](#)
[BLOG](#)
[CONTACT](#)

Sunscreen SPF 30

This soft, luxurious and non-oily all natural sunscreen is formulated with Royal Oregano, Minerals and Zinc Oxide to protect the skin from both UVA and UVB rays. It is enriched with antioxidants from botanical sources such as: Shea Butter, Pomegranate Extract and Marigold Flower Extract to increase skin hydration, and protect it from environmental damage.

- Protects from UVA and UVB rays
- Increases skin hydration
- Enriched with antioxidants



\$35 / 70 ml / 2.3 fl. oz.

Quantity
 1

2

3

4

5

ADD TO CART

Directions
Apply liberally 15 minutes before sun exposure. Reapply immediately after swimming, sweating or towel drying, and at least every 2 hours.

What to Expect

- **Texture:** medium-weight cream
- **Scent:** subtle herbal scent
- **Sensation on skin:** non sticky, non oily, matte finish


Ingredients

Active Ingredients:
Zinc Oxide 20% (Sunscreen)

Inactive Ingredients:
Butyrospermum parkii (shea) butter, caprylic/capric triglyceride, carrageenan, Calthamus trichotomus (puffblower) seed oil, cetearyl alcohol, cetearyl glucoside, cetyl palmitate, coco-caprylate, dimethicone, glucose, glucose oxidase, Helianthus annuus (sunflower) seed oil, isosorbate acid, lactoperoxidase, lecithin, lysine/ethinyl, methylcellulose, polyglyceryl-3 polyricinoleate, polyhydroxy stearic acid, Punica granatum (pomegranate) fruit extract, pullulan, Rosmarinus officinalis (rosemary) leaf extract, scirobium gum, Sea Salt extract (Glebeal Organic Mineral Water), sorbitan oleate, sorbitan palmitate, stearyl alcohol, Tagetes erecta flower extract, xanthan gum

The FTC requires us to add the following: "Dimethicone, a synthetic ingredient, is 8% of the sunscreen formula, the remaining 92% are natural products."

You might also like...



Lip Balm

\$7

Broad-spectrum protection UVA/UVB

Opinion of the Commission

Attachment B



ABOUT PRODUCTS NUTRITION FAQ CONTACT

Our Ingredients

California Naturel uses only the finest natural ingredients and offers ingredients based on science. All our formulations are based on science and our products are made with natural ingredients. Our ingredients have been thoughtfully selected for their high quality properties, safety, purity, and availability.



Final Order

FINAL ORDER

The Commission has heard this matter upon the Motion for Summary Decision filed by Complaint Counsel, and upon the briefs and responses filed in support thereof and in opposition thereto. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to grant the Motion for Summary Decision. Accordingly,

IT IS ORDERED that the following Order to cease and desist be, and it hereby is, entered:

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “respondent” shall mean California Naturel, Inc., a corporation, its successors and assigns, and its officers, agents, representatives, and employees.
- B. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not make any representation, expressly or by implication, including through the use of a product name, trademark, or trade name, about:

- A. whether such product is all natural or 100% natural;
- B. the extent to which such product contains any natural or synthetic ingredient or component;

Final Order

- C. the ingredients or composition of such product; or
- D. the environmental or health benefits of such product,

unless the representation is non-misleading, including that, at the time such representation is made, the respondent possesses and relies upon competent and reliable evidence, which when appropriate based on the expertise of professionals in the relevant area must be competent and reliable scientific evidence, that is sufficient in quality and quantity based on standards generally accepted in the relevant fields when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true. For the purposes of this Provision:

1. “competent and reliable evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results; and
2. “competent and reliable *scientific* evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.

II.

IT IS FURTHER ORDERED that respondent California Naturel, Inc., and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;

Final Order

- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

III.

IT IS FURTHER ORDERED that respondent California Naturel, Inc., and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent must maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

IV.

IT IS FURTHER ORDERED that respondent California Naturel, Inc., and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about

Final Order

which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re California Naturel, Docket No. 9370.

V.

IT IS FURTHER ORDERED that respondent California Naturel, Inc., and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VI.

IT IS FURTHER ORDERED that the final and effective date of this Order is the 60th day after this Order is served. This Order will terminate on December 5, 2036, or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Provision in this Order that terminates in less than 20 years;
- B. This Order if such complaint is filed after the Order has terminated pursuant to this Provision. If such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or

Concurring and Dissenting Statement

upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

**Statement of Commissioner Maureen K. Ohlhausen
Concurring in Part and Dissenting in Part**

This matter is before us on a motion for summary decision filed by complaint counsel and opposed by California Naturel. When deciding such a motion, we resolve all factual ambiguities and draw all justifiable inferences in the light most favorable to the party opposing the motion. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970).

Prior to early 2016, California Naturel expressly marketed its sunscreen as an “all natural” product and stated that it “uses only the purest, most luxurious and effective ingredients found in nature.” The company does not dispute that it made these claims and admits that its sunscreen contained a substantial amount (eight percent) of a synthetic ingredient, dimethicone. Based on these undisputed facts, I agree with my colleagues that those unqualified “all natural” claims were false and misleading in violation of Sections 5 and 12 of the FTC Act at the time they were made. I also agree that the recent addition by California Naturel of a disclaimer on its website does not excuse deception that has already occurred. *See, e.g., Libbey-Owens-Ford Glass Co. v. FTC*, 352 F.2d 415, 418 (6th Cir. 1965). Thus, I would

Concurring and Dissenting Statement

grant summary judgment and impose a remedial order solely on this basis.¹

I do not support, however, the Commission's grant of summary decision regarding the effect of California Naturel's later-added disclaimer and new product stickers. First, that question is not properly before the Commission because it is immaterial to resolving the present motion. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) ("Factual disputes that are irrelevant or unnecessary will not be counted" in resolving summary-judgment motions.); WRIGHT & MILLER, 10A FED. PRAC. & PROC. CIV. § 2725.1 (4th ed. 2016) ("[A] factual issue that is not necessary to the decision is not material within the meaning of Rule 56(a) and a motion for summary judgment may be granted without regard to whether it is in dispute."). Complaint counsel moved for summary decision on the ground that California Naturel violated Sections 5 and 12 of the FTC Act because "it expressly claimed that its Sunscreen SPF 30 was 'all natural'" and "admitted in a submission to the Commission on May 6, 2016, that its Sunscreen SPF 30 formula contains 8% Dimethicone, a synthetic ingredient." MSD, p. 1. We can—and do—grant summary decision on that basis. It is irrelevant to the pending motion whether California Naturel subsequently disclosed to consumers that the product contains eight percent of a synthetic ingredient.

Further, the question whether California Naturel's subsequent disclaimers and product stickers provided adequate disclosure would be a fact question that the Commission should not resolve on summary decision. Some courts have granted summary judgment in matters where disclaimers were in fine print and distant from the challenged claims. *See, e.g., FTC v. Cyberspace.com, LLC*, 453 F.3d 1196 (2006). But other courts have denied summary judgment where there is a genuinely disputed factual issue about whether disclaimers are prominent and easily visible. *See, e.g., FTC v. Dalbey*, No. 11-cv-1396, 2013 WL 934986 (D. Colo. Mar. 11, 2013). As noted above, the standard for summary decision requires us to resolve all factual

¹ I support the fencing-in relief based on the ease with which California Naturel's claims may be transferred from its Sunscreen SPF 30 to other products.

Concurring and Dissenting Statement

ambiguities and draw all justifiable inferences in the light most favorable to California Naturel, the party opposing the motion. Given this standard and the facts as presented, I believe the question of whether the later-added disclosure and new product stickers adequately qualified the “all natural” claim is a genuinely disputed material fact and thus not appropriate for summary decision in this matter.

For those reasons, I dissent on that portion of the Commission opinion.

Complaint

IN THE MATTER OF

GENERAL MOTORS LLCCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4596; File No. 152 3101**Complaint, December 8, 2016 – Decision, December 8, 2016*

This consent order addresses General Motors, LLC's failure to disclose issues with used motor vehicles. The complaint alleges that the respondent has represented that the used motor vehicles it markets and advertises have been subject to rigorous inspection, including for safety issues, but has failed to disclose that these used motor vehicles are subject to open recalls for safety issues. The complaint further alleges that when the respondent allegedly advertised Certified Pre Owned ("CPO") vehicles that are subject to open recalls for safety issues, it provided no accompanying clear and conspicuous disclosure of this fact. The consent order requires the respondent to notify every consumer who purchased a CPO used motor vehicle from a GM dealership between July 1, 2013 and the date of entry of the Order, and whose vehicle has not had the open recall repaired, that (1) the consumer's vehicle has been recalled for safety issues that have not been repaired, and (2) how to get the vehicle repaired.

Participants

For the *Commission: Courtney Estep, Peter Lamberton, Michael White, and Evan Zullow.*

For the *Respondent: Lindsey Barns, Lawrence Lines, Lorelei Misajlovich, and James Williams, in-house counsel.*

COMPLAINT

The Federal Trade Commission, having reason to believe that General Motors Company ("Respondent" or "GM") has violated provisions of the Federal Trade Commission Act ("FTC Act"), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a Delaware limited liability company with its principal office or place of business at 300 Renaissance Center,

Complaint

Detroit, MI 48265. Respondent has marketed and advertised for sale used GM motor vehicles.

2. The acts or practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3. Since at least November 2014, Respondent has disseminated or has caused to be disseminated advertisements promoting the sale of “Certified Pre-Owned Vehicles.” Respondent establishes criteria for certifying pre-owned vehicles, which are then inspected and sold by Respondent’s local dealerships. Respondent provides consumers a 12-month/12,000-mile “bumper to bumper” warranty for each Certified Pre-Owned Vehicle.

4. Respondent’s advertisements for Certified Pre-Owned Vehicles include, but are not necessarily limited to, advertisements and marketing materials posted on the website www.gmcertified.com, excerpts of which are attached as Exhibits A through F. On this website, Respondent advertises Certified Pre-Owned Vehicles that are available at its affiliated local dealerships by, among other things, allowing consumers to search for individual cars and providing descriptions of these cars.

5. Respondent’s advertisements on its website have included the following claims regarding its Certified Pre-Owned Vehicles:

**“We check it, so you don't have to.
172-Point Inspection and Reconditioning**

Our detailed, 172-Point Vehicle Inspection and Reconditioning Process is one of the most comprehensive in the industry. Before any Chevy, Buick, or GMC used vehicle earns the title of Certified Pre-Owned, it must first meet all of our rigorous standards.

Our 172-Point Vehicle Inspection and Reconditioning Process is conducted only by highly trained technicians and adheres to strict,

Complaint

factory-set standards to ensure that every vehicle's engine, chassis, and body are in excellent condition. The technicians ensure that everything from the drivetrain to the windshield wipers is in good working order, or they recondition it to our exacting standards. The vehicles are road-tested, put up on a lift for a complete underbody and frame inspection, and then completely checked for any cosmetic flaws.

And we do check it all. From the engine block to the shocks, right down to the floor mats, no major system is overlooked. If it fails a single point, we completely recondition it – or it won't be Certified."

Exhibit A.

6. Respondent also provides on its website a checklist of all items that its local dealers review as part of Respondent's 172-point inspection. This checklist includes "open recalls":

REVIEW THE VEHICLE'S HISTORY: PASS
 FAIL
 . . .
 Open Recalls

Exhibit B.

7. Even though it has made the claims set forth in Paragraphs 5 and 6, until at least June 2015, Respondent has advertised on its website numerous Certified Pre-Owned vehicles available at its local dealerships with open recalls for safety issues.

8. In some instances, these open safety recalls have included recalls for defects that can cause serious injury. For example, Respondent has advertised Certified Pre-Owned vehicles that have an open safety recall for a key ignition switch defect, which can affect engine power, power steering, braking, and airbag deployment, thereby increasing the risk of a crash and occupant injury. Respondent also has advertised Certified Pre-Owned

Complaint

vehicles that have an open safety recall for a defect associated with the body control module connection system, which can result in a variety of issues with the brakes that may increase the risk of a crash. Respondent also has advertised Certified Pre-Owned vehicles that have an open safety recall for a defect associated with the chassis electronic module, which can cause engine stalls, thereby increasing the risk of a crash.

9. In numerous instances, until at least June 2015, when Respondent has advertised Certified Pre-Owned vehicles that are subject to open recalls for safety issues making the claims set forth in Paragraph 5 and 6, it has provided no accompanying clear and conspicuous disclosure of this fact.

10. When consumers search for particular categories of vehicles on Respondent's website, there is no disclosure of open safety recalls. An example of such search results includes the following:

CERTIFIED PRE-OWNED BARKLEY BUICK GMC

VEHICLE SEARCH DEALER LOCATOR CERTIFIED ADVANTAGE VEHICLE MODELS

Search Results
63 listings match your search within 100 miles of 35405. VEHICLES PER PAGE: 50 PAGE: 1 of 2 GO

YOUR SEARCH
35405 UPDATE
Search All Makes
Search All Models
ADVANCED FILTER

DISTANCE FROM 35405
100 miles

YEAR
2014 to 2014

PRICE
Any to Any

MILEAGE
Under 30,000 miles

EXTERIOR COLOR
All Colors

BODY STYLE
 Car SUV/Crossover Truck Van

SEAT CAPACITY
All Seat Capacities

FUEL TYPE
All Fuel Types

Vehicle Image	Year Make Model	Price	Mileage	Color	Distance from 35405	More Details
	2014 GMC TERRAIN SLT-2	\$28,995	16,908	Silver	2.19 miles from 35405	MORE DETAILS
	2014 BUICK ENCLAVE LEATHER	\$34,995	22,709	Red	2.19 miles from 35405	MORE DETAILS
	2014 BUICK ENCLAVE LEATHER	\$37,995	25,890	Black	2.19 miles from 35405	MORE DETAILS
	2014 CHEVROLET EQUINOX 1LT	\$23,995	29,366	White	2.19 miles from 35405	MORE DETAILS
	2014 BUICK ENCLAVE LEATHER	\$36,995	18,946			MORE DETAILS

Exhibit C.

Complaint

11. When consumers have viewed specific vehicle listings on Respondent’s website, there is no disclosure regarding open safety recalls. An example of a listing for a Certified Pre-Owned vehicle with an open safety recall includes the following:

2010 CHEVROLET IMPALA LT
\$15,991 Market Based Price
 Mileage: 17,275
 Exterior Color: N/A
 Interior Color: N/A
 12 months/120,000 miles additional Certified Pre-Owned Bumper-to-Bumper Limited Warranty¹
 Info about how to get a free vehicle history report.
 Contact Dealer

Vehicle Features

SPECIFICATIONS TECHNICAL ELECTRONIC SAFETY INTERIOR EXTERIOR BENEFITS

Vehicle Specifications

VIN	2G1WB5EK2A1Z09685	TRANSMISSION	4-Speed Automatic
BODY	4 Door Sedan	ENGINE	3.5L V6 12V MPFI OHV Flexible Fuel
DOORS	4	DRIVETRAIN	Front-Wheel Drive
SEATING CAPACITY	N/A	PAYLOAD CAPACITY	N/A
WHEEL BASE	110.5		

1.9% APR
 1.9% APR for well-qualified buyers on Chevrolet Cruze, Buick LaCrosse and GMC Terrain.

DRAPER CHEVROLET COMPANY
 (989) 790-0800
 4200 BAY RD
 SAGINAW, MI 48603

DRAPER CHEVROLET COMPANY
 (989) 790-0800
 View Inventory Contact Dealer

48603
 Get Directions

¹Dealer sets price. Tax, title, license, dealer fees, and other optional equipment extra.
²Mileage comes first, from date of purchase. See participating dealer for limited warranty details.
³Coverage example is based on current available data. Contact your dealer for actual coverage amounts and full limited warranty details.

Information
 Contact Us
 FAQ
 YouTube

Tools
 Trade-In Estimator
 Monthly Payment Calculator

GM Sites
 Chevrolet.com
 Buick.com
 GMC.com
 More GM Sites

Legal
 Copyright/Trademark
 Privacy Statement
 Ad Choices

© 2013 General Motors

Exhibit D.

12. Another example of a listing for a Certified Pre-Owned vehicle with an open safety recall appears as follows:

Complaint

2011 CHEVROLET CAMARO
\$27,654 Market Based Price
 Mileage: 24,260
 Exterior Color: Silver Ice Metallic
 Interior Color: N/A

12 months/12,000 miles additional Certified Pre-Owned Bumper-to-Bumper Limited Warranty¹

CARFAX Vehicle History Report

Want to find out the history of this 2011 Chevrolet Camaro? Like a Certified Pre-Owned car, truck, crossover or SUV in our or the dealer's inventory? Make sure its vehicle history report is flawless. Get a CARFAX[®] Vehicle History Report and protect yourself against used vehicles with costly hidden problems. Here's a preview of this Certified Pre-Owned vehicle's history:

- CARFAX 5-Owner
- No Total Loss Reported to CARFAX
- No Airbag Deployment Reported to CARFAX
- No Accidents / Damage Reported to CARFAX
- Vehicle Qualifies for the CARFAX Buyback Guarantee
- No Structural Frame Damage Reported to CARFAX
- No Indication of an Odometer Rollback

Get a Free CARFAX Vehicle History Report

Vehicle Features

Vehicle Specifications

VIN	2G3FT1EW89120181	TRANSMISSION	N/A
BODY	2 Door Coupe	ENGINE	6.2L V8 16V MPPI OHV
DOORS	2	DRIVETRAIN	Rear-Wheel Drive with Limited-Slip Differential
SEATING CAPACITY	4	PAYLOAD CAPACITY	N/A
WHEEL BASE	112.3		

1.9% APR
 1.9% APR for well-qualified buyers on Chevrolet Cruze, Buick LaCrosse and GMC Terrain.

CERTIFIED PRE-OWNED

Information
 Contact Us
 FAQ
 YouTube

Tools
 Trade-In Estimator
 Monthly Payment Calculator

GM Sites
 Chevrolet.com
 Buick.com
 GMC.com
 More GM Sites

Legal
 Copyright/Trademark
 Privacy Statement
 Ad Choices

© 2013 General Motors

Exhibit E.

13. In some listings for Certified Pre-Owned vehicles, such as the example shown in Paragraph 12, there is a line that reads “CARFAX Vehicle History Report.” Underneath that line,

Complaint

Respondent provides a “preview” of the vehicle history report. If a consumer were to locate this information, understand that one could click on the line reading “Get a Free CARFAX Vehicle History Report” to access additional information, and click on the line, a vehicle history report potentially containing information about an open safety recall would appear.

14. In many instances in which a Certified Pre-Owned vehicle is subject to an open safety recall, such as the example shown in Paragraph 12, GM’s preview of the vehicle history report has excluded that information.

15. In contrast, in many instances in which a Certified Pre-Owned vehicle has no open safety recall, GM’s preview of the vehicle history report includes that information. An example of such a listing includes the following:

2012 CHEVROLET CAMARO 2SS
\$27,950 (MSRP) (dealer set price)
 Mileage: 16,985
 Exterior Color: Ashen Gray Metallic
 Interior Color: N/A

Certified Pre-Owned Warranty
 See the full number of months available on the Bumper-to-Bumper Limited Warranty cover on a Certified Pre-Owned vehicle. The full number is the aggregate number of months available on the original warranty added to our Certified Pre-Owned 12-month/12,000-mile Bumper-to-Bumper warranty.
 Remaining warranty at time of purchase:
15 months/31,111 miles*
*This is the amount of factory Bumper-to-Bumper Limited Warranty remaining on this vehicle. Actual performance may vary. ©2012 GM
3 months/19,111 miles remaining in the factory warranty
12 months/12,000 miles additional Certified Pre-Owned Bumper-to-Bumper Limited Warranty¹

CARFAX® Vehicle History Report
 Want to find out the history of this 2012 Chevrolet Camaro?
 Like a Certified Pre-Owned car, truck, crossover or SUV, in use or the dealer's inventory? Take a look at the vehicle history report to help you. Get a CARFAX® Vehicle History Report and protect yourself against used vehicles with costly hidden conditions. Here's a preview of this Certified Pre-Owned vehicle's history:

- ✓ CARFAX 1-Owner
- ✓ No Total Loss Reported to CARFAX
- ✓ No Airbag Deployment Reported to CARFAX
- ✓ No Accidents / Damage Reported to CARFAX
- ✓ Vehicle Qualifies for the CARFAX Buyback Guarantee
- ✓ No Structural Frame Damage Reported to CARFAX
- ✓ No Indication of an Odometer Rollback
- ✓ No Manufacturer Recalls Reported to CARFAX

Vehicle Features
 SPECIFICATIONS MECHANICAL ELECTRONIC SAFETY INTERIOR EXTERIOR BENEFITS

Vehicle Specifications

VIN	2G1FK1E13C9162721	TRANSMISSION	6-Speed Automatic
BODY	2 Door Coupe	ENGINE	6.2L V8 10V MPFI OHV
DOORS	2		

Complaint

The screenshot shows a vehicle configuration interface with the following details:

- SEATING CAPACITY: 4
- WHEEL BASE: 112.3
- DRIVE (HAZ): Four-Wheel Drive with Limited-Slip Differential
- PAYLOAD CAPACITY: N/A

Below the configuration details, there are three small footnotes:

- ¹ Dealer sets up tax, title, license charges, fees, and other optional equipment extra.
- ² Mileage varies from first drive date of purchase. See participating dealer for limited warranty details.
- ³ Coverage example is based on current available data. Contact your dealer for actual coverage amounts and full details/warranty details.

At the bottom of the page, there are four columns of links:

- Information:** Contact Us, FAQ, YouTube
- Tools:** ¹Scale Estimator, ²Monthly Payment Calculator
- GM Sites:** Chevrolet.com, Buick.com, GMC.com, More GM Sites
- Legal:** Copyright/Trademark, Privacy Statement, and Choices

The GM logo and "© 2015 General Motors" are visible in the bottom left corner.

Exhibit F.**VIOLATION OF THE FEDERAL TRADE COMMISSION
ACT****Count I**

16. In connection with the marketing or advertising of used GM motor vehicles, Respondent has represented, directly or indirectly, expressly or by implication, that used motor vehicles it advertises have been subject to rigorous inspection, including for safety issues.

17. In numerous instances in connection with the representation set forth in Paragraph 16, Respondent has failed to disclose, or disclose adequately, that used vehicles it advertises are subject to open recalls for safety issues.

18. Respondent's failure to disclose, or disclose adequately, the material information set forth in Paragraph 17 above, in light of the representation described in Paragraph 16, above, constitutes a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

THEREFORE, the Federal Trade Commission, this eighth day of December, 2016, has issued this complaint against Respondent.

By the Commission.

Complaint

Exhibit A

Car Inspection: 172-Point Inspection | GM Certified Pre-Owned

http://www.gmcertified.com/certified-benefits/vehicle-car-inspection



- OVERVIEW (CERTIFIED-BENEFITS)
- BUILT-IN VALUE (CERTIFIED-BENEFITS/BUILT-IN-VALUE)
- TWO-YEAR WARRANTY (CERTIFIED-BENEFITS/SAVED-CAR-WARRANTY)
- SCHEDULED MAINTENANCE (CERTIFIED-BENEFITS/USED-CAR-MAINTENANCE-PLAN)
- 172-POINT INSPECTION (CERTIFIED-BENEFITS/VEHICLE-CAR-INSPECTION)
- 3-DAY/50-MILE GUARANTEE (CERTIFIED-BENEFITS/CUSTOMER-SATISFACTION-3-DAY-50-MILE)
- HISTORY REPORT (CERTIFIED-BENEFITS/VEHICLE-HISTORY-REPORT)
- ONSTAR/RSIDUM TRIAL OFFERS (CERTIFIED-BENEFITS/ONSTAR-RADIO-ONSTAR-TRIAL)
- VIDEOS (CERTIFIED-BENEFITS/VIDEOS)

We check it, so you don't have to. 172-Point Inspection and Reconditioning

Our detailed, 172-Point Vehicle Inspection and Reconditioning Process is one of the most comprehensive in the industry. Before any Chevy, Buick, or GMC used vehicle earns the title of Certified Pre-Owned, it must first meet all of our rigorous standards.

Our 172-Point Vehicle Inspection and Reconditioning Process is conducted only by highly trained technicians and adheres to strict, factory-set standards to ensure that every vehicle's engine, chassis, and body are in excellent condition. The technicians ensure that everything from the drivetrain to the windshield wipers is in good working order, or they recondition it to our exacting standards. The vehicles are road tested, put up on a lift for a complete underbody and frame inspection, and then completely checked for any cosmetic flaws.

And we do check it all. From the engine block to the hood, right down to the floor mats, no major system is overlooked. If it fails a single point, we completely recondition it—or it won't be Certified.

View the points of our inspection below.
 Download a copy of the 172-Point Vehicle Inspection and Reconditioning Process (Content/pdf/certified-advantage/CPO_172-PointInspectionChecklist022913.pdf)

Find Vehicles Start your Search Now

Zip Code (Required)

Search All Makes

Search All Models

SEARCH NOW

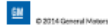
ZERO%EVENT

0% APR for well-qualified buyers on Chevrolet Cruze, Equinox, Impala, and Malibu. Buick LaCrosse and Verano, and GMC Terrain.

APR Details

(offers/ap-special)

Information Contact Us (start-over) FAQ (frequently-asked-questions) Your Site (http://www.gm.com) User (gmcertified)	Tools Trade-In Estimator (vehicle-trade-in-estimator) Monthly Payment Calculator (monthly-vehicle-payment-calculator)	GM Sites Chevrolet.com (http://www.chevrolet.com/) Buick.com (http://www.buick.com/) GMC.com (http://www.gmc.com/) More GM Sites (gm.com)	Legal Copyright/Trademark (http://www.gm.com/copyright-trademark) Privacy Statement (http://www.gm.com/privacy/privacyStatement.html) All Cookies
--	--	--	---



Complaint

Exhibit B

CERTIFIED PRE-OWNED
CHEVROLET BUICK GMC
172-POINT VEHICLE INSPECTION AND RECONDITIONING

Investigation Date: _____ Mileage: _____
 Year: _____ Make: _____ Model: _____
 VIN: _____
 Dealer Name: _____
 Dealer Address: _____
 Dealer Phone: _____

Reference Number: _____
 License Plate: _____
 State: _____
 Inspection Date: _____
 Inspector Name: _____
 Signature: _____

Verify that inspection has undergone repair and re-inspection in accordance with the CCC Certified Pre-Owned Vehicle process and that repairs are done in accordance with the CCC 172-Point Vehicle Inspection Report.

MAINTENANCE, CONT.

ROAD TEST

FUNCTIONAL, CONT.

INTERIOR

EXTERIOR

MAINTENANCE

DETAILING

FUNCTIONAL

ENGINE COMPARTMENT

UNDER VEHICLE

HYBRID VEHICLES

Exhibit B, Page 3

Complaint

Exhibit C

http://www.gmcertified.com/vehicle/list... Locate Used Cars, Trucks &... X

CERTIFIED PRE-OWNED
SEARCH VEHICLE SEARCH DEALER LOCATOR CERTIFIED ADVANTAGE VEHICLE MODELS

Search Results
63 listings match your search within 100 miles of 35405

YOUR SEARCH: 35405
SEARCH ALL MODELS
ADVANCED FILTER

DISTANCE FROM 35405: 100 miles
YEAR: 2014
PRICE: Any
MILEAGE: Under 30,000 miles
EXTENSION COLOR: All Colors
BODY STYLE: Car SUV/Crossover Truck Van
SEAT CAPACITY: All Seat Capacities
FUEL TYPE: All Fuel Types

2014 GMC TERRAIN SLT-2
\$28,995
Mileage: 16,908
Color: Silver
BARKLEY BUICK GMC CADILLAC, INC
2.19 miles from 35405

2014 BUICK ENCLAVE LEATHER
\$34,995
Mileage: 22,799
Color: Red
BARKLEY BUICK GMC CADILLAC, INC
2.19 miles from 35405

2014 BUICK ENCLAVE LEATHER
\$37,995
Mileage: 25,890
Color: Black
BARKLEY BUICK GMC CADILLAC, INC
2.19 miles from 35405

2014 CHEVROLET EQUINOX 1LT
\$23,995
Mileage: 29,366
Color: White
BARKLEY BUICK GMC CADILLAC, INC
2.19 miles from 35405

2014 BUICK ENCLAVE LEATHER
\$36,995
Mileage: 18,945
BARKLEY BUICK GMC CADILLAC, INC

Exhibit C, Page 1

Complaint

Exhibit D



[Back to Results](#)

[Print Vehicle Details](#)



2010 CHEVROLET IMPALA LT

\$15,991 Market-Based Price*

Mileage: **17,275**

Exterior Color: **N/A**

Interior Color: **N/A**

12 months/12,000 miles additional Certified Pre-Owned Bumper-to-Bumper Limited Warranty¹

Info about how to get a free vehicle history report.

[Contact Dealer](#)

DRAPER CHEVROLET COMPANY
(989) 790-0800 [Visit Dealer Site](#)
4200 BAY RD
SAGINAW, MI 48603

[View Inventory](#) [Contact Dealer](#)



To get driving directions, please enter your address below.

[Get Directions](#)

1.9% APR
1.9% APR for well-qualified buyers on Chevrolet Cruze, Buick LaCrosse and GMC Terrain.
CERTIFIED PRE-OWNED CHEVROLET BUICK GMC [APR Details](#)

Vehicle Features

- SPECIFICATIONS**
- TECHNICAL
- ELECTRONIC
- SAFETY
- INTERIOR
- EXTERIOR
- BENEFITS

Vehicle Specifications

VIN	2G1WB5EK2A1209685	TRANSMISSION	4-Speed Automatic
BODY	4 Door Sedan	ENGINE	3.5L V6 12V MPFI On-V Flexible Fuel
DOORS	4	DRIVETRAIN	Front-Wheel Drive
SEATING CAPACITY	N/A	PAYLOAD CAPACITY	N/A
WHEEL BASE	110.5		

¹Dealer sets price. Tax, title, license, dealer fees, and other optional equipment extra.

²Whichever comes first, from date of purchase. See participating dealer for limited warranty details.

³Coverage example is based on current available data. Contact your dealer for actual coverage amounts and full limited warranty details.

Information

[Contact Us](#)
[FAQ](#)
[YouTube](#)

Tools

[Trade-In Estimator](#)
[Monthly Payment Calculator](#)

GM Sites

[Chevrolet.com](#)
[Buick.com](#)
[GMC.com](#)
[Here GM Sites](#)

Legal


[Copyright/Trademark](#)
[Privacy Statement](#)
[Ad Choices](#)




© 2010 General Motors

Complaint

Exhibit E



◀ Back to Results



2011 CHEVROLET CAMARO
\$27,654 Market Based Price*

Mileage: **24,260**

Exterior Color: **Silver Ice Metallic**
 Interior Color: **N/A**

12 months/12,000 miles additional Certified Pre-Owned Bumper-to-Bumper Limited Warranty¹

CARFAX® Vehicle History Report

CARFAX Want to find out the history of this 2011 Chevrolet Camaro? Use a Certified Pre-Owned car, truck, crossover or SUV in our or the dealer's inventory? Make sure its vehicle history report is flawless. Get a CARFAX® Vehicle History Report and protect yourself against used vehicles with costly hidden problems. Here's a preview of this Certified Pre-Owned vehicle's history:

- ✔ CARFAX 1-Owner
- ✔ No Total Loss Reported to CARFAX
- ✔ No Airbag Deployment Reported to CARFAX
- ✔ No Accidents / Damage Reported to CARFAX
- ✔ Vehicle Qualifies for the CARFAX Buyback Guarantee
- ✔ No Structural Frame Damage Reported to CARFAX
- ✔ No Indication of an Odometer Rollback


[Get a Free CARFAX Link to History Report](#)

[Print Vehicle Details](#)

LEN STOLER CHEVROLET-CADILLAC
 (410) 876-2233 [Call Dealer](#)

343 BALTIMORE BLVD
 WESTMINSTER, MD 21157

[View Inventory](#) [Contact Dealer](#)



To get driving directions, please enter your address below:

[Get Directions](#)

1.9% APR

1.9% APR for well-qualified buyers on Chevrolet Cruze, Buick LaCrosse and GMC Terrain.

CERTIFIED PRE-OWNED
GM

Vehicle Features

SPECIFICATIONS
TECHNICAL
ELECTRONIC
SAFETY
INTERIOR
EXTERIOR
BENEFITS

Vehicle Specifications

VIN	2G1FT1EW68R120381	TRANSMISSION	N/A
BODY	2 Door Coupe	ENGINE	6.2L V8 16V MPFI OHV
DOORS	2	DRIVETRAIN	Rear-Wheel Drive with Limited-Slip Differential
SEATING CAPACITY	4	PAYLOAD CAPACITY	N/A
WHEELBASE	112.3		

*Dealer sets price. Tax, title, license, dealer fees, and other optional equipment extra.
¹Vehicle comes first, from date of purchase. See participating dealer for limited warranty details.

Complaint

Coverage examples based on current rates and data. Contact your dealer for actual coverage amounts and full on-road warranty details.

Information

Contact Us
FAQ
YouTube

Tools

Trade-In Estimator
Monthly Payment Calculator

GM Sites

Chevrolet.com
Buick.com
GMC.com
More GM Sites

Legal

Copyright/Trademark
Privacy Statement
Accessibility



© 2015 General Motors

Complaint

Exhibit F

2012 CHEVROLET CAMARO 2SS
\$27,950 Market Based Price
 Mileage: **16,985**
 Exterior Color: **Ashen Gray Metallic**
 Interior Color: **N/A**

Certified Pre-Owned Warranty
 See the total number of months available on the Bumper-to-Bumper Limited Warranty coverage of a Certified Pre-Owned vehicle. The total number is the aggregate number of months available on the original warranty added to our Certified Pre-Owned 12-month/12,000-mile Bumper-to-Bumper warranty.¹
 Remaining warranty at time of purchase:
15 months/31,111 miles¹
This is the amount of factory Bumper-to-Bumper Limited Warranty remaining on this vehicle. Anticipated Purchase Date: January 21, 2013.
3 months/19,111 miles remaining in the factory warranty.
12 months/12,000 miles additional Certified Pre-Owned Bumper-to-Bumper Limited Warranty.¹

CARFAX[®] Vehicle History Report
 Want to find out the history of this 2012 Chevrolet Camaro?
 Like a Certified Pre-Owned car, track, crossover or SUV in color or the dealer's inventory? Make sure its vehicle history report is flawless. Get a CARFAX[®] Vehicle History Report and protect yourself against used vehicles with costly hidden problems. Here's a preview of this Certified Pre-Owned vehicle's history.

- CARFAX 1-Owner
- Vehicle Qualified for the CARFAX Buyback Guarantee
- No Total Loss Reported to CARFAX
- No Structural Frame Damage Reported to CARFAX
- No Airbag Deployment Reported to CARFAX
- No Indication of an Odometer Rollback
- No Accidents / Damage Reported to CARFAX
- No Manufacturer Recalls Reported to CARFAX

1.9% APR
 1.9% APR for well-qualified buyers on Chevrolet Cruze, Buick LaCrosse and GMC Terrain.

Vehicle Features
 SPECIFICATIONS TECHNICAL ELECTRONIC SAFETY INTERIOR EXTERIOR BENEFITS

Vehicle Specifications

VIN	2G1FK1E11C9162721	TRANSMISSION	6-Speed Automatic
BODY	2 Door Coupe	ENGINE	6.2L V8 16V MPFI OHV
DOORS	2		

Exhibit F, Page 1

Complaint

SEATING CAPACITY	4	DRIVE SHAFT	Rear-Wheel Drive with Limited-Slip Differential
WHEEL BASE	112.3	PAYLOAD CAPACITY	N/A

*Dealer sets price. Tax, title, license, dealer fees, and other optional equipment extra.
†MSRP does not include destination charge. See participating dealer for limited warranty details.
‡Coverage example is based on current available data. Contact your dealer for actual coverage amounts and full limited warranty details.

Information Contact Us FAQ YouTube	Tools Trade-In Calculator Monthly Payment Calculator	GM Sites Chevrolet.com Buick.com GMC.com How GM Works	Legal Copyright/Trademark Privacy Statement Accessibility
--	---	--	---

 © 2013 General Motors

Decision and Order

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of certain acts and practices of the Respondent named in the caption. The Commission’s Bureau of Consumer Protection (“BCP”) prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violation of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statements by Respondent that it neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission’s Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. Respondent General Motors LLC is a Delaware limited liability company with its principal office or place of business at 300 Renaissance Center, Detroit, MI 48265.

Decision and Order

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For the purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “Respondent” or “GM” shall mean General Motors LLC, and its successors and assigns. The term “Respondent” shall not include a GM dealer if the dealer is not an agent or legal representative of Respondent for purposes of used vehicle advertising.
- B. “Advertisement” or “Advertising” shall mean a commercial message in any medium that directly or indirectly promotes a consumer transaction.
- C. “Clearly and conspicuously” means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
 1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be made through the same means through which the representation requiring the disclosure is presented.
 2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any

Decision and Order

accompanying text or other visual elements so that it is easily noticed, read, and understood.

3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
 4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
 5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.
 6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
 7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
- D. “Material” shall mean likely to affect a person’s choice of, or conduct regarding, goods or services.
- E. “Motor vehicle” shall mean:
1. Any self-propelled vehicle designed for transporting persons or property on a street, highway, or other road;
 2. Recreational boats and marine equipment;
 3. Motorcycles;
 4. Motor homes, recreational vehicle trailers, and slide-in campers; and

Decision and Order

5. Other vehicles that are titled and sold through dealers

I.

IT IS HEREBY ORDERED that Respondent and its officers, agents, representatives, and employees, directly or indirectly, in connection with the marketing or advertising of used motor vehicles shall not, in any manner, expressly or by implication:

- A. Represent that used motor vehicles that Respondent advertises are safe, have been repaired for safety issues, or have been subject to a rigorous inspection, unless:

1. The used motor vehicles are not subject to any open recalls relating to safety, and the representation is otherwise not misleading, or
2. Respondent discloses, clearly and conspicuously, and in close proximity to such representation, any qualifying information related to open recalls, including but not limited to:
 - a. the fact that used motor vehicles that it advertises may be subject to recalls for safety issues that have not been repaired, and
 - b. how consumers can determine whether an individual used motor vehicle has been subject to a recall for safety issues that has not been repaired,

and the representation is otherwise not misleading.

- B. Misrepresent the following:
 1. Whether there is or is not an open recall for safety issues on any used motor vehicle;

Decision and Order

2. Whether Respondent or GM dealers have repaired used motor vehicles for open safety recalls; and
3. Any other material fact about the safety of the used motor vehicles it advertises for sale.

II.

IT IS FURTHER ORDERED that Respondent, no later than February 6, 2017, must provide, by first class mail to the last known address of every consumer who purchased a Certified Pre-Owned motor vehicle with an open recall for a safety issue from a GM dealership between July 1, 2013 and December 8, 2016, and whose vehicle has not had the open recall repaired, a notice bearing Respondent's name and corporate logo that clearly and conspicuously notifies the consumer (i) that the consumer's vehicle has been recalled for safety issues that have not been repaired and (ii) how to get the vehicle repaired.

Respondent shall not include any advertising, marketing, or other promotional information in the notice. Moreover, the mailing shall not include any other documents.

If Respondent has sent such a notice after August 1, 2015, it shall be deemed to meet the requirements of this proviso.

III.

IT IS FURTHER ORDERED that Respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

- A. Each advertisement or other marketing material that makes any representation covered by the order unless, in comparison to an advertisement or other marketing material already maintained by Respondent pursuant to this Section, the advertisement or marketing material: (i) is a duplicate, or (ii) differs only in the description of the vehicle or other ways not related to any representations covered by this order, including a

Decision and Order

website which differs only with respect to individual vehicle details displayed in inventory or search page(s) of the site;

- B. All materials that were relied upon in disseminating the representation;
- C. All evidence in its possession or control that relates to used vehicle advertising and that contradicts, qualifies, or calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. Any documents reasonably necessary to demonstrate full compliance with each provision of this order, including but not limited to all documents obtained, created, generated, or that in any way relate to the requirements, provisions, or terms of this order, and all reports submitted to the Commission pursuant to this order.

IV.

IT IS FURTHER ORDERED that Respondent shall deliver a copy of this order to all current and future principals, corporate directors, Chief Executive Officer - General Motors, President - General Motors, Executive Vice President and President- North America, Executive Vice President - Global Manufacturing, Executive Vice President and General Counsel, Executive Vice President - Global Product Development and Purchasing, Executive Vice President and Chief Financial Officer, Senior Vice President - Human Resources, Executive Vice President and President - Cadillac, Vice President - Controller and Chief Accounting Officer, Executive Vice President and President - South America, Executive Vice President and President - Europe, Executive Vice President and President - GM China, and Executive Vice President and President - GM International Operations, and to all current and future managers, employees, agents, and representatives having supervisory responsibilities

Decision and Order

with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order, with any electronic signatures complying with the requirements of the E-Sign Act, 15 U.S.C. § 7001 *et seq.* Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580. The subject line must begin: *In re General Motors LLC*.

VI.

IT IS FURTHER ORDERED that Respondent, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

Analysis to Aid Public Comment

VII.

This order will terminate on December 8, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of this order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from General Motors, LLC. The proposed consent order has been placed on the public record for thirty (30) days for

Analysis to Aid Public Comment

receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

The respondent is an automobile manufacturer that sells the cars it manufactures through local franchise dealerships. According to the FTC complaint, the respondent has represented that the used motor vehicles it markets and advertises have been subject to rigorous inspection, including for safety issues, but has failed to disclose that these used motor vehicles are subject to open recalls for safety issues.

For instance, the respondent has posted advertisements on its website that make the following representations about vehicles that purportedly undergo a rigorous 172-point inspection:

We check it, so you don't have to.

172-Point Inspection and Reconditioning

Our 172-Point Vehicle Inspection and Reconditioning Process is conducted only by highly trained technicians and adheres to strict, factory-set standards to ensure that every vehicle's engine, chassis, and body are in excellent condition. The technicians ensure that everything from the drivetrain to the windshield wipers is in good working order, or they recondition it to our exacting standards. The vehicles are road-tested, put up on a lift for a complete underbody and frame inspection, and then completely checked for any cosmetic flaws.

And we do check it all. From the engine block to the shocks, right down to the floor mats, no major system is overlooked. If it fails a single point, we completely recondition it – or it won't be Certified.

Even though it makes such claims, the respondent has allegedly advertised on its website numerous Certified Pre Owned

Analysis to Aid Public Comment

(“CPO”) vehicles that were subject to open recalls for safety issues. In numerous instances, when the respondent allegedly advertised CPO vehicles that are subject to open recalls for safety issues, it provided no accompanying clear and conspicuous disclosure of this fact. The proposed complaint alleges that this failure to disclose constitutes a deceptive act or practice under Section 5 of the FTC Act.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices in the future. Part I prohibits the respondent from representing that used motor vehicles it markets or advertises are safe, have been repaired for safety issues, or have been subject to a rigorous inspection unless the used motor vehicles are not subject to any open recalls for safety issues or the respondent discloses, clearly and conspicuously, in close proximity to such representation, any material qualifying information related to open recalls for safety issues. Part II is a provision that orders the respondent to notify every consumer who purchased a CPO used motor vehicle from a GM dealership between July 1, 2013 and the date of entry of the Order, and whose vehicle has not had the open recall repaired, that (1) the consumer’s vehicle has been recalled for safety issues that have not been repaired, and (2) how to get the vehicle repaired.

Parts III through VII of the proposed order are reporting and compliance provisions. Part III requires the respondent to maintain for five years, and produce to the Commission upon demand, any relevant ads and associated documentary material. Part IV is an order distribution provision that requires the respondent to provide the Order to certain current and future principals, officers, and directors, and to all current employees, agents, and representatives having responsibilities with respect to the subject matter of the Order. Part V requires the respondent to notify the Commission of corporate changes that may affect compliance obligations. Part VI requires the respondent to submit a compliance report to the Commission 60 days after entry of the order, and also additional compliance reports within 10 business days of a written request by the Commission. Part VII “sunsets” the order after twenty years, with certain exceptions.

Analysis to Aid Public Comment

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

Complaint

IN THE MATTER OF

LITHIA MOTORS, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4597; File No. 152 3102**Complaint, December 8, 2016 – Decision, December 8, 2016*

This consent order addresses Lithia Motors, Inc.'s failure to disclose open recalls for safety issues. The complaint alleges that respondent has represented that the used motor vehicles it sells have been subject to rigorous inspection, including for safety issues, but has failed to disclose that the used motor vehicles it sells are subject to open recalls for safety issues. The consent order prohibits the respondent from representing that used motor vehicles it offers for sale are safe, have been repaired for safety issues, or have been subject to an inspection for issues related to safety unless the used motor vehicles are not subject to any open recalls for safety issues or the respondent discloses, clearly and conspicuously, in close proximity to such representation, any material qualifying information related to open recalls for safety issues.

Participants

For the *Commission*: Courtney Estep, Peter Lamberton, Michael White, and Evan Zullow.

For the *Respondents*: Mike Goodman, Lucy Morris, and Joel Winston, Hudson Cook LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that Lithia Motors, Inc., a corporation (“Respondent”), has violated provisions of the Federal Trade Commission Act (“FTC Act”), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is an Oregon corporation with its principal office or place of business at 150 North Bartlett Street, Medford OR 97591. Respondent has marketed, advertised, offered for sale, and sold used motor vehicles.

Complaint

2. The acts or practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3. Since at least January 2015, Respondent has disseminated or has caused to be disseminated advertisements promoting the sale of used motor vehicles.

4. Respondent’s advertisements include, but are not necessarily limited to, advertisements and marketing materials posted on the website www.lithia.com, excerpts of which are attached as Exhibits A through D. On its website, on a page prominently touting the features of the dealer-backed, Lithia “60 Day/3,000 Mile” warranty Lithia claims that its “60 Day/3,000 Mile vehicles are put through an exhaustive 160-checkpoint Quality Assurance Inspection.” It goes on to state, “We want the vehicles to look, feel and smell as new as possible. We inspect everything from the tires and the brakes to suspension, drive train, engine components and even the undercarriage. Only vehicles that pass all 160 checkpoints (as appropriate to vehicle content) can receive our 60 Day/3,000 miles Limited Warranty.”

Exhibit A.

5. Even though it makes the claims set forth in Paragraph 4, Respondent has advertised numerous used “60 Day/3,000 Mile” vehicles with open recalls for safety issues on its website.

6. In some instances, these open recalls for safety issues have included recalls for defects that can cause serious injury. For example, Respondent has advertised used “60 Day/3,000 Mile” vehicles that have an open recall for safety issues for a key ignition switch defect, which can affect engine power, power steering, power braking, and airbag deployment, thereby increasing the risk of a crash and occupant injury. Respondent also has advertised used vehicles that have an open recall for safety issues for a side impact air bag wiring harness defect, which could result in the failure of side impact airbags and seat belt pretensioners to deploy in a crash, increasing the risk of injury.

Complaint

7. In numerous instances, when Respondent has advertised used “60 Day/3,000 Mile” vehicles that are subject to open recalls for safety issues making the claims set forth in Paragraph 4, it has provided no accompanying clear and conspicuous disclosure of this fact.

8. When consumers search for particular categories of vehicles on Respondent’s website, there is no disclosure regarding open recalls for safety issues. An example of such search results includes the following:

The screenshot displays the Lithia Auto Stores website interface. At the top, there is a navigation bar with links for Home, Vehicles, Service, Body Shops, Specials, Videos, About Us, Store Locator, and Careers. A search bar is located in the top right corner. Below the navigation bar, the 'Inventory' section is active, showing search results for 2011 Chrysler vehicles. The search filters on the left include 'All Conditions', '2011 (3)', 'Chrysler (3)', 'All Models', 'All Body Styles', 'All Mileage', 'All Prices', 'All Locations', 'All States', and 'Zip Code'. The search results are sorted by Year, Color, Mileage, and Price. Three vehicles are listed:


Vehicle Model	Price	Location
2011 Chrysler 200 Touring Sedan	\$12,999	Ultra Dodge of Las Cruces
2011 Chrysler 300C Base Sedan	\$21,995	Dodge of Eureka
2011 Chrysler Town & Country Touring Van LWB Passenger Van	\$19,998	Lithia Ford Lincoln of Fresno

Each vehicle listing includes a small image of the car, a 'Watch Video' link, a 'Save This Car!' button, and a 'Get Price Alerts' button. A prominent '60 DAY' warranty badge is displayed on each listing, indicating a 60-day warranty with up to 3,000 miles. The badge also features the AutoCheck logo.

Exhibit B.

9. When consumers view specific vehicle listings on Respondent’s website, there is no disclosure of open recalls for safety issues. An example of such a listing with an open safety recall includes the following:

Complaint



Chat Live
Contact Us


Search

Home
Vehicles
Service
Body Shops
Specials
Videos
About Us
Store Locator
Careers

2013 Chevrolet Cruze LTZ Sedan

Back To Inventory

Submit our "Get ePrice" form below for great pricing online!



Price **\$15,995**

Get ePrice

Your estimated monthly payment:


\$253 per month

60 Months @ 0.9% A.P.R. (estimated financing rate)
(\$3,100 Down Payment)

Calculate another payment

Save This Car!

Get Price Alerts



Finance Your Vehicle

Request More Info

Make An Offer


Schedule a Test Drive

Trade-In Value

Location


Lithia Kia of Anchorage
4434 Old Seward Highway
Anchorage, AK 99503
Sales: 877-475-1723

Map



Get Directions


Similar



2013 Chevrolet Sonic LTZ Auto Hatchback

\$12,995


View Details



2012 Chevrolet Traverse 1LT SUV

\$19,495

View Details



2014 Chevrolet Impala Limited LTZ Sedan

\$17,961

View Details


Overview
Tech Specs
Warranty

Year:	2013
Make:	Chevrolet
Model:	Cruze
Trim:	LTZ
Bodystyle:	Sedan
Doors:	4 door
Mileage:	23,534 miles
Engine:	1.4L I-4 cyl
Transmission:	AUTOMATIC
Drive Line:	Front wheel Drive
Fuel Type:	regular unleaded
Exterior Color:	Silver Ice
Interior Color:	JET BLACK
VIN:	1G1PG5SB1D7264534
Model Code:	1PW09
Stock #:	D7264534

Fuel Efficiency Rating

City MPG:

26



Hwy MPG:

38

Actual rating will vary with options, driving conditions, habits and vehicle condition.

Complaint

Comments: ONLY 23,505 Miles! PRICED TO MOVE \$800 below Kelley Blue Book!, EPA 38 MPG Hwy/26 MPG City! Heated Leather Seats, CD Player, iPod/MP3 Input, Remote Engine Start, Onboard Communications System, Turbo Charged, Aluminum Wheels SEE MORE!

KEY FEATURES INCLUDE

Leather Seats, Heated Driver Seat, Back-Up Camera, Turbocharged, Satellite Radio, iPod/MP3 Input, CD Player, Onboard Communications System, Aluminum Wheels, Remote Engine Start, Heated Seats, Heated Leather Seats MP3 Player, Keyless Entry, Child Safety Locks, Steering Wheel Controls, Heated Mirrors. LTZ with SILVER ICE METALLIC exterior and JET BLACK interior features a 4 Cylinder Engine with 138 HP at 4900 RPM*.

EXPERTS ARE SAYING

CarAndDriver.com explains The Cruze brings a compelling mix of elegant styling and fuel economy to the compact-car ranks... Great Gas Mileage: 38 MPG Hwy.

A GREAT VALUE

AutoCheck One Owner This Cruze is priced \$800 below Kelley Blue Book.

WHO WE ARE

By taking a page from Kia themselves, Lithia Kia of Anchorage challenges many consumers' perspective of exactly what is the quintessential car-buying experience. When you visit Lithia Kia of Anchorage for complete car specs or to take a test drive, you'll find we deliver an extensive product lineup, deft service and auto repair, and perhaps most importantly - a one-of-a-kind mix of professionalism and approachability. Stop by and see us today!

Pricing analysis performed on 12/10/2014. Horsepower calculations based on trim engine configuration. Fuel economy calculations based on original manufacturer data for trim engine configuration. Please confirm the accuracy of the included equipment by calling us prior to purchase.

* While every reasonable effort is made to ensure the accuracy of this information, we are not responsible for any errors or omissions contained on these pages. Please verify any information in question with Lithia Auto Stores.

User Reviews

Nothing posted yet.

[Post a Review](#)

[Careers](#) [Lithia4Kids](#) [Lithia Privacy](#) [Investor Relations](#) [CA Supply Chain Disclosure](#) [Corporate Sustainability](#) [Customer Service](#)

webSite by
DEALER.COM

Exhibit C

Complaint

10. Another example of a listing for a vehicle with an open safety recall appears as follows:

Used 2013 Chevrolet Camaro For Sale in Midford | D9119687A - Internet Explorer

http://www.lithia.com/used/ Used 2013 Che... CARFAX Vehicle... CARFAX Vehicle... Recall Results Lo...

Login 5 Recently Viewed Cars 0 Saved Cars 0 Price Alerts Contact Social Info Hide

2013 Chevrolet Camaro 1SS Coupe

Submit our "Get aPrice" form below for great pricing online!

Photos Video 360°

Price **\$26,999** [Get aPrice](#)

Your estimated monthly payment: **\$427** per month

60 Months @ 6.9% A.P.R. (estimated financing rate) (\$5,000 Down Payment)

[Calculate another payment](#)

[Save This Car!](#) [Get Price Alerts](#)

CARFAX 1 OWNER **40 DAY MONEY BACK GUARANTEE**

All American Chrysler Jeep Dodge of Midland
3801 W Wall St
Midland, TX 79703
Sales: 877-475-1816

Location

All American Chrysler Jeep Dodge of Midland
3801 W Wall St
Midland, TX 79703
Sales: 877-475-1816

Map

Similar

Year	Make	Model	Trim	Bodystyle	Doors	Mileage	Engine	Transmission	Drive Line	Fuel Type	Exterior Color	Interior Color
2013	Chevrolet	Camaro	1SS	Coupe	2 door	14,123 miles	6.2L V-8 cyl	6 speed manual	Rear-wheel Drive	premium unloaded	Black	N/A

Fuel Efficiency Rating

City MPG: **16** Hwy MPG: **24**

Actual rating will vary with options, driving conditions, habits and vehicle condition.

2012 Chevrolet Colorado Truck Crew Cab \$23,999 [View Details](#)

2013 Chevrolet Camaro ZL1 Coupe \$45,999 [View Details](#)

2014 Chevrolet Camaro LT w/LLT Coupe [View Details](#)

http://www.lithia.com/used/Chevrolet/2013-Chevrolet-Camaro--99c7cbcf9a0a0e0351600b...

Exhibit D.

11. To uncover any information about open recalls for safety issues through Respondent's website, a consumer viewing a listing such as the one shown in Paragraph 10 would have to locate and click on the "Carfax" links on the search results page or the vehicle listing page to access a vehicle history report. In other instances, such as the listing shown in Paragraph 9, the vehicle history report contains no information about open recalls for safety issues.

Complaint

**VIOLATION OF THE FEDERAL TRADE COMMISSION
ACT**

Count I

12. In connection with the marketing, advertising, offering for sale, or sale of used motor vehicles, Respondent has represented, directly or indirectly, expressly or by implication, that used motor vehicles it sells have been subject to rigorous inspection, including for safety issues.

13. In numerous instances in connection with the representation set forth in Paragraph 12, Respondent has failed to disclose, or disclose adequately, that used vehicles it sells are subject to open recalls for safety issues.

14. Respondent's failure to disclose, or disclose adequately, the material information set forth in Paragraph 13 above, in light of the representation described in Paragraph 12, above, constitutes a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

THEREFORE, the Federal Trade Commission, this eighth day of December, 2016, has issued this complaint against Respondent.

By the Commission.

Complaint
Exhibit A

LITHIA AUTO STORES

Home Vehicles

2011 Chrysler Passenger

Lithia 60 Day/3,000 Mile Warranty Includes:

160-Point Quality Inspection*
Lithia 60 Day/3,000 Mile vehicles are put through an exhaustive 160-checkpoint Quality Assurance Inspection. We want the vehicle to look, feel and smell as new as possible. We inspect everything from the tires and the brakes to the suspension, drive train, engine components and even the undercarriage. Only vehicles that pass all 160 checkpoints (as appropriate to vehicle content) can receive our 60 Day/3,000 miles Limited Warranty. See dealer for details.

Comprehensive Title Report*
A vehicle title (also known as a car title or pink slip) is a legal form establishing a person or business as the legal owner of a vehicle. A "clean" title is a term used to refer to an automobile title that is free of liens and is not a salvage title. When someone purchases a car with a loan, the title is held by the Loan Company or bank, even though it is issued in the name of the buyer by the state Department of Motor Vehicles (DMV). The loan company or bank is known as the "lien holder" and the title is marked in a way that clearly indicates that the vehicle is subject to a financial obligation. In this case, the title is not a "clean" title.

Vehicle History Report*
The vehicle check will supply history information about the vehicle such as previous accidents that were reported, and title records such as ownership changes. As the prospective buyer you can then assess whether the cars history is going to subject you to further costs or concerns. Examples of what you might see on a vehicle history report: odometer problems, State of the title, Number of title, Title information, Accident history, Lemon history, Auction history, Salvage information, Warranty availability, Service records, Mileage and Total fees information from insurance companies.

Eligible for Purchase of Lithia Assured Service Contract and Lifetime Oil Plan*
For Peace of Mind Down the Road, our Assured Service Contracts will keep your vehicle running its best for years to come. Our Base Plan covers: Powertrain, Steering, Front Suspension, Electrical, Drives and Factory Air Conditioning. Our Comprehensive Plan is designed to give you the finest in vehicle owner protection - by protecting you from unexpected repair costs, and taking the worry out of driving. The Comprehensive Plan combines the Powertrain & High-Tech Plans and adds much more. The Comprehensive Plan enhances and extends the Manufacturer's New Vehicle Warranty. It provides major electrical & mechanical component coverage, which protects you & your new purchase for just a few dollars per day. This is the ideal plan for those who want extensive coverage & maximum protection for their automobile investment. Our Roadside Assistance Program protects you 24 hours a day, 365 days a year in the U.S. & Canada with Tire Road Hazard Protection & Trip Interruption Coverage. This coverage is available on our Powertrain, High-Tech & Comprehensive plans. We offer the convenience of nationwide coverage for authorized service & repairs.

PREMIUM FEATURES ON THIS CHRYSLER TOWN & COUNTRY INCLUDE:
SECURITY GROUP, remote start system, security alarm, KEYLESS ENTRY/GO, LOAD LEVELING & HEIGHT CONTROL, SUSPENSION, 2IN. TOWING CAPACITY, PRESSURE-COIL SPRING SELECTION, PKG 3.6L V6 engine, 6-speed auto trans, 6-SPEED AUTOMATIC TRANSMISSION (WAUTOSTICK) (STD), 3.6L 24-VALVE VVT V6 FLEX FUEL ENGINE (STD).

CHRYSLER TOWN & COUNTRY: UNMATCHED DEPENDABILITY
CARFAX 1-Owner. Qualifies for CARFAX Buyback Guarantee.

KEY FEATURES ON THIS TOWN & COUNTRY INCLUDE:
Third Row Seat, Dual Sunroof, Seats, Power Windows, Rear Air, Backup Camera, Satellite Radio, iPod/iPad, CD Player, Aluminum Wheels, Dual Zone A/C, Power Fourth Passenger Door MP3 Player, Privacy Glass, Remote Trunk Release, Steering Wheel Controls, Towing with Dual Channel Plecter and Brake-Light Graystone Interior features a V6 Cylinder Engine with 265 HP at 4400 RPM!

BEST IN CLASS: TOWN & COUNTRY
Great Gas Mileage 23 MPG Hwy.

WHY BUY FROM US
We'll find the lowest price for you on any new or used vehicle. We'll match it or beat it. We'll take care of you.

Chrysler Touring 3.6L V6 \$19,999
Chrysler 300 8-Speed \$28,999
Chrysler 200 161 \$13,999

View Photos

Full-Mo

Overview

Year:

Make:

Model:

Trim:

Body Style:

Color:

Mileage:

Engine:

Transmission:

Drive Line:

Fuel Type:

Exterior Color:

Interior Color: GRAYSTONE

VIN:

Model Code:

Stock #:

Comments: FUE Row Seat, Back Passenger Door

*See dealer for complete details.

Back To Inventory

Show

Show

Show

Show

Show

Show

Complaint

Exhibit B

The screenshot displays the Lithia Auto Stores website's inventory search interface. At the top, the Lithia Auto Stores logo is visible alongside a search bar and navigation links. The main content area is titled 'Inventory' and features a search sidebar on the left and a list of vehicle results on the right.

Search Sidebar (Left):

- Search:** Includes filters for All Conditions, 2011 (3), Chrysler (3), All Models, All Body Styles, All Mileage, All Prices, All Locations, and All States. It also has a Zip Code field and a Mileage Range dropdown set to 'Any Range'.
- Location:** Lists 'Lithia Chrysler Jeep Dodge of Euweka (7)', 'Lithia Dodge of Lee Crooks (1)', and 'Lithia Ford Lincoln of Plains (1)'.
- Condition:** Filtered to 'Pre-Owned (3)'.
- Model:** Filtered to '200 (1)', '300C (1)', and 'Town & Country (1)'.
- Body Style:** Filtered to 'Sedan (2)' and 'Van LWB Passenger Van (1)'.
- Mileage:** Filtered to '45,000 or less (1)', '50,000 or less (1)', '55,000 or less (2)', '70,000 or less (3)', '80,000 or less (3)', '90,000 or less (2)', and '100,000 or less (3)'.
- Price:** Filtered to '\$10,000 - \$15,999 (2)' and '\$20,000 - \$25,999 (1)'.
- Features:** Includes '3rd Row Seat (1)', 'Adjustable Pedals (2)', 'Fog Lights (2)', 'Heated Seats (1)', 'Leather Seats (1)', 'Memory Seats (1)', 'Navigation System (1)', 'Parking Sensors / Assist (1)', and 'Power Seats (2)'.

Vehicle Listings (Right):

The listings are sorted by Year, Color, Mileage, and Price. Three vehicles are displayed:

- 2011 Chrysler 200 Touring Sedan:** Price \$12,999. Features include 2.4L I4 engine, 200HP, 21 MPG city, 30 MPG hwy, and 2700 miles. Stock # B428274.
- 2011 Chrysler 300C Base Sedan:** Price \$21,995. Features include 3.6L V6 engine, 270HP, 21 MPG city, 29 MPG hwy, and 2100 miles. Stock # B481433.
- 2011 Chrysler Town & Country Touring Van LWB Passenger Van:** Price \$19,998. Features include 3.6L V6 engine, 270HP, 21 MPG city, 29 MPG hwy, and 2400 miles. Stock # B481433.

Each listing includes a 'View More' link, a 'Save This Car' button, and a 'Get Price' button. The bottom of the page shows 'Compare Selected', 'Download All', and 'Page 1 of 1'.


Exhibit B, Page 1


Complaint



Complaint

Exhibit C






Search

Home
Vehicles
Service
Body Shops
Specials
Videos
About Us
Store Locator
Careers

2013 Chevrolet Cruze LTZ Sedan

Back To Inventory

Submit our "Get ePrice" form below for great pricing online!



Price **\$15,995**

Get ePrice


Your estimated monthly payment:

\$253 per month

60 Months @ 6.9% A.P.R. (estimated financing rate)
(\$3,100 Down Payment)


Calculate another payment

Save This Car
Get Price Alerts



60 DAY
 UNFINISHED BUSINESS
 3,000 MILE

Share



Finance Your Vehicle

Request More Info

Make An Offer


Schedule a Test Drive

Trade-In Value

Location


Lithia Kia of Anchorage
 4434 Old Seward Highway
 Anchorage, AK 99503
 Sales: 877-475-1723


Map




Get Directions

Similar

 2013 Chevrolet Sonic LTZ Auto Hatchback
\$12,995 View Details


 2012 Chevrolet Traverse 1LT SUV
\$19,495 View Details

 2014 Chevrolet Impala Limited LTZ Sedan
\$17,961 View Details

Overview
Tech Specs
Warranty

Year:	2013
Make:	Chevrolet
Model:	Cruze
Trim:	LTZ
Bodystyle:	Sedan
Doors:	4 door
Mileage:	23,534 miles
Engine:	1.4L I-4 cyl
Transmission:	AUTOMATIC
Drive Line:	Front-wheel Drive
Fuel Type:	regular unleaded
Exterior Color:	Silver Ice
Interior Color:	JET BLACK
VIN:	1G1PG5SB1D7264534
Model Code:	1PW89
Stock #:	D7264534

Fuel Efficiency Rating

City MPG: **26**  **38** Hwy MPG

Actual rating will vary with options, driving conditions, habits and vehicle condition.

Complaint

Comments: ONLY 23,505 Miles! PRICED TO MOVE \$800 below Kelley Blue Book!, EPA 38 MPG Hwy/26 MPG City! Heated Leather Seats, CD Player, iPod/iMP3 Input, Remote Engine Start, Onboard Communications System, Turbo Charged, Aluminum Wheels SEE MORE!

KEY FEATURES INCLUDE

Leather Seats, Heated Driver Seat, Back Up Camera, Turbocharged, Satellite Radio, iPod/iMP3 Input, CD Player, Onboard Communications System, Aluminum Wheels, Remote Engine Start, Heated Seats, Heated Leather Seats MP3 Player, Keyless Entry, Child Safety Locks, Steering Wheel Controls, Heated Mirrors. LTZ with SILVER ICE METALLIC exterior and JET BLACK interior features a 4 Cylinder Engine with 138 HP at 4900 RPM*.

EXPERTS ARE SAYING

CarAndDriver.com explains The Cruze brings a compelling mix of elegant styling and fuel economy to the compact-car ranks . Great Gas Mileage: 38 MPG Hwy.

A GREAT VALUE

AutoCheck One Owner This Cruze is priced \$800 below Kelley Blue Book.

WHO WE ARE

By taking a page from Kia themselves, Lithia Kia of Anchorage challenges many consumers' perspective of exactly what is the quintessential car-buying experience. When you visit Lithia Kia of Anchorage for complete car specs or to take a test drive, you'll find we deliver an extensive product lineup, deft service and auto repair, and perhaps most importantly - a one-of-a-kind mix of professionalism and approachability. Stop by and see us today!

Pricing analysis performed on 12/10/2014. Horsepower calculations based on trim engine configuration. Fuel economy calculations based on original manufacturer data for trim engine configuration. Please confirm the accuracy of the included equipment by calling us prior to purchase.

* While every reasonable effort is made to ensure the accuracy of this information, we are not responsible for any errors or omissions contained on these pages. Please verify any information in question with Lithia Auto Stores.

User Reviews

Nothing posted yet!

Post a Review

[Careers](#) [Lithia4Kids](#) [Lithia Privacy](#) [Investor Relations](#) [CA Supply Chain Disclosure](#) [Corporate Sustainability](#) [Customer Service](#)

website by
DEALER.COM

Decision and Order

Exhibit D

Used 2013 Chevrolet Camaro For Sale in Midland | D913887A - Internet Explorer

http://www.lithia.com/used/... Used 2013 Che... CARFAX Vehicle... CARFAX Vehicle... Recalls: Results Lo...

Login 5 Recently Viewed Cars 0 Saved Cars 0 Price Alerts Contact Social Info Hide

2013 Chevrolet Camaro 1SS Coupe

Submit our "Get a Price" form below for great pricing online!

Photos Video 360°

Price **\$26,999** [Get a Price](#)

Your estimated monthly payment:
\$427 per month
20 Months @ 6.9% A.P.R. (estimated financing rate)
\$5,900 Down Payment
[Calculate another payment](#)

[Save This Car!](#) [Get Price Alerts](#)

CARFAX 1 OWNER **60 DAY WARRANTY**

432-522-3115

All American Chrysler Jeep Dodge of Midland
3801 W Wall St
Midland, TX 79703
Sales: 877-475-1916

Location: **All American Chrysler Jeep Dodge of Midland**
3801 W Wall St
Midland, TX 79703
Sales: 877-475-1916

Map: [Get Directions](#)

Overview Tech Specs Warranty

Year:	2013
Make:	Chevrolet
Model:	Camaro
Trim:	1SS
Bodystyle:	Coupe
Doors:	2 door
Mileage:	14,123 miles
Engine:	6.2L V-8 cyl
Transmission:	6 speed manual
Drive Line:	Rear-wheel Drive
Fuel Type:	premium unleaded
Exterior Color:	Black
Interior Color:	N/A

Fuel Efficiency Rating
City MPG: **16** Hwy MPG: **24**
Actual rating will vary with options, driving conditions, habits and vehicle condition.

Similar

- 2012 Chevrolet Colorado Truck Crew Cab \$23,999 [View Details](#)
- 2013 Chevrolet Camaro ZL1 Coupe \$46,999 [View Details](#)
- 2014 Chevrolet Camaro LT w/1LT [View Details](#)

http://www.lithia.com/used/Chevrolet/2013-Chevrolet-Camaro-09c7dcbf8a0a0e131600b...

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondent named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the

Decision and Order

Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violation of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statement by Respondent that it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission’s Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. Respondent Lithia Motors, Inc. is an Oregon corporation, with its principal office or place of business at 150 North Bartlett Street, Medford OR 97591.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

Decision and Order

- A. Unless otherwise specified, “Respondent” shall mean Lithia Motors, Inc., and its successors and assigns.
- B. “Advertisement” shall mean a commercial message in any medium that directly or indirectly promotes a consumer transaction.
- C. “Clearly and conspicuously” shall mean that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
 - 1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be made through the same means through which the representation requiring the disclosure is presented.
 - 2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
 - 3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
 - 4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
 - 5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.

Decision and Order

6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
 7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
- D. “Material” shall mean likely to affect a person’s choice of, or conduct regarding, goods or services.
- E. “Motor vehicle” shall mean:
1. Any self-propelled vehicle designed for transporting persons or property on a street, highway, or other road;
 2. Recreational boats and marine equipment;
 3. Motorcycles;
 4. Motor homes, recreational vehicle trailers, and slide-in campers; and
 5. Other vehicles that are titled and sold through dealers.

I.

IT IS HEREBY ORDERED that Respondent and its officers, agents, representatives, and employees, directly or indirectly, in connection with the marketing, advertising, offering for sale, or sale of used motor vehicles to consumers shall not, in any manner, expressly or by implication:

- A. Represent that used motor vehicles that Respondent offers for sale are safe, have been repaired for safety issues, or have been subject to an inspection for issues related to safety unless:

Decision and Order

1. The used motor vehicles are not subject to any open recalls for safety issues, and the representation is otherwise not misleading, or
2. Respondent discloses, clearly and conspicuously, and in close proximity to such representation, any material qualifying information related to open recalls for safety issues, including but not limited to:
 - a. the fact that its used motor vehicles may be subject to unrepaired recalls for safety issues, and
 - b. how consumers can determine whether an individual motor vehicle is subject to an open recall for a safety issue that has not been repaired,

and the representation is otherwise not misleading. *Provided further that* if Respondent receives any written notification from a manufacturer that an individual used motor vehicle is subject to an open recall for a safety issue, Respondent must clearly and conspicuously provide that written notification, or a document that conveys the same information using a substantially similar format, to the consumer prior to consummation of the sale of that motor vehicle.

- B. Misrepresent the following:
1. Whether there is or is not an open recall for safety issues for any used motor vehicle;
 2. Whether Respondent repairs used motor vehicles for open recalls for safety issues; and
 3. Any other material fact about the safety of the used motor vehicles it advertises for sale.

Decision and Order

II.

IT IS FURTHER ORDERED that Respondent, no later than February 6, 2017, must provide, by first class mail to the last known address of every consumer who purchased a Lithia Warranty used motor vehicle from Respondent between July 1, 2013 and December 8, 2016, a notice on Respondent's letterhead that clearly and conspicuously discloses the following:

“We want to alert you that some of the used vehicles we recently sold had been recalled for safety issues, but weren't repaired as of the date they were sold. You can check whether the vehicle you bought from us is subject to an unrepaired recall at the National Highway Traffic Safety Administration's recall website, <https://vinrcl.safercar.gov/vin/>. That site also provides information on how to get your vehicle fixed if it's been recalled.”

Respondent shall not include any advertising, marketing, or other promotional information in the notice. Moreover, the mailing shall not include any other documents. The envelope enclosing the notice shall have printed thereon in a clear and conspicuous fashion the disclosure “Important Safety Recall Information.”

Provided, however, that Respondent is not required to provide this notice for (A) any motor vehicle that Respondent can demonstrate was not subject to an open recall for a safety issue at the time of purchase and delivery, or (B) any motor vehicle that was the subject of one or more open recalls for safety issues at the time of purchase and delivery that Respondent can demonstrate have subsequently been fixed.

For purposes of Subpart (A) of this proviso, records showing that the vehicle was not listed as subject to an open recall for a safety issue, as of the date of the purchase, on the Original Equipment Manufacturer's recall database, on the National Highway Traffic Safety Administration's www.safercar.gov database, or on a database with information on vehicle recalls that is generally accepted based on the expertise of professionals in the relevant

Decision and Order

area to yield accurate and reliable results, shall be deemed to be sufficient to demonstrate that the vehicle was not subject to an open recall for a safety issue at the time of purchase and delivery.

For purposes of Subpart (B) of this proviso, (i) repair records generated by the dealer in the ordinary course of business that demonstrate that a vehicle with an open recall for a safety issue has been repaired; or (ii) records showing that the vehicle is no longer listed as subject to an open recall for a safety issue on the Original Equipment Manufacturer's recall database, on the National Highway Traffic Safety Administration's www.safercar.gov database, or on a database with information on vehicle recalls that is generally accepted based on the expertise of professionals in the relevant area to yield accurate and reliable results, shall be deemed sufficient to demonstrate that an open recall for a safety issue has been fixed.

For the purposes of this provision, "Lithia Warranty" shall mean used vehicles subject to Lithia's 60 Day/3,000 Mile Limited Warranty.

III.

IT IS FURTHER ORDERED that Respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

- A. Each advertisement or other marketing material that makes any representation covered by the order unless, in comparison to an advertisement or other marketing material already maintained by Respondent pursuant to this Section, the advertisement or marketing material: (i) is a duplicate, or (ii) differs only in the description of the vehicle in ways not related to any representations covered by this order;
- B. All materials that were relied upon in disseminating the representation;

Decision and Order

- C. All evidence in its possession or control that contradicts, qualifies, or calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. Any documents reasonably necessary to demonstrate full compliance with each provision of this order, including but not limited to all documents obtained, created, generated, or that in any way relate to the requirements, provisions, or terms of this order, and all reports submitted to the Commission pursuant to this order.

IV.

IT IS FURTHER ORDERED that Respondent shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order, with any electronic signatures complying with the requirements of the E-Sign Act, 15 U.S.C. § 7001 *et seq.* Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided,*

Decision and Order

however, that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580. The subject line must begin: *In re Lithia Motors, Inc.*

VI.

IT IS FURTHER ORDERED that Respondent, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VII.

This order will terminate on December 8, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Analysis to Aid Public Comment

Provided, further, that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Lithia Motors, Inc. The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

The respondent is a car dealership that sells used motor vehicles. According to the FTC complaint, respondent has represented that the used motor vehicles it sells have been subject to rigorous inspection, including for safety issues, but has failed to disclose that the used motor vehicles it sells are subject to open recalls for safety issues.

For instance, the respondent has posted advertisements on its website that make the following representations about vehicles that carry a dealer-backed “60 Day/3000 Mile” warranty: “160-Point Quality Inspection--Lithia 60 Day/3,000 Mile vehicles are

Analysis to Aid Public Comment

put through an exhaustive 160-checkpoint Quality Assurance Inspection. We want the vehicles to look, feel and smell as new as possible. We inspect everything from the tires and the brakes to the suspension, drive train, engine components and even the undercarriage. Only vehicles that pass all 160 checkpoints (as appropriate to vehicle content) can receive our 60 Day/3,000 miles Limited Warranty. See dealer for details.”

Even though it makes such claims, the respondent has allegedly advertised on its websites numerous Lithia 60-Day/3,000 Mile used vehicles that were subject to open recalls for safety issues. In numerous instances, when the respondent allegedly advertised Lithia 60-Day/3,000 Mile used vehicles that are subject to open recalls for safety issues, it provided no accompanying clear and conspicuous disclosure of this fact. The proposed complaint alleges that this failure to disclose constitutes a deceptive act or practice under Section 5 of the FTC Act.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices in the future. Part I prohibits the respondent from representing that used motor vehicles it offers for sale are safe, have been repaired for safety issues, or have been subject to an inspection for issues related to safety unless the used motor vehicles are not subject to any open recalls for safety issues or the respondent discloses, clearly and conspicuously, in close proximity to such representation, any material qualifying information related to open recalls for safety issues. Part II is a provision that orders the respondent to notify every consumer who purchased from it a 60-Day/3,000 Mile used motor vehicle between July 1, 2013 and the date of entry of the Order that some of the used vehicles it sold during this time had been recalled for safety issues which weren't repaired as of the date they were sold, how to determine whether a vehicle is subject to an unrepaired recall, and information on how to get a vehicle fixed if it is subject to an open recall.

Parts III through VII of the proposed order are reporting and compliance provisions. Part III requires the respondent to maintain for five years, and produce to the Commission upon demand, any relevant ads and associated documentary material. Part IV is an order distribution provision that requires the

Analysis to Aid Public Comment

respondent to provide the Order to current and future principals, officers, directors, and managers, and to all current employees, agents, and representatives having responsibilities with respect to the subject matter of the Order. Part V requires the respondent to notify the Commission of corporate changes that may affect compliance obligations. Part VI requires the respondent to submit a compliance report to the Commission 60 days after entry of the order, and also additional compliance reports within 10 business days of a written request by the Commission. Part VII “sunsets” the order after twenty years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order’s terms.

Complaint

IN THE MATTER OF

**JIM KOONS MANAGEMENT COMPANY
D/B/A
JIM KOONS AUTOMOTIVE COMPANIES**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4598; File No. 152 3104
Complaint, December 8, 2016 – Decision, December 8, 2016*

This consent order addresses Jim Koons Management Company's failure to disclose open recalls for safety issues. The complaint alleges that respondent has represented that the used motor vehicles it sells have been subject to rigorous inspection, including for safety issues, but has failed to disclose that the used motor vehicles it sells are subject to open recalls for safety issues. The consent order prohibits the respondent from representing that used motor vehicles it offers for sale are safe, have been repaired for safety issues, or have been subject to an inspection for issues related to safety unless the used motor vehicles are not subject to any open recalls for safety issues or the respondent discloses, clearly and conspicuously, in close proximity to such representation, any material qualifying information related to open recalls for safety issues.

Participants

For the *Commission: Courtney Estep, Peter Lamberton, Michael White, and Evan Zullow.*

For the *Respondent: Mike Goodman, Lucy Morris, and Joel Winston, Hudson Cook LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Jim Koons Management Company, also d/b/a Jim Koons Automotive Companies ("Respondent"), has violated provisions of the Federal Trade Commission Act ("FTC Act"), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a Maryland corporation, with its principal office or place of business at 2000 Chain Bridge Road, Vienna,

Complaint

Virginia 22182. Respondent has marketed, advertised, offered for sale, and sold used motor vehicles.

2. The acts or practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3. Since at least December 2014, Respondent has disseminated or has caused to be disseminated advertisements promoting the sale of used motor vehicles.

4. Respondent’s advertisements include, but are not necessarily limited to, advertisements and marketing materials posted on the website www.koons.com, excerpts of which are attached as Exhibits A through D. On its website, until at least June 2015, on a page prominently titled, “Koons Used Car Advantage,” and other pages similarly touting the “Koons Used Car Advantage,” it has made claims regarding the advantages of buying from Koons. These marketing materials have included the following representations regarding certified used vehicles:

“Backed by the Koons Used Car Advantage, each vehicle we carry has been carefully selected and tested”

Exhibit A at 1-2.

“The Koons Used Car Advantage Guarantees:

Koons Quality Inspection

Every certified Koons Outlet vehicle must pass a rigorous and extensive quality inspection before it can be sold. Our certified mechanics check all major mechanical and electrical systems and every power accessory as part of our rigid quality controls.”

Exhibit B.

Complaint

5. Even though it has made the claims set forth in Paragraph 4, Respondent has advertised numerous certified used vehicles subject to open recalls for safety issues on its website.

6. In some instances, these open recalls for safety issues have included recalls for defects that can cause serious injury. For example, Respondent has advertised a used certified vehicle that has an open recall for safety issues for a key ignition switch defect, which can affect engine power, power steering, braking, and airbag deployment, thereby increasing the risk of a crash and occupant injury. Respondent has also advertised a certified used vehicle that has an open recall for safety issues for defects associated with the alternator, which can result in the vehicle unexpectedly shutting down or in an electrical fire. Respondent has also advertised a certified used vehicle that has a rear suspension defect that could result in a fuel leak or fire.

7. In numerous instances, until at least June 2015, when Respondent has advertised certified used vehicles that are subject to open recalls for safety issues making the claims set forth in paragraph 4, it has provided no accompanying clear and conspicuous disclosure of this fact.

8. When consumers search for particular categories of vehicles on Respondent's website, there is no disclosure regarding open recalls for safety issues. An example of such search results includes the following:

Certified Pre-Owned

KOONS USED CAR ADVANTAGE
Quality Used Cars at Low Outlet Prices!


We're Gonna Wow Ya!
FIND OUT MORE

Vehicle Keyword Search **391 Items Matching:** All Listings Select View

Search

Sort by: Year Make Model Bodystyle Color Mileage WOW Price Drivetrain Page 1 of 18

2009 Toyota Yaris Hatchback **WOW PRICE: \$8,750***


 **WATCH VIDEO**

Drive Line: Front-wheel Drive	Transmission: Automatic	Interior Color: Silver	Exterior Color: Dark Gray/Black
Model Code: 1482	Engine: 1.8 99	Stock #: Q18088A	Bodytype: Hatchback
Mileage: 79,457 miles	MPG Range: 29-37	Location: Koons Arlington	Toyota - Used Car
		Lot:	

More

Power Package w/Key Wheels | Convenience Package | Power Door Locks | Power Windows | Central Power Outside Rearview Mirror. ...

2009 Toyota Yaris Hatchback **WOW PRICE: \$9,890***

 **WATCH VIDEO**

Drive Line: Front-wheel Drive	Transmission: Automatic	Interior Color: Metallic	Exterior Color: Dark Green/Red
Model Code: 1482	Engine: 1.8 99	Stock #: Q15000A	Bodytype: Hatchback
Mileage: 57,140 miles	MPG Range: 29-37	Location: Koons Arlington	Toyota - Used Car
		Lot:	

More

Power Package w/Key Wheels | Convenience Package | Power Door Locks | Power Windows | Central Power Outside Rearview Mirror. ...

Location

- Koons Arlington Toyota - Used Car Lot (20)
- Koons Easton Toyota (9)
- Koons Falls Church Ford (9)
- Koons Kia of Baltimore (2)
- Koons Kia of Woodbridge (20)

Complaint

Exhibit C.

9. When consumers have viewed specific vehicle listings on Respondent’s website, there is no disclosure regarding open recalls for safety issues. An example of such a listing includes the following:

The screenshot shows a web browser interface for a car listing. At the top, there are navigation links for 'Locations', 'New', 'Pre-Owned', 'Financing', 'Specials', 'Parts', 'Service', 'Collision', and 'Employment'. The main heading is '2009 Toyota Yaris Hatchback'. Below this, there is a large photo of a silver hatchback with a '7 DAY EXCHANGE' badge. To the right of the photo, the price is listed as 'WOW PRICE: \$8,750*' and 'KBB Retail Value: \$9,582'. A 'CLICK HERE TO CONFIRM AVAILABILITY' button is prominent. Below the photo, there are 'Save This Car!' and 'Get Price Alerts' buttons. A 'Comments' section contains a paragraph of text. At the bottom, there is a table with vehicle specifications.

Overview	Options & Packages	Tech Specs	
Engine:	I-4 cyl	Stock #:	0150550A
Fuel Type:	regular unleaded	Transmission:	Automatic
Make:	Toyota	MPG Range:	29/35
Drive Line:	Front-wheel Drive	Engine Class:	1.5L
Exterior Color:	Silver	Bodystyle:	Hatchback
Interior Color:	Dark Charcoal	Mileage:	70,407 miles
Model Code:	1482	VIN:	JTDKT903085275080

Exhibit D.

Complaint

10. To uncover any information about open recalls for safety issues through Respondent's website, until at least June 2015, a consumer would have to locate the "Carfax" link on the search results page or the vehicle listing page and click on it to access a vehicle history report. Moreover, in numerous instances, even these reports omit information about open recalls for safety issues.

**VIOLATION OF THE FEDERAL TRADE COMMISSION
ACT****Count I**

11. In connection with the marketing, advertising, offering for sale, or sale of used motor vehicles, Respondent has represented, directly or indirectly, expressly or by implication, that used motor vehicles it sells have been subject to rigorous inspection, including for safety issues.

12. In numerous instances in connection with the representation set forth in Paragraph 11, Respondent has failed to disclose, or disclose adequately, that used vehicles it sells are subject to open recalls for safety issues.

13. Respondent's failure to disclose, or disclose adequately, the material information set forth in Paragraph 12 above, in light of the representation described in Paragraph 11, above, constitutes a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

THEREFORE, the Federal Trade Commission, this eighth day of December, 2016, has issued this complaint against Respondent.

By the Commission.

Complaint

Exhibit A

OVER 2 MILLION VEHICLES SOLD!

Locations | New | Pre-Owned | Financing | Specials | Parts | Service | Collision | Employment

Did You Know...
You may be eligible for **Additional Rebates** on top of the **KOONS WOW PRICE!**

- Recent College Graduate Programs
- Former or Active Duty Military Rebates
- Owner Loyalty Rebates
- Competitive Bonus Programs!
- Finance Rebates

These Are Just A Few Examples!
Ask a member of our Sales Staff for more details.

New Vehicles | **Pre-Owned Vehicles** | **Hybrid Center** | **Luxury Center**

TOYOTA | Ford | CHEVROLET | Jeep | BUICK | GMC | HONDA | ACURA | LEXUS | Mercedes-Benz | LINCOLN | KIA | NISSAN | SUBARU | MAZDA

Join the conversation!
Find us on Facebook
Koons Automotive Companies | Like 10,562

19 KOONS LOCATIONS
MARYLAND • VIRGINIA AND DELAWARE
FEATURED COMMERCIAL

Jim Koons Automotive Companies
Visit a Jim Koons Automotive Dealership - A Premier New & Used Car Dealer in Baltimore, Washington, DC and Beyond

Thank you for visiting Koons.com and Jim Koons Automotive Companies.

We have 19 locations throughout Washington DC and Baltimore MD!

To better serve our customers, we have a wide selection of vehicles to choose from, and teams of specialists who have the knowledge and expertise to assist you throughout your car buying experience.

Of course, we don't limit ourselves to new and used car sales. You can also find auto finance options, car service, auto repair, and access to parts and accessories you need for your vehicle.

If you are in the market for a new Ford, Toyota, Chevrolet or other model offered at a Koons Automotive dealership nearest to you, we can help. We have sold over two million vehicles to residents in the Maryland, Virginia and Delaware areas. We are committed to ensuring that you find the right vehicle for you. On our end, that means answering questions, comparing models, and getting you behind the wheel for a closer look.

Of course, we may be known throughout Northern Virginia, Maryland and Delaware for our fantastic

Complaint

selection of new cars, but we've also garnered quite a reputation for offering high-quality used cars for sale as well. Backed by the Koons Used Car Advantage, each vehicle we carry has been carefully selected and tested to not only meet your undoubtedly high standards for quality, but to exceed them as well.

Car Loans and Lease Solutions Offered by Jim Koons Automotive Companies - Serving the Greater Baltimore and Washington DC Areas

You can always ask a Jim Koons Automotive dealership for assistance with auto financing. The finance team at each of our locations can explain your car loan and lease options in detail after you've gone for a test drive. That way, you can know exactly what it will cost to take home the vehicle you want.

Auto Repairs, Collision Repair and Auto Parts for Maryland, Virginia and Delaware

Koons Automotive Companies has service and repair locations serving the greater Baltimore and Washington DC areas. If you bought a vehicle from a Koons Automotive dealership a day ago, a month, a year, or longer, you're a member of the family. Whether it's a quick tune-up, a recall, or the need for a more immediate fix, you can visit the service center at the dealership nearest to you. Once you've scheduled an appointment online, over the phone, or in person, our automotive enthusiasts will take on nearly any job, big or small.

We could talk all day about everything we have to offer our valued customers, but truth be told, we would love to show you firsthand. We cordially invite you and your family to come visit us any time, at one of our many dealership locations. Whatever your automotive needs may be, we will work incredibly hard to meet them.

The spokesperson for Jim Koons Automotive Companies is Krystal Koons.

[click to hide](#)

WE'RE GONNA WOW YA!

Home	Locations	New	Pre-Owned	Financing	Specials	Parts	Service	COLLISION
		New Vehicles	Used Car Inventory	Finance Payment Calculator	New Car Specials	Parts Order Form	Service Appointment	
		New Commercial Vehicles	Certified Pre-Owned	Rebates and Incentives	Military Discounts	Parts Specials	Service Specials	
		Showroom Car Finder	Bargain Inventory		College Rebate Program			

[Web Policy](#) | [Privacy Policy](#) | [Browser Support](#)

www.koons.com/privacy.htm Authorized by DEALERUSA

Complaint

Exhibit B

Koons Used Car Advantage

QUALITY USED CARS AT LOW OUTLET PRICES!

Koons Used Car Advantage

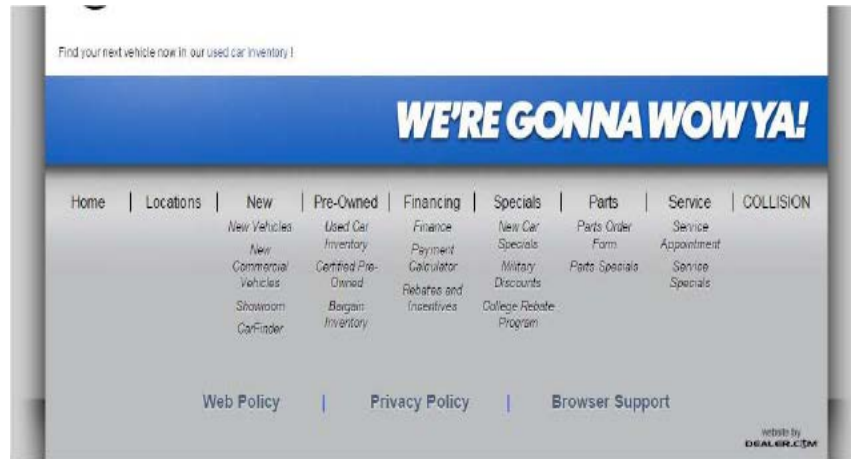
Quality Used Cars at Low Outlet Prices!
Koons Used Car Outlets are clearance centers for the various Koons Automotive Companies located in Northern Virginia, Maryland, and Delaware with a multi-million dollar inventory of pre-owned vehicles. At Koons, we hand pick the best trade-ins, auction, off-lease, and factory vehicles available in the marketplace. You get the "Best of the Best" selection at prices far below market value.

The Koons Used Car Advantage guarantees:

- CARFAX VEHICLE HISTORY REPORTS**
Using CARFAX vehicle history reports, every used vehicle's title can be researched against an extensive database of used vehicle records coming from over 20,000 data sources. CARFAX Vehicle History Reports include title information (including salvaged or junked titles), flood damage history, total loss accident history, odometer readings, lemon history, number of owners, accident indicators (such as airbag deployments), state emissions inspection results, service records, and vehicle use (taxi, rental, lease, etc.). This high level of consumer protection allows you to choose and purchase any of our quality vehicles with the confidence you deserve.
- 7 Day Exchange Policy**
True customer satisfaction starts with a quality car at a great price and continues with the Koons Used Car Outlet "7 Day Exchange Policy." This policy simply states if you are not completely satisfied with your vehicle purchase, bring it back to us for a full credit towards your next vehicle, no questions asked! What other car company offers this kind of protection and guarantee?
- Lowest Prices Everyday**
Our prices are based on the Official Blue Book pricing guide. We post an itemized Koons price on the window up front, no games. It's easy to make an educated purchase from us.
- Koons Quality Inspection**
Every certified Koons Outlet vehicle must pass a rigorous and extensive quality inspection before it can be sold. Our certified mechanics check all major mechanical and electrical systems and every power accessory as part of our rigid quality controls.
- We'll Buy Your Car**
All Koons customers are guaranteed an honest and straight forward appraisal of their trade-in's value. We'll be happy to appraise your trade whether you purchase a car from us or not.
- Credit Rebuilding Programs**
Take advantage of the Koons Outlet finance approval power. The Koons organization sends thousands of credit applications to a variety of lending sources every month. As a result, our lending sources are eager to approve quickly and at affordable terms. Most of our customers drive home their vehicle the same day!
- Financing That Suits Your Budget**
The Koons Outlet uses a variety of national lending sources and local banks to secure the best finance arrangements for you. Our computerized system easily shops competitive terms and rates within minutes.
- Service Contracts That Cover 1-2-3**
1. 7 day unconditional used vehicle exchange policy, no questions asked.
2. Many Koons vehicles come with the balance of the original manufacturer's factory warranty.
3. Customized extended service contracts for up to 6 years and 24-hour roadside assistance plans available.
- Online Shopping at Koons.com**
Shopping online has never been easier. At koons.com, you can do the research, choose from thousands of vehicles, get a quote and schedule a test drive. It's that easy! Plus, you can even appraise your trade instantly with our Kelley Blue Book trade-in report. It's a snap online at Koons.com.

Exhibit B, Page 1

Complaint



Complaint
Exhibit C

1 Cars | 0 Saved Cars | 0 Price Alerts

Certified Pre-Owned

KOONS USED CAR ADVANTAGE
 Quality Used Cars at Low Outlet Prices!

We're Gonna Wow You!

FIND OUT MORE

Vehicle Keyword Search **391 Items Matching:** All Listings Select View

Search ▾

All Locations ▾

All Years ▾

All Makes ▾

All Models ▾

All Mileage ▾

All Trims ▾

All Body Styles ▾

All Prices ▾

All Highway MPG's ▾

Location

- Koons Arlington Toyota - Used Car Lot (20)
- Koons Easton Toyota (0)
- Koons Falls Church Ford (9)
- Koons Kia of Baltimore (2)
- Koons Kia of Woodbridge (20)
- Koons Silver Spring
- Ford/LINCOLN/Mazda (44)
- Koons Sterling Ford (14)
- Koons Tysons Chevvy Buick GMC

5.htm

Sort by Year Make Model Bodystyle Color Mileage WOW Price Drivetrain Page 1 of 16 ▶

2009 Toyota Yaris Hatchback **WOW PRICE: \$8,750***

	Drive Line: Front-wheel Drive Transmission: Automatic Model Code: 1402 Engine: I4 cyl Mileage: 70,407 miles MPG Range: 24/35	Exterior Color: Silver Interior Color: Dark Charcoal Stock #: 0110050A Bodystyle: Hatchback Location: Koons Arlington Toyota - Used Car Lot	KBB Retail Value: \$9,582 Koons Savings: \$832
--	---	---	---

More ▶
 Power Package w/Alloy Wheels (Convenience Package, Power Door Locks, Power Windows, Colored Power Outside Rearview Mirrors, ...)

2009 Toyota Yaris Hatchback **WOW PRICE: \$9,890***

	Drive Line: Front-wheel Drive Transmission: Automatic Model Code: 1402 Engine: I4 cyl Mileage: 87,140 miles MPG Range: 24/35	Exterior Color: Metallic Interior Color: Dark Charcoal Stock #: 0110050A Bodystyle: Hatchback Location: Koons Arlington Toyota - Used Car Lot	KBB Retail Value: \$10,720 Koons Savings: \$830
--	---	---	--

More ▶
 Power Package w/Alloy Wheels (Convenience Package, Power Door Locks, Power Windows, Colored Power Outside Rearview Mirrors, ...)

2009 Scion tC Coupe **WOW PRICE: \$9,904***

	Drive Line: Front-wheel Drive Transmission: Automatic	Exterior Color: Black Interior Color: Black	KBB Retail Value: \$12,620
--	--	--	----------------------------

Complaint

Exhibit D

By:
Price Alerts

OVER 2 MILLION VEHICLES SOLD!

[Español](#)
[Follow us on](#)

[Home](#) | [Locations](#) | [New](#) | [Pre-Owned](#) | [Financing](#) | [Specials](#) | [Parts](#) | [Service](#) | [Collision](#) | [Employment](#)

2009 Toyota Yaris Hatchback

[Back to Inventory](#)

Photos Video

WOW PRICE: \$8,750*

KBB Retail Value: \$9,582
Koons Savings: -\$832

CLICK HERE ANYTIME

Save This Car
 Get Price Alerts

Share

- [Facebook](#)
- [Twitter](#)
- [LinkedIn](#)
- [Email](#)
- [Print](#)

Chat Live Now

- [Request More Info](#)
- [Schedule a Test Drive](#)
- [Track-In Approval](#)
- [Kelley Blue Book](#)

Fuel Efficiency Rating

City MPG

29

Highway MPG

35

*Actual mileage varies with driving conditions, habits and vehicle condition.

Location

Koons Arlington Toyota - Used Car Lot
3212 Lee Hwy
Arlington, VA 22207
Sales: (800) 920-7241

Map

Similar

2008 Toyota RAV4 SUV

[View Details](#)

2010 Toyota FJ Cruiser Base SUV

[View Details](#)

2009 Toyota Matrix S Hatchback

[View Details](#)

Comments:

CD Hatchback, 1.5L I4 DOHC VVT-i 15V, ONE OWNER and 4-Speed Automatic. Toyota FEVER! Your satisfaction is our business! Call to schedule a test drive today... 703 522-2421. Buy with confidence... Koons Toyota of Arlington offers a 7 day exchange policy on every pre-owned vehicle. A vehicle history report, Odometer and Title check. Thorough mechanical and condition check. We do the research to ensure you are receiving a great vehicle at a great value. \$\$\$ Koons is Proud to be a part of Washington Metropolitan Area since 1987's. How economical is that! Just in, this stunning 2009 Toyota Yaris comes with a 1.5L I4 DOHC VVT-i 15V engine and FWD. Your garage will only be the second one this one-owner Yaris has parked in, and you can definitely see the pride of ownership experienced in that first garage. When You're Talkin' Cars You're Talkin' Koons!

Overview	Options & Packages	Tech Specs
Engine:	I-4 cyl	Stock #: 0150050A
Fuel Type:	Regular unleaded	Transmission: Automatic
Make:	Toyota	MPG Range: 29/35
Drive Line:	Front-wheel Drive	Engine Class: 1.5L
Exterior Color:	Silver	Bodystyle: Hatchback
Interior Color:	Dark Charcoal	Mileage: 70,407 miles
Model Code:	1402	VIN: JTDK1903000276000

Included Packages

Power Package w/Alloy Wheels

- Convenience Package
- Power Door Locks
- Power Windows
- Colored Power Outside Rearview Mirrors

Decision and Order

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of certain acts and practices of the Respondent named in the caption. The Commission’s Bureau of Consumer Protection (“BCP”) prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violation of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statement by Respondent that it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission’s Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered the comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. Respondent Jim Koons Management Company, also d/b/a Jim Koons Automotive Companies, a corporation, is a Maryland corporation, with its principal office or place of business at 2000 Chain Bridge Road, Vienna VA 22182.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

Decision and Order

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “Respondent” shall mean Jim Koons Management Company, also d/b/a Jim Koons Automotive Companies, a corporation, and its successors and assigns.
- B. “Advertisement” shall mean a commercial message in any medium that directly or indirectly promotes a consumer transaction.
- C. “Clearly and conspicuously” shall mean that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:
 - 1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be made through the same means through which the representation requiring the disclosure is presented.
 - 2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
 - 3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

Decision and Order

4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
 5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.
 6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
 7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
- D. “Material” shall mean likely to affect a person’s choice of, or conduct regarding, goods or services.
- E. “Motor vehicle” shall mean:
1. Any self-propelled vehicle designed for transporting persons or property on a street, highway, or other road;
 2. Recreational boats and marine equipment;
 3. Motorcycles;
 4. Motor homes, recreational vehicle trailers, and slide-in campers; and
 5. Other vehicles that are titled and sold through dealers.

I.

IT IS HEREBY ORDERED that Respondent and its officers, agents, representatives, and employees, directly or

Decision and Order

indirectly, in connection with the marketing, advertising, offering for sale, or sale of used motor vehicles to consumers shall not, in any manner, expressly or by implication:

- A. Represent that used motor vehicles that Respondent offers for sale are safe, have been repaired for safety issues, or have been subject to an inspection for issues related to safety unless:
1. The used motor vehicles are not subject to any open recalls for safety issues, and the representation is otherwise not misleading, or
 2. Respondent discloses, clearly and conspicuously, and in close proximity to such representation, any material qualifying information related to open recalls for safety issues, including but not limited to:
 - a. the fact that its used motor vehicles may be subject to unrepaired recalls for safety issues, and
 - b. how consumers can determine whether an individual motor vehicle is subject to an open recall for a safety issue that has not been repaired,

and the representation is otherwise not misleading. *Provided further that* if Respondent receives any written notification from a manufacturer that an individual used motor vehicle is subject to an open recall for a safety issue, Respondent must clearly and conspicuously provide that written notification, or a document that conveys the same information using a substantially similar format, to the consumer prior to consummation of the sale of that motor vehicle.

Decision and Order

- B. Misrepresent the following:
1. Whether there is or is not an open recall for safety issues for any used motor vehicle;
 2. Whether Respondent repairs used motor vehicles for open recalls for safety issues; and
 3. Any other material fact about the safety of the used motor vehicles it advertises for sale.

II.

IT IS FURTHER ORDERED that Respondent, no later than February 6, 2017, must provide, by first class mail to the last known address of every consumer who purchased a certified used motor vehicle from Respondent between July 1, 2013 and June 15, 2015, a notice on Respondent's letterhead that clearly and conspicuously discloses the following:

“We want to alert you that some of the used vehicles we recently sold had been recalled for safety issues, but weren't repaired as of the date they were sold. You can check whether the vehicle you bought from us is subject to an unrepaired recall at the National Highway Traffic Safety Administration's recall website, <https://vinrcl.safercar.gov/vin/>. That site also provides information on how to get your vehicle fixed if it's been recalled.”

Respondent shall not include any advertising, marketing, or other promotional information in the notice. Moreover, the mailing shall not include any other documents. The envelope enclosing the notice shall have printed thereon in a clear and conspicuous fashion the disclosure “Important Safety Recall Information.”

Provided, however, that Respondent is not required to provide this notice for (A) any motor vehicle that Respondent can demonstrate was not subject to an open recall for a safety issue at the time of purchase and delivery, or (B) any motor vehicle that

Decision and Order

was the subject of one or more open recalls for safety issues at the time of purchase and delivery that Respondent can demonstrate have subsequently been fixed.

For purposes of Subpart (A) of this proviso, records showing that the vehicle was not listed as subject to an open recall for a safety issue, as of the date of the purchase, on the Original Equipment Manufacturer's recall database, on the National Highway Traffic Safety Administration's www.safercar.gov database, or on a database with information on vehicle recalls that is generally accepted based on the expertise of professionals in the relevant area to yield accurate and reliable results, shall be deemed to be sufficient to demonstrate that the vehicle was not subject to an open recall for a safety issue at the time of purchase and delivery.

For purposes of Subpart (B) of this proviso, (i) repair records generated by the dealer in the ordinary course of business that demonstrate that a vehicle with an open recall for a safety issue has been repaired; or (ii) records showing that the vehicle is no longer listed as subject to an open recall for a safety issue on the Original Equipment Manufacturer's recall database, on the National Highway Traffic Safety Administration's www.safercar.gov database, or on a database with information on vehicle recalls that is generally accepted based on the expertise of professionals in the relevant area to yield accurate and reliable results, shall be deemed sufficient to demonstrate that an open recall for a safety issue has been fixed.

III.

IT IS FURTHER ORDERED that Respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

- A. Each advertisement or other marketing material that makes any representation covered by the order unless, in comparison to an advertisement or other marketing material already maintained by Respondent pursuant to this Section, the advertisement or marketing material:
 - (i) is a duplicate, or
 - (ii) differs only in the description

Decision and Order

of the vehicle in ways not related to any representations covered by this order;

- B. All materials that were relied upon in disseminating the representation;
- C. All evidence in its possession or control that contradicts, qualifies, or calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. Any documents reasonably necessary to demonstrate full compliance with each provision of this order, including but not limited to all documents obtained, created, generated, or that in any way relate to the requirements, provisions, or terms of this order, and all reports submitted to the Commission pursuant to this order.

IV.

IT IS FURTHER ORDERED that Respondent shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order, with any electronic signatures complying with the requirements of the E-Sign Act, 15 U.S.C. § 7001 *et seq.* Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

V.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising

Decision and Order

under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to Debrief@ftc.gov or sent by overnight courier (not U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580. The subject line must begin: *In re Jim Koons Management Company*.

VI.

IT IS FURTHER ORDERED that Respondent, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

VII.

This order will terminate on December 8, 2036, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;

Analysis to Aid Public Comment

- B. This order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Jim Koons Management Company. The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

The respondent is a car dealership that sells used motor vehicles. According to the FTC complaint, respondent has represented that the used motor vehicles it sells have been subject to rigorous inspection, including for safety issues, but has failed to

Analysis to Aid Public Comment

disclose that the used motor vehicles it sells are subject to open recalls for safety issues.

For instance, the respondent has posted advertisements on the website www.koons.com which prominently featured the “Koons Used Car Advantage” and included the representation that “[b]acked by the Koons Used Car Advantage, each vehicle we carry has been carefully selected and tested... .” The website listed among the “Koons Used Car Advantage Guarantees” the following representation: “Every certified Koons Outlet vehicle must pass a rigorous and extensive quality inspection before it can be sold. Our certified mechanics check all major mechanical and electrical systems and every power accessory as part of our rigid quality controls.”

Even though it makes such claims, the respondent has allegedly advertised on its websites numerous certified used vehicles that were subject to open recalls for safety issues. In numerous instances, when the respondent allegedly advertised certified used vehicles that are subject to open recalls for safety issues, it provided no accompanying clear and conspicuous disclosure of this fact. The proposed complaint alleges that this failure to disclose constitutes a deceptive act or practice under Section 5 of the FTC Act.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices in the future. Part I prohibits the respondent from representing that used motor vehicles it offers for sale are safe, have been repaired for safety issues, or have been subject to an inspection for issues related to safety unless the used motor vehicles are not subject to any open recalls for safety issues or the respondent discloses, clearly and conspicuously, in close proximity to such representation, any material qualifying information related to open recalls for safety issues. Part II is a provision that orders the respondent to notify every consumer who purchased from it a certified used motor vehicle between July 1, 2013 and June 15, 2015 that some of the used vehicles it sold during this time had been recalled for safety issues which weren't repaired as of the date they were sold. The notice also specifies how consumers can check whether the vehicle is subject to an unrepaired recall at the National Highway

Analysis to Aid Public Comment

Traffic Safety Administration's website, <https://vinrcl.safercar.gov/vin/>. This website also provides information on how to get a vehicle fixed if it is subject to an open recall.

Parts III through VII of the proposed order are reporting and compliance provisions. Part III requires the respondent to maintain for five years, and produce to the Commission upon demand, any relevant ads and associated documentary material. Part IV is an order distribution provision that requires the respondent to provide the Order to current and future principals, officers, directors, and managers, and to all current employees, agents, and representatives having responsibilities with respect to the subject matter of the Order. Part V requires the respondent to notify the Commission of corporate changes that may affect compliance obligations. Part VI requires the respondent to submit a compliance report to the Commission 60 days after entry of the order, and also additional compliance reports within 10 business days of a written request by the Commission. Part VII “sunsets” the order after twenty years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order’s terms.

Complaint

IN THE MATTER OF

MARS PETCARE US, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4599; File No. 152 3229**Complaint, December 12, 2016 – Decision, December 12, 2016*

This consent order addresses Mars Petcare US, Inc.'s advertising, marketing, and sale of dog food under the Eukanuba brand. The complaint alleges that respondent violated Section 5 of the FTC Act by falsely representing that dogs in a ten-year study that were fed Eukanuba brand dog food and received proper care lived exceptionally long lives – including 30 percent or more longer than their typical lifespan. The complaint also alleges that respondent falsely represented that scientific tests prove that feeding dogs its Eukanuba brand dog food can enable dogs to live exceptionally long lives or to live 30 percent or more longer than their typical lifespan.. The consent order prohibits respondent from making misleading or unsubstantiated claims regarding the health benefits of any pet food and requires that respondent possess and rely upon “competent and reliable scientific evidence” to substantiate any such representation.

Participants

For the *Commission*: David M. Newman.

For the *Respondent*: Richard Mann, Keller & Heckman; John Graubert, Covington & Burling.

COMPLAINT

The Federal Trade Commission, having reason to believe that Mars Petcare US, Inc., (“Respondent”) has violated provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a Delaware corporation with its principal office or place of business at 310 Cool Springs Boulevard, Franklin, Tennessee 37067.
2. Respondent has manufactured, advertised, labeled, promoted, offered for sale, sold and distributed dog food under

Complaint

the brand name Eukanuba, among others. Respondent's dog foods are "foods," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

3. The acts and practices of Respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Eukanuba Dog Foods

4. Respondent markets and promotes its Eukanuba brand dog food as a premium dog food. The retail price of Eukanuba brand dog foods ranges from \$13.99 to \$57.99, depending on the formulation and size of the packaging.

5. Beginning in May 2015, and continuing for approximately one month, Respondent disseminated or caused to be disseminated advertisements, packaging and promotional materials for its Eukanuba brand dog food, including but not necessarily limited to the television, online and print advertisements excerpted in the attached Exhibits A to C. These materials contain the following statements and depictions:

a. (Exhibit A – online video):

Man is always searching for the fountain of youth,
a way to live longer yet stay younger.

One decade ago, Eukanuba set out on the same quest.
We launched a long life study, with a band of
Labradors, their devoted caretakers, and enough
Eukanuba to last them a lifetime.

Or so we thought. While the typical Labrador lives 12
years, some dogs in the study even lived past the age
of 16.

Like our relentless fetcher Iowa
Iowa at Age 17
Living 30% longer than her typical lifespan
Typical Labrador lifespan: 12 years

Complaint

Or the water lover Utah
Utah at Age 17
Living 30% longer than his typical lifespan
Typical Labrador lifespan: 12 years

And not just them:
Georgia at Age 17
Living 30% longer than her typical lifespan
Typical Labrador lifespan: 12 years

Bunny at age 16
Typical Labrador lifespan: 12 years

Clown at age 16
Typical Labrador lifespan: 12 years

Each living an exceptionally long life and still full of vitality.

b. (Exhibit B – television commercial and online video):

10 Years ago, we launched a long life study.
What we observed was astonishing.
With Eukanuba and proper care,
Dogs in the study were able to live beyond their
typical lifespan.

Iowa at Age 17
Living 30% longer than her typical lifespan
*typical Labrador lifespan: 12 years

Utah at Age 17
Living 30% longer than his typical lifespan
*typical Labrador lifespan: 12 years

Living an exceptionally long life
And still full of vitality

c. (Exhibit C – two-sided point-of-sale card):

Complaint

Utah at age 17. Living 30% longer than his typical lifespan. He's enjoying an exceptionally long life, with many more adventures ahead.

Iowa at age 17. Living 30% longer than her typical lifespan. She's enjoying an exceptionally long life, with plenty of chase left to give.

6. Beginning in June 2015, Respondent disseminated or caused to disseminated advertisements, packaging and promotional materials for its Eukanuba brand dog food, including but not necessarily limited to the television and online advertisements excerpted in the attached Exhibit D. These materials contain the following statements and depictions:

a. (Exhibit D – television commercial and online video):

10 Years ago, we launched a long life study.
What we observed was astonishing.
With Eukanuba and proper care,
some dogs in the study were able to live exceptionally
long lives.

Meet Iowa at Age 17, our relentless fetcher

Meet Utah at Age 17, our tireless explorer

This is the life we want for all dogs, to live long and be
full of vitality.

Count I

False or Unsubstantiated Efficacy Claims

7. In connection with the advertising, promotion, offering for sale or sale of Eukanuba brand dog food, Respondent has represented, directly or indirectly, expressly or by implication, that

a. With Eukanuba, dogs live 30 percent or more longer than their typical lifespan; and

Complaint

- b. Eukanuba brand dog foods enable dogs to live exceptionally long lives.

8. The representations set forth in Paragraph 7 were, and are, false or misleading or were not substantiated at the time the representations were made.

Count II
False Establishment Claims

9. In connection with the advertising, promotion, offering for sale or sale of Eukanuba brand dog food, Respondent has represented, directly or indirectly, expressly or by implication, that

- a. Scientific tests prove that, with Eukanuba, dogs live 30 percent or more longer than their typical lifespan; and
- b. Scientific tests prove that Eukanuba brand dog foods enable dogs to live exceptionally long lives.

10. In fact,

- a. Scientific tests do not prove that, with Eukanuba, dogs live 30 percent longer than their typical lifespan; and
- b. Scientific tests do not prove that Eukanuba brand dog foods enable dogs to live exceptionally long lives.

Among other things, the evidence relied on by Respondent for its representations concerning the Eukanuba brand dog food consisted primarily of results from a single study, the results of which showed no significant difference in the median age at death of the dogs in the study relative to the typical age at death of dogs of the same breed. Therefore, the representations set forth in Paragraph 8 were, and are, false or misleading.

Complaint

Violations of Sections 5 and 12

11. The acts and practices of Respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twelfth day of December, 2016, has issued this complaint against Respondent.

By the Commission.

Complaint

Exhibit A

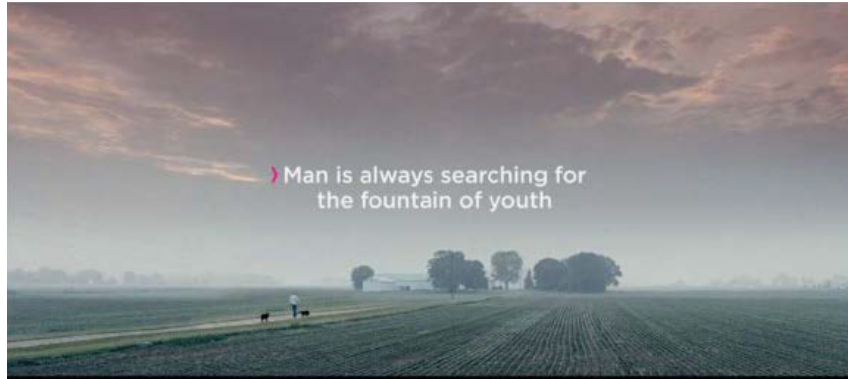


Exhibit A

Complaint



Exhibit A

Complaint

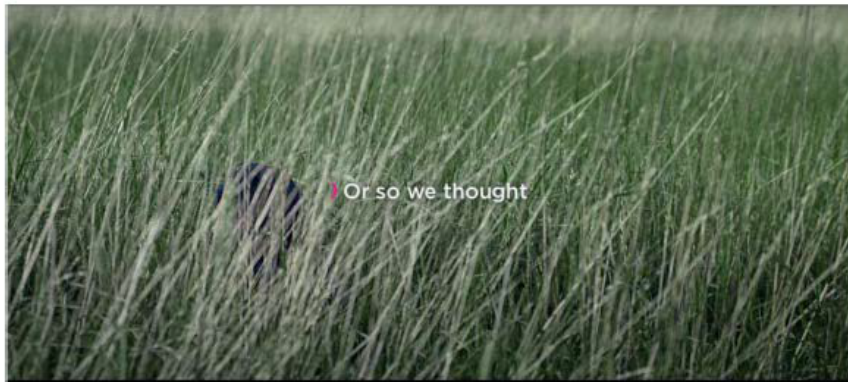
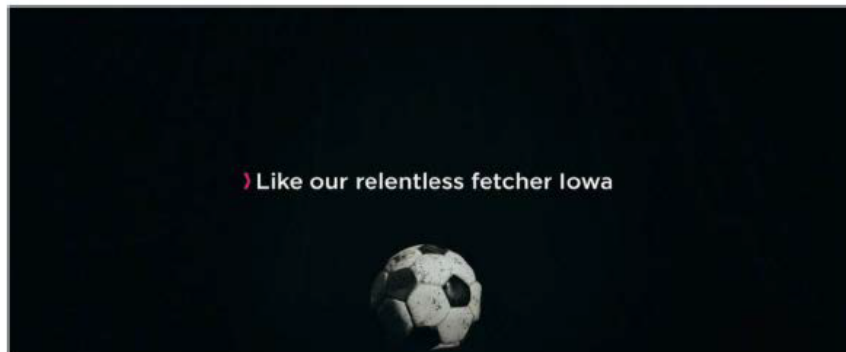
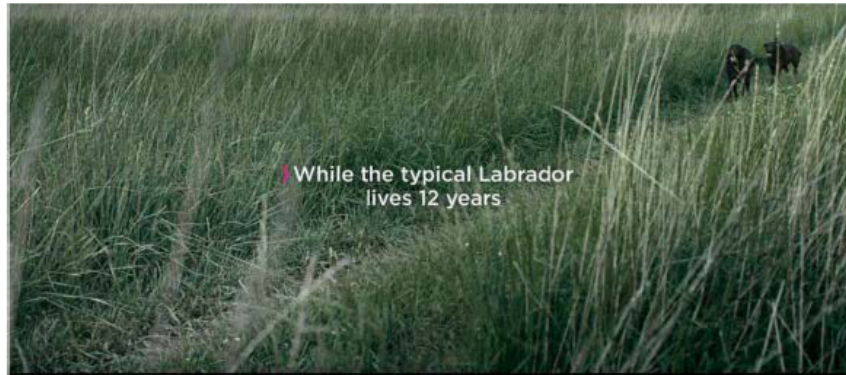


Exhibit A

Complaint



Complaint

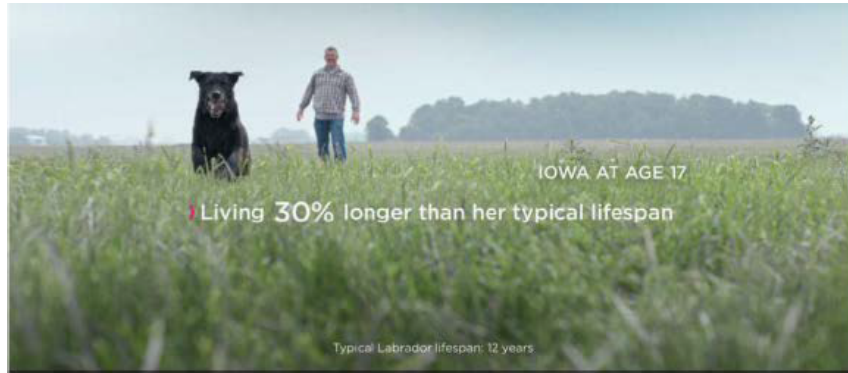


Exhibit A

Complaint

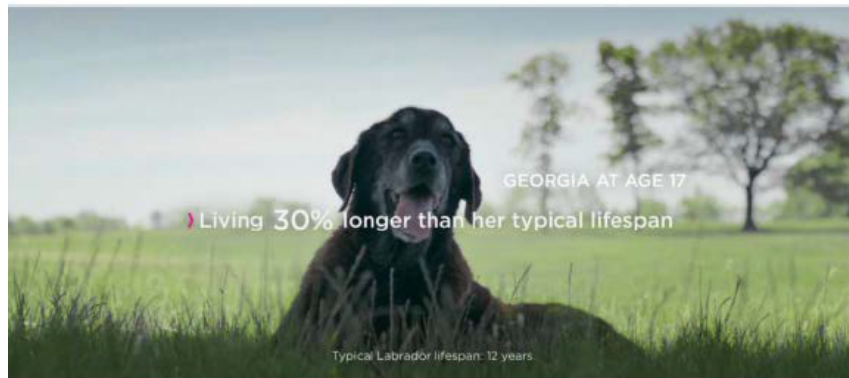


Exhibit A

Complaint



Exhibit A

Complaint

Exhibit B

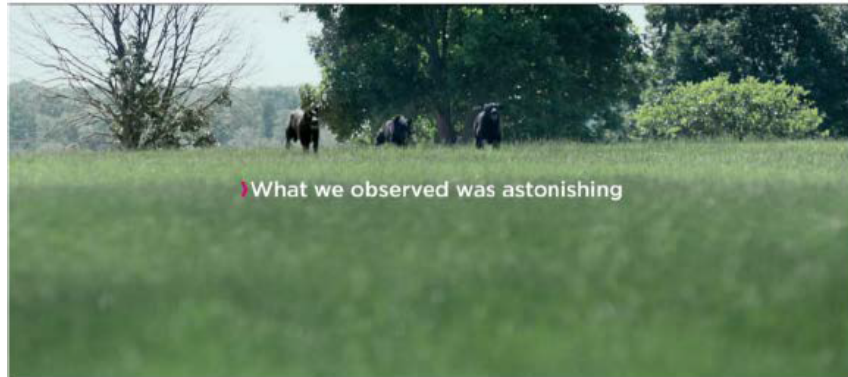
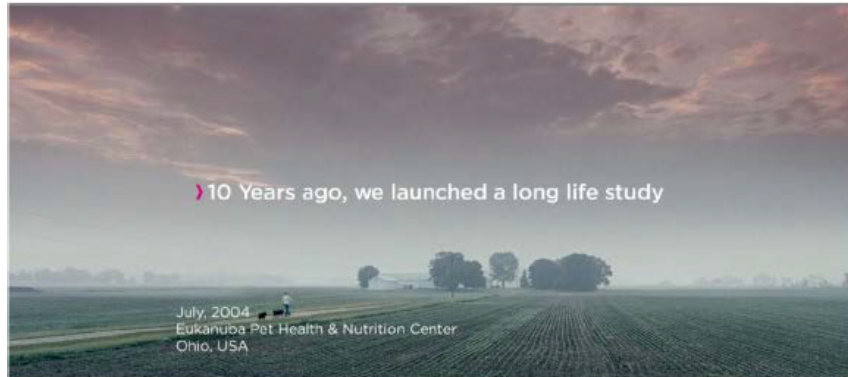


Exhibit B

Complaint

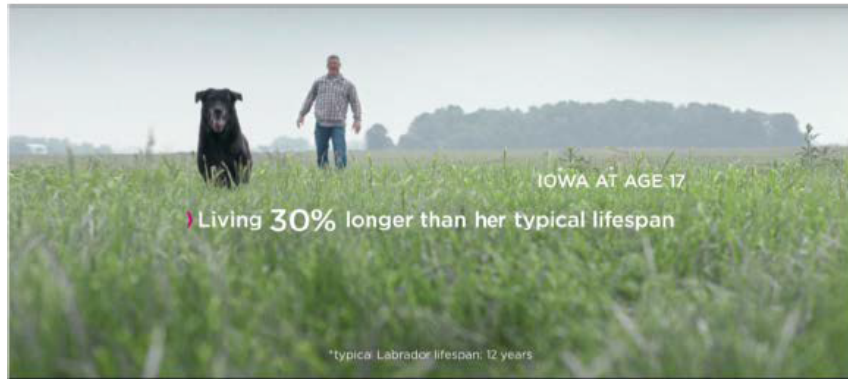


Exhibit B

Complaint

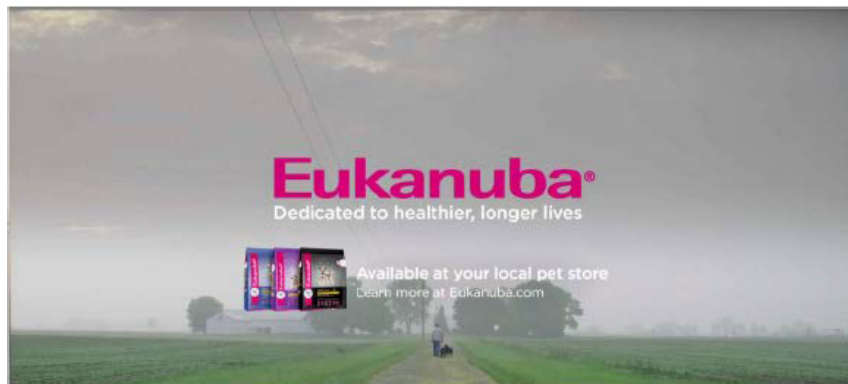
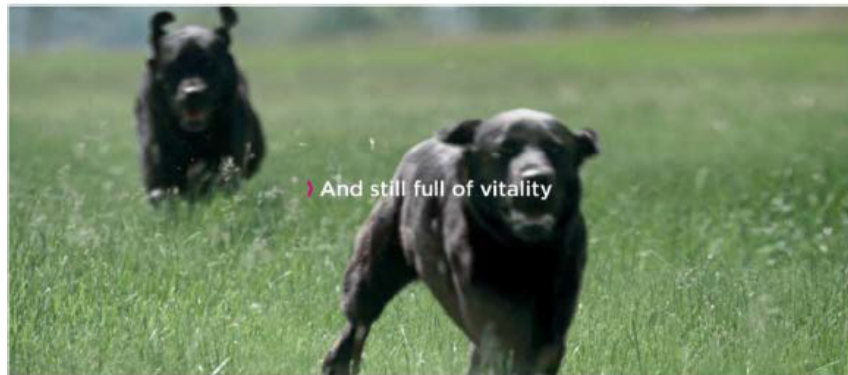
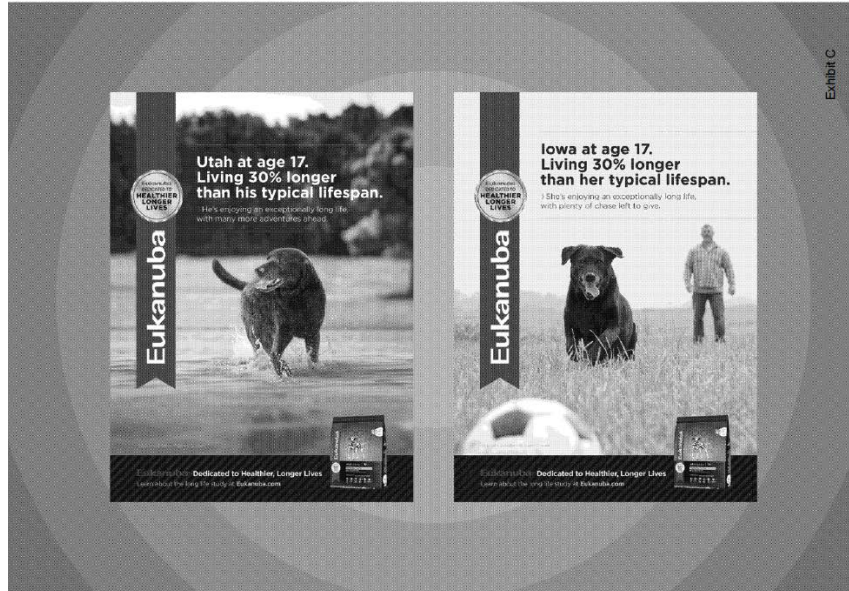


Exhibit B

Complaint

Exhibit C



Complaint

Exhibit D

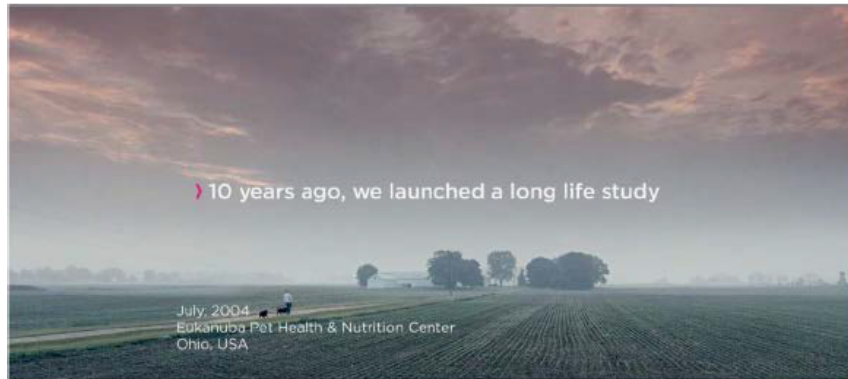


Exhibit D

Complaint



Exhibit D

Complaint

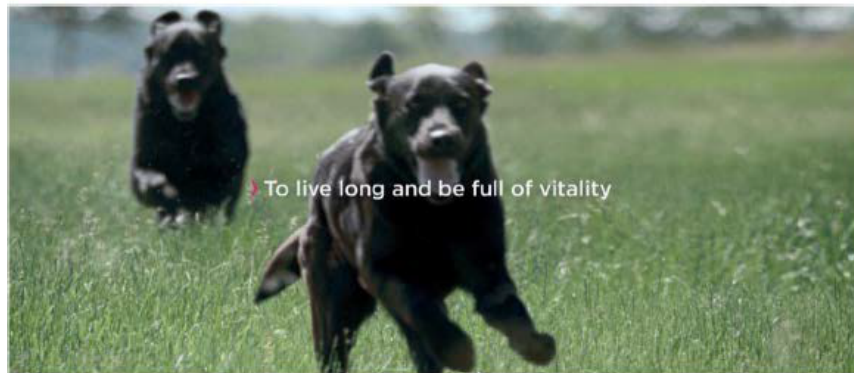


Exhibit D

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) initiated an investigation of certain acts and practices of the Respondent named above in the caption. The Commission’s Bureau of Consumer Protection (“BCP”) prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violation of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statements by Respondent that it neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission’s Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered the comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. Respondent Mars Petcare US, Inc., is a Delaware corporation with its principal office or place of business at 310 Cool Springs Boulevard, Franklin, Tennessee.

Decision and Order

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**Definitions**

For purposes of this Order, the following definitions apply:

- A. “Food” means: (a) any article used for food or drink for humans or other animals; (b) chewing gum; and (c) any article used for components of any such article.
- B. “Pet Food” means any Food that is used for food or drink for domestic pets.

Provisions**I. Prohibited Misleading and Unsubstantiated Representations about Longevity and Other Health Benefits of Pet Foods**

IT IS ORDERED that Respondent, and Respondent’s officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Eukanuba-brand dog food or any other Pet Food, must not make any representation, expressly or by implication:

- A. That with such Pet Food, dogs live 30 percent or more longer than their typical lifespan;
- B. That such Pet Food can enable dogs to live exceptionally long lives; or
- C. About the health benefits of such products

Decision and Order

unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Provision, “competent and reliable scientific evidence” means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

II. Prohibited Misrepresentations Regarding Tests or Studies

IT IS FURTHER ORDERED that Respondent, and Respondent’s officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Pet Food must not make any misrepresentation, expressly or by implication:

- A. About the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, including that studies, research, or trials prove that, with Respondent’s Pet Foods, dogs live 30 percent or more longer or substantially longer than their typical lifespan or that Respondent’s Pet Foods enable dogs to live exceptionally long lives; or
- B. That any health benefits of such product are scientifically proven or otherwise established.

III. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

Decision and Order

- A. Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.
- B. Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reporting. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.
- C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

IV. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondent make timely submissions to the Commission:

- A. One year after the issuance date of this Order, Respondent must submit a compliance report, sworn under penalty of perjury, in which Respondent must:
 - 1. identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Respondent;
 - 2. identify all of Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses;

Decision and Order

3. describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales;
 4. describe in detail whether and how Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes Respondent made to comply with the Order; and
 5. provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.
- B. Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
1. any designated point of contact; or
 2. the structure of Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.
- C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Respondent within 14 days of its filing.
- D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: “I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____” and supplying the date, signatory’s full name, title (if applicable), and signature.

Decision and Order

- E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Mars Petcare US, Inc., Docket No. C-4599.

V. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records and retain each such record for five (5) years. Specifically, Respondent must create and retain the following records:

- A. accounting records showing the revenues from all goods or services sold;
- B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;
- C. copies or records of all consumer complaints and refund requests concerning the subject matter of this Order, whether received directly or indirectly, such as through a third party, and any response;
- D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;
- E. a copy of each unique advertisement or other marketing material making a representation subject to this Order; and

Decision and Order

- F. for five (5) years from the date of the last dissemination of any representation covered by this Order:
1. all materials that were relied upon in making the representation; and
 2. all tests, analyses, research, studies, demonstrations, or other evidence in Respondent's possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

- A. Within 10 days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.
- B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present.
- C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of

Decision and Order

identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

VII. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate December 12, 2036, or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Provision in this Order that terminates in less than 20 years;
- B. This Order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

If such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order from Mars Petcare US, Inc. (“respondent”). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

This matter involves the advertising, marketing, and sale by respondent of dog food under the Eukanuba brand. Respondent has marketed its Eukanuba brand dog foods through retail outlets. According to the FTC complaint, respondent claimed that its dog food could increase the longevity of dogs by 30 percent or more.

Specifically, the FTC complaint alleges that respondent represented that dogs in a ten-year study that were fed Eukanuba brand dog food and received proper care lived exceptionally long lives – including 30 percent or more longer than their typical lifespan. The complaint alleges that these claims are false or unsubstantiated and thus violate the FTC Act. The complaint also alleges that respondent represented that scientific tests prove that feeding dogs its Eukanuba brand dog food can enable dogs to live exceptionally long lives or to live 30 percent or more longer than their typical lifespan. The complaint alleges that these claims are false and thus violate the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. Specifically, Part I addresses the unsubstantiated claims alleged in the complaint. Part I prohibits respondent from making misleading or unsubstantiated representations that its Eukanuba-brand pet foods or any other pet food can enable dogs to live 30 percent or more longer than their typical lifespan or live exceptionally long lives. It also prohibits respondent from making misleading or unsubstantiated claims regarding the health

Analysis to Aid Public Comment

benefits of any pet food. It requires that respondent possesses and relies upon “competent and reliable scientific evidence” to substantiate any such representation.

Part II of the proposed order addresses the allegedly false claims that scientific tests prove that feeding dogs respondent’s Eukanuba brand dog food can enable dogs to live 30 percent or more longer or substantially longer than their typical lifespan. Part II prohibits respondent, when advertising any pet food, from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or misrepresenting that any health benefits of the pet food are scientifically proven.

Parts III-VI of the proposed order contain compliance and recordkeeping requirements. Part III requires respondent acknowledge receipt of the order, to provide a copy of the order to certain current and future principals, officers, directors and employees, and to obtain an acknowledgement from each such person that they have received a copy of the order. Part IV requires the filing of compliance reports within one year after the order becomes final and within 14 days of any change in respondent that would affect compliance with the order. Part V requires respondent to maintain certain records, including records necessary to demonstrate compliance with the order. Part VI requires respondent to submit additional compliance reports when requested by the Commission and to permit the Commission or its representatives to interview respondent’s personnel. Finally, Part VII provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint and proposed order or to modify the proposed order’s terms in any way.

INTERLOCUTORY, MODIFYING,
VACATING, AND MISCELLANEOUS
ORDERS

IN THE MATTER OF

AMERICAN AIR LIQUIDE HOLDINGS, INC.

Docket No. C-4574. Order, August 31, 2016

Letter approving the divestiture of facilities for the production of various bulk gases as well as packaged gases retail locations to Matheson Tri-Gas, Inc.

LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

Elaine Ewing, Esq.
Cleary Gottlieb Steen & Hamilton LLP

*Re: In the Matter of American Air Liquide Holdings, Inc., Docket
No. C-4574*

Dear Ms. Ewing:

This is in reference to the petition for the approval of the proposed divestiture of certain assets filed by American Air Liquide Holdings, Inc. (“Air Liquide”) and received on June 21, 2016 (“Petition”). Pursuant to the Decision and Order in Docket No. C-4574, Air Liquide requests prior Commission approval of its proposal to divest certain gases assets to Matheson Tri-Gas, Inc. (“Matheson”).

After consideration of Air Liquide’s Petition and other available information, the Commission has determined to approve the proposed divestiture as set forth in the Petition. In reaching this decision, the Commission has relied upon the information submitted and the representations made by Air Liquide and Matheson in connection with the Petition and has assumed them to be accurate and complete.

By direction of the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

**THE PENN STATE HERSHEY MEDICAL
CENTER
AND
PINNACLEHEALTH SYSTEM**

Docket No. 9368. Order, October 14, 2016

Order granting a Joint Expedited Motion for a Continuance of Administrative Proceedings to continue all current deadlines in this matter—including the commencement of the administrative hearing—by one week.

ORDER GRANTING CONTINUANCE

On September 27, 2016, the Court of Appeals for the Third Circuit issued its Opinion and Judgment directing the District Court for the Middle District of Pennsylvania to preliminarily enjoin the merger between Penn State Hershey Medical Center and PinnacleHealth System, pending the outcome of this administrative proceeding.¹ In light of prior Commission orders, the administrative hearing was therefore scheduled to commence on October 18.

Complaint Counsel and Respondents now request that the Commission continue the administrative hearing for one week and grant a corresponding extension of all pre-hearing deadlines.² Hershey represents that it needs additional time to allow its board of directors to determine whether to continue pursuing the merger following the Third Circuit's ruling. The parties state that a one-week continuance will give Respondents sufficient time to finalize their decision and may obviate the expenditure of unnecessary resources in preparation for the hearing in this matter, without imposing any countervailing harms.

¹ *Fed. Trade Comm'n v. Penn State Hershey Med. Ctr.*, --- F.3d ---, 2016 WL 5389289 (3d Cir. Sept. 27, 2016), at <https://www.ftc.gov/system/files/documents/cases/160927pinnacledecision.pdf>.

² *Penn State Hershey Med. Ctr.*, Docket No. 9368, Joint Expedited Motion for Continuance of the Administrative Hearing (Oct. 11, 2016).

Interlocutory Orders, Etc,

In light of the foregoing, we find that there is good cause to grant the requested continuance. Accordingly,

IT IS HEREBY ORDERED that the evidentiary hearing shall commence on October 25, 2016, and that all pre-hearing deadlines shall be extended until October 24, 2016.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

**ADVOCATE HEALTH CARE NETWORK,
ADVOCATE HEALTH AND HOSPITALS
CORPORATION,
AND
NORTSHORE UNIVERSITY HEALTHSYSTEM**

Docket No. 9369. Order, October 14, 2016

Order granting a joint motion seeking to continue the administrative hearing for one week.

ORDER GRANTING CONTINUANCE

On September 27, 2016, the Court of Appeals for the Third Circuit issued its Opinion and Judgment directing the District Court for the Middle District of Pennsylvania to preliminarily enjoin the merger between Penn State Hershey Medical Center and PinnacleHealth System, pending the outcome of this administrative proceeding.¹ In light of prior Commission orders, the administrative hearing was therefore scheduled to commence on October 18.

Complaint Counsel and Respondents now request that the Commission continue the administrative hearing for one week and grant a corresponding extension of all pre-hearing deadlines.² Hershey represents that it needs additional time to allow its board of directors to determine whether to continue pursuing the merger following the Third Circuit's ruling. The parties state that a one-week continuance will give Respondents sufficient time to finalize their decision and may obviate the expenditure of unnecessary resources in preparation for the hearing in this matter, without imposing any countervailing harms.

1 *Fed. Trade Comm'n v. Penn State Hershey Med. Ctr.*, --- F.3d ---, 2016 WL 5389289 (3d Cir. Sept. 27, 2016), at <https://www.ftc.gov/system/files/documents/cases/160927pinnacledecision.pdf>.

2 *Penn State Hershey Med. Ctr.*, Docket No. 9368, Joint Expedited Motion for Continuance of the Administrative Hearing (Oct. 11, 2016).

Interlocutory Orders, Etc,

In light of the foregoing, we find that there is good cause to grant the requested continuance. Accordingly,

IT IS HEREBY ORDERED that the evidentiary hearing shall commence on October 25, 2016, and that all pre-hearing deadlines shall be extended until October 24, 2016.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

**HEIDELBERGCEMENT AG
AND
ITALCEMENTI S.P.A**

Docket No. C-4579. Order, November 15, 2016

Letter approving the divestiture of the Martinsburg Cement Business to Argos USA LLC, a subsidiary of Cementos Argos S.A.

LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

David P. Wales, Esq.
Jones Day

*Re: In the Matter of HeidelbergCement AG and Italcementi S.p.A.,
Docket No. C-4579*

Dear Mr. Wales:

This letter responds to the Application For Approval Of Divestiture Of Martinsburg (“Divestiture Application”) filed by Respondents HeidelbergCement AG and Italcementi S.p.A. on September 18, 2016. The Divestiture Application requests that the Federal Trade Commission approve, pursuant to the Order in this matter, Respondents’ proposed divestiture of the Martinsburg Cement Business to Argos USA LLC. The Application was placed on the public record for comments until October 24, 2016. No comments were received.

After consideration of the proposed divestiture as set forth in Respondents’ Divestiture Application, as well as other available information, the Commission has determined to approve the proposed divestiture. In according its approval, the Commission has relied upon the information submitted and representations made in connection with Respondents’ Divestiture Application and has assumed them to be accurate and complete.

By direction of the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

**ADVOCATE HEALTH CARE NETWORK,
ADVOCATE HEALTH AND HOSPITALS
CORPORATION,
AND
NORTSHORE UNIVERSITY HEALTHSYSTEM**

Docket No. 9369. Order, November 15, 2016

Order granting a joint motion seeking to continue the administrative hearing.

ORDER GRANTING CONTINUANCE

On October 31, 2016, the Court of Appeals for the Seventh Circuit reversed the denial of the Commission's motion for a preliminary injunction by the U.S. District Court for the Northern District of Illinois. The Seventh Circuit's injunction preventing Respondents from merging pending the District Court's reconsideration of the preliminary injunction motion remains in place.¹ The administrative hearing is currently scheduled to begin on November 21, 2016.²

Complaint Counsel and Respondents jointly request that the Commission continue the administrative hearing and grant an extension of all pre-hearing deadlines.³ The parties state that the requested continuance will both ease the burden on third parties and expert witnesses to prepare for the administrative hearing and

1 *Fed. Trade Comm'n v. Advocate Health Care Network*, ___ F.3d ___ 7th Cir. (October 31, 2016), at https://www.ftc.gov/system/files/documents/cases/161101advocate_ca7_opinion.pdf (Opinion); Final Judgment at https://www.ftc.gov/system/files/documents/cases/161101advocate_judgment.pdf.

2 *See Advocate Health Care Network*, Docket No. 9369, Order Granting Continuance (June 28, 2016), at <https://www.ftc.gov/system/files/documents/cases/160628advhcnorder.pdf>.

3 *Advocate Health Care Network*, Docket No. 9369, Joint Expedited Motion for Continuance of Administrative Proceedings (Nov. 10, 2016), at https://www.ftc.gov/system/files/documents/cases/161115_d09369_joint_expedited_motion_administrative_proceedings.pdf.

Interlocutory Orders, Etc.

allow time to narrow the scope of issues to be presented at the administrative hearing, without imposing any countervailing harms.

In light of the foregoing, we find that there is good cause to grant the requested continuance. Accordingly,

IT IS HEREBY ORDERED that the administrative hearing shall commence 21 days after the U.S. District Court for the Northern District of Illinois rules on the Commission's request for a preliminary injunction, and that all pre-hearing deadlines shall be extended until after the District Court issues its decision, as determined by the Administrative Law Judge.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

CALIFORNIA NATUREL, INC.

Docket No. 9370. Order, November 21, 2016

Order extending time to issue Commission's decision on Complaint Counsel's Motion for Summary Decision.

**ORDER EXTENDING TIMETABLE FOR RULING ON MOTION FOR
SUMMARY DECISION**

In order to give full consideration to the issues presented by Complaint Counsel's Motion for Summary Decision in this proceeding, the Commission has determined, pursuant to Rule 4.3(b), 16 C.F.R. § 4.3(b), to extend, the time period for issuing a ruling on that Motion until December 5, 2016.

IT IS SO ORDERED.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

AMERICAN AIR LIQUIDE HOLDINGS, INC.

Docket No. C-4574. Order, December 16, 2016

Letter approving the divestiture of the Gases Assets related to the Galva, Iowa and Sergeant Bluff, Iowa portions of the CO₂ Business to Reliant Processing, Ltd., whose limited partner is Reliant Holdings, Ltd.

LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

Brian Byrne, Esq.
Cleary Gottlieb Steen & Hamilton LLP

Re: *In the Matter of American Air Liquide Holdings, Inc.*, Docket
No. C-4574

Dear Mr. Byrne:

This is in reference to the petition for the approval of the proposed divestiture of certain assets filed by American Air Liquide Holdings, Inc. (“Air Liquide”) and received on October 7, 2016 (“Petition”). Pursuant to the Decision and Order in Docket No. C-4574, Air Liquide requests prior Commission approval of its proposal to divest certain CO₂/dry ice production assets to Reliant Holdings, Ltd. (“Reliant”).

After consideration of Air Liquide’s Petition and other available information, the Commission has determined to approve the proposed divestiture as set forth in the Petition. In according its approval, the Commission has relied upon the information submitted and the representations made by Air Liquide and Reliant in connection with the Petition and has assumed them to be accurate and complete.

By direction of the Commission.

RESPONSES TO PETITIONS TO QUASH OR LIMIT COMPULSORY PROCESS

CELLMARK BIOPHARMA LLC AND LEXIUM INTERNATIONAL, LLC

FTC File No. 162 3133 - Decision, July 25, 2016
FTC File No. 162 3134

RESPONSE TO CELLMARK BIOPHARMA LLC AND LEXIUM INTERNATIONAL, LLC'S PETITIONS TO QUASH OR LIMIT SUBPOENAS DATED MAY 24, 2016

By McSWEENY, Commissioner:

CellMark Biopharma LLC (“CellMark”) and Lexium International, LLC (“Lexium”) have petitioned to limit or quash Civil Investigative Demands (CIDs) issued by the Commission under Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1. For the reasons stated below, the petitions are denied.

I. BACKGROUND

CellMark is a limited liability company formed in 2015. It sells and promotes two dietary supplements – “CellAssure” and “Cognify.” In advertising and promotional materials, CellMark claims that these products mitigate the negative effects of chemotherapy and related cancer treatments. Derek Vest is an officer and the sole shareholder of Cellmark.

Lexium is a limited liability company that, according to its petition, used to be known as Gentech Pharmaceutical, LLC (“Gentech”). Gentech, which was formed in 2010, developed and sold dietary supplement products for cognitive function, weight loss, and sleep aid, which Lexium continues to market and sell. Mr. Vest was a former officer of both Gentech and Lexium, but no longer has such roles; he currently serves as a consultant to Lexium.

On May 24, 2016, the Commission issued CIDs to CellMark and Lexium as part of an investigation of the companies’ marketing claims about their products. Each CID calls for

Responses to Petitions to Quash

responsive “documents and information in [the company’s] possession or under [its] actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of [the company’s] . . . directors, officers, employees, and other agents and consultants.” Pets. Exh. 1 ¶ II.I. Each CID defines “Company” to include “affiliates, and all directors, officers, employees, agents, consultants, and other persons working for or on behalf of the foregoing.” Cellmark Pet. Exh. 1 ¶ I.H; Lexium Pet. Exh. 1 ¶ I.G. Thus, the CIDs require Cellmark and Lexium to produce all responsive documents in their possession, custody, and control, including any such documents held by their officers and consultants.

On June 13, 2016, Cellmark and Lexium filed almost identical petitions to limit or quash the CIDs, and both attach a copy of a “target letter” issued by the U.S. Attorney’s Office for the Middle District of Florida to Mr. Vest. This letter informs Mr. Vest that he is the “target of a Federal Grand Jury investigation . . . [for] introducing and delivering for introduction into interstate commerce misbranded drugs and other matters, and possible violations of federal criminal laws.” Pets. Exh. 2. Cellmark and Lexium state that they filed their petitions “to ensure that [Mr. Vest’s] Fifth Amendment right against self-incrimination is not waived by the production of information to the FTC.” Pets. at 1. They ask the Commission to strike the requirement that they produce responsive documents and information that Mr. Vest has or controls. Additionally, they ask the Commission to relieve the companies from their obligation under the CIDs to certify that all responsive documents and information have been produced. For the reasons stated below, we deny both petitions.

II. ANALYSIS

It is well established that the Fifth Amendment “privilege against self-incrimination is essentially a personal one, applying only to natural individuals.” *United States v. White*, 322 U.S. 694, 698 (1944). As a result, courts have held for over a century that a corporate officer may not invoke his personal Fifth Amendment privilege as a basis for resisting compliance with

Responses to Petitions to Quash

compulsory process seeking corporate records. *See, e.g., Wilson v. United States*, 221 U.S. 361 (1911). “If the corporation were guilty of misconduct, [its officer] could not withhold its books to save it; and if he were implicated in the violations of law, he could not withhold the books to protect himself from the effect of their disclosures.” *Id.* at 384. A corporate officer’s personal privilege against self-incrimination does not prevent the production of corporate records even when the corporate officer is the sole shareholder and the only person authorized to manage a corporation’s business affairs. *See, e.g., Braswell v. United States*, 487 U.S. 99, 101-02, 119 (1988) (finding sole shareholder and officer “could not resist the subpoena for corporate documents”); *Bellis v. United States*, 417 U.S. 85, 100 (1974) (“[N]o privilege can be claimed by the custodian of corporate records, regardless of how small the corporation may be.”); *United States v. McDonald Chevrolet & Oldsmobile, Inc.*, 514 F. Supp. 83, 90 (N.D. Ga. 1981) (“[A] corporate officer may be compelled to produce corporate documents, even though he is the sole shareholder or alter ego of the corporation and the records may incriminate him.”).

Cellmark and Lexium do not, nor can they, dispute this well-established law. Instead, they cite a supposed exception established by the Supreme Court in *United States v. Hubbell*, 530 U.S. 27 (2000), and argue they may invoke the protections of the Fifth Amendment on behalf of Mr. Vest because, in producing responsive documents, Mr. Vest would tacitly “admit their existence and authenticity.” *Pets.* at 3. Cellmark and Lexium misinterpret the Supreme Court’s holding in *Hubbell*.

In *Hubbell*, the Supreme Court recognized that the compelled production of documents can be “testimonial” and thus implicate the Fifth Amendment to the extent that the production communicates a statement of fact – for example, that papers existed and were in the control of the custodian. *Id.* at 34-37. The Court held that, in such circumstances, the government could not rely on the act of production in a *subsequent* criminal proceeding against the custodian. *Id.* at 35-36. Nowhere in the *Hubbell* opinion does the Court address, let alone deviate from, the fundamental principle endorsed most recently by the Supreme Court in *Braswell* – that an individual may not rely on

Responses to Petitions to Quash

the privilege against compulsory self-incrimination to avoid the production of corporate records that he holds in a representative capacity, even if those records might incriminate him. *Braswell*, 487 U.S. at 101-02, 119; *see also Bellis*, 417 U.S. at 88-89.

Not surprisingly, courts that have examined whether the *Hubbell* case changed the law have concluded, as we do, that the rule remains the same; corporate officers cannot rely on the Fifth Amendment to avoid the production of corporate records. *See, e.g., In re Grand Jury Empaneled on May 9, 2014*, 786 F.3d 255, 263 n.2 (3d Cir. 2015) (“[T]here is no reason to suspect that *Hubbell* altered, in any way, the analysis set forth in *Braswell*.”); *Amato v. United States*, 450 F.3d 46, 51 (1st Cir. 2006) (noting that post-*Hubbell*, “the act-of-production doctrine is not an exception to the collective-entity doctrine even when the corporate custodian is the corporation’s sole shareholder, officer and employee”); *Armstrong v. Guccione*, 470 F.3d 89, 98 (2d Cir. 2006) (“[W]e reject any suggestion that *Hubbell* so undermined *Braswell* that we are no longer compelled to follow its holding. . . . We remain bound by the Supreme Court’s holding in *Braswell*.”); *S.E.C. v. Narvett*, 16 F. Supp. 3d 979, 981-83 (E.D.Wis. 2014) (act-of-production doctrine provides no support for a corporation’s sole employee and shareholder to refuse to comply with SEC subpoena).

The CIDs at issue are directed to the corporations and seek only corporate documents. Mr. Vest is an officer of Cellmark and a consultant of Lexium – in both cases, he is acting in a representative capacity as a corporate agent. The documents demanded by the CID, including those within Mr. Vest’s possession, custody, or control, are corporate records that are within the companies’ control, *see, e.g., Flagg v. City of Detroit*, 252 F.R.D. 346, 353 (a company is under an “affirmative duty to seek that information reasonably available to [it] from [its] employees, agents, or others subject to [its] control”), and the corporations and Mr. Vest must produce them even if the documents are incriminating to Mr. Vest personally.¹

¹ Lexium also claims that, as an ex-employee, Mr. Vest may assert a Fifth Amendment privilege to refuse to produce documents belonging to his former employer. Lexium Pet. at 5. However, Mr. Vest has a continuing “connection to Lexium . . . as a consultant.” Lexium Pet. at 1.

Responses to Petitions to Quash

Accordingly, there is no basis for limiting or quashing the CIDs to excuse the production of documents in Mr. Vest's possession, custody, or control. Nor do we excuse Cellmark or Lexium from their obligation to certify that they have produced all responsive documents and information.

Cellmark and Lexium also assert that the production of the information requested in the CIDs' interrogatories would "implicate[] Vest's Fifth Amendment rights." Pets. at 2. Interrogatories are inherently testimonial in nature. Therefore, individuals who properly assert a privilege against self-incrimination cannot be compelled to answer them. Nonetheless, a corporation is still obligated to respond, and must do so by selecting an officer, employee, or "agent who could, without fear of self-incrimination, furnish such requested information as was available to the corporation." See *United States v. Kordel*, 397 U.S. 1, 8 (1970) (quoting *United States v. 3963 Bottles . . . of . . . Enerjol Double Strength*, 265 F.2d 332, 336 (7th Cir. 1959) ("It would indeed be incongruous to permit a corporation to select an individual to verify the corporation's answers, who because he fears self-incrimination may thus secure for the corporation the benefits of a privilege it does not have.")). Both CIDs at issue identify and list officers and employees other than Mr. Vest. Cellmark and Lexium can call on any of them to respond on behalf of the corporations without impinging on Mr. Vest's personal Fifth Amendment rights.

Finally, Cellmark and Lexium contend that the Supreme Court's decisions in *Citizens United v. F.E.C.*, 558 U.S. 310 (2010), and *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), should be read expansively to extend the Fifth Amendment privilege against compulsory self-incrimination to corporations and other collective entities and thereby provide a basis to quash the two CIDs. Pets. at 5-6. This argument is also meritless. Those cases address the application of the First Amendment to corporations. Nothing in those decisions signals any departure from century-old precedents recognizing the Fifth Amendment privilege against self-incrimination as a uniquely individual right. See *In re Grand Jury Empaneled on May 9, 2014*, 786 F.3d at 263 n.1 (stating the court can "discern nothing in Supreme Court jurisprudence that suggests the Court has, in

Responses to Petitions to Quash

any way, signaled its readiness to depart from its longstanding precedent regarding corporate custodians' inability to invoke the Fifth Amendment privilege against self-incrimination").

III. CONCLUSION

For the foregoing reasons, we deny Cellmark's and Lexium's petitions to limit or quash the Commission's CIDs.

IT IS HEREBY ORDERED THAT the Petitions to Limit or Quash Civil Investigative Demand filed by CellMark Biopharma LLC and Lexium International, LLC be, and they hereby are **DENIED**.

IT IS FURTHER ORDERED THAT all documents and information responsive to the specifications in the Civil Investigative Demands to CellMark Biopharma LLC and Lexium International, LLC must now be produced on or before August 15, 2016.

By the Commission.

TABLE OF COMMODITIES

VOLUME 162

	<u>Page(s)</u>
Acitretin Oral Capsule, generic	563
<i>Adderall</i> , generic	563
Alendronate Sodium Oral Tablet, generic	563
<i>Alesse-28</i> , generic	563
Amphetamine Aspartate/Amphetamine Sulfate/Dextroamphetamine Saccharate/Dextroamphetamine Sulfate Oral Capsule, generic	563
Argon, bulk	141
Armodafinil Oral Tablet, generic	563
Aspirin/Dipyridamole Extended Release Oral Capsule, generic	563
Benzoyl Peroxide/Clindamycin Phosphate Gel, generic	563
Beverage Cans, Aluminum	418
Body Lotion	1
Budesonide Inhalation Suspension, generic	563
Buprenorphine/Naloxone Buccal Film, generic	563
Buspiron HCl Oral Tablet, generic	563
Carbidopa/Levodopa Oral Tablet, generic	563
Carbon Dioxide, Liquid, bulk	141
Carisoprodol Tablets, generic	798
<i>Certified Pre-Owned</i> vehicles	1099
Clarithromycin Extended Release Oral Tablet, generic	563
Clonidine HCl Extended Release Transdermal Film, generic	563
.....	563
Clozapine Oral Tablet, generic	563
Conditioner	27
<i>Cyclessa</i> , generic	563
Cyclosporine Oral Capsule, generic	563
Cyclosporine Oral Solution, generic	563

continued

Demulen 1/35 , generic	563
Desmopressin Acetate Oral Tablet, generic	563
Desogestrel/Ethinyl Estradiol Oral Tablet, generic	563
Desogestrel/Ethinyl Estradiol/Ethinyl Estradiol Oral Tablet, generic	563
Dexmethylphenidate HCl Extended Release Oral Capsule, generic	563
Dextroamphetamine Sulfate Extended Release Oral Capsule, generic	563
Diazepam Oral Tablet, generic	563
Dienogest/Estradiol Valerate and Estradiol Valerate Oral Tablet, generic	563
Disopyramide Phosphate Oral Capsule, generic	563
Dog Food	1172
Drospirenone/Ethinyl Estradiol Oral Tablet, generic	563
Dry Ice	141
Ductile Iron Pipe	891
Epirubicin Injection Vial, generic	563
Estazolam Oral Tablet, generic	563
Estradiol Oral Tablet, generic	563
Estrostep FE , generic	563
Ethinyl Estradiol/Ethinodiol Diacetate Oral Tablet, generic	563
Ethinyl Estradiol/Etonogestrel Vaginal Ring, generic	563
Ethinyl Estradiol/Levonorgestrel Oral Tablet, generic	563
Ethinyl Estradiol/Norethindrone Acetate Oral Tablet, generic	563
Ethinyl Estradiol/Norethindrone Acetate/Ferrous Fumarate Oral Tablet, generic	563
Ethinyl Estradiol/Norethindrone Oral Tablet, generic	563
Ethinyl Estradiol/Norgestrel Oral Tablet, generic	563
Eukanuba	1172
Ezetimibe/Simvastatin Tablets, generic	563
Felbamate Tablets, generic	798
Fentanyl Buccal Tablet, generic	563
Fludarabine Lyophilized Vial Injection, generic	563
Fluocinonide Cream Emulsified Base, generic	563
Fluocinonide Topical Cream, generic	563
Flutamide Oral Capsule, generic	563

Table of Commodities - continued

Glyburide/Metformin HCl Oral Tablet, generic	563
Griseofulvin Microcrystalline Oral Liquid Suspension, generic	563
.....	563
Grocery Stores, full-line retail	945
Hair Care Products	27
Hand Lotion	1
Hydroxyzine Pamoate Oral Capsule, generic	563
Imiquimod Topical Cream, generic	563
Information Security	246
Insulated-Gate Bipolar Transistors	910
<i>Koons Used Car Advantage</i>	1150
Levalbuterol HCl Inhalation Solution, generic	563
<i>Levlite-28</i> , generic	563
<i>Lo Seasonique</i> , generic	563
<i>Lo/Ovral-28</i> , generic	563
<i>Loestrin 21 1.5/30</i> , generic	563
<i>Loestrin 21 1/20</i> , generic	563
<i>Loestrin FE 1.5/30</i> , generic	563
<i>Loestrin FE 1/20</i> , generic	563
Medications, generic	563, 798
Metformin HCl/Saxagliptin Extended Release Tablet, generic	563
.....	563
Methotrexate Injection, generic	563
Methylphenidate HCl Extended Release Capsule, generic	563
Methylphenidate HCl Extended Release Tablet, generic	563
Metoclopramide HCl Oral Tablet, generic	563
<i>Micronor 28</i> , generic	563
<i>Middle Earth: Shadow of Mordor</i>	1040
Minocycline HCl Oral Capsule, generic	563
<i>Mircette</i> , generic	563
Mirtazapine Oral Disintegrating Tab, generic	563
<i>Modicon 28</i> , generic	563
Motor Vehicles, used	1099, 1126, 1150

continued

NAB Paclitaxel Injectable Suspension, generic	563
Nabumetone Oral Tablet, generic	563
<i>Natazia</i> , generic	563
Nitrofurantoin Oral Capsules, generic	563
Nitrogen, bulk	141
Nitrous Oxide, bulk	141
<i>Nordette</i> , generic	563
Norethindrone Oral Tablet, generic	563
<i>Nor-QD</i> , generic	563
Nortriptyline HCl Oral Capsule, generic	563
Oxygen, bulk	141
PEEK	97
Phentermine HCl/Topiramate Extended Release Capsule, generic	563
Polyetheretherketone	97
Portland Cement	504
Propofol Injection Emulsion, generic	563
Propranolol HCl Oral Tablet, generic	563
<i>Quartette</i> , generic	563
Ramelteon Tablet, generic	563
Rotigotine Transdermal Patch, generic	563
Routers, computer	203
<i>Seasonique</i> , generic	563
Services:	
General Acute Care Inpatient Hospital	60, 1015
Outpatient Surgical	60
Shampoo	27
Shower Gel	1
Sodium Chlorate	373
Sunscreen	49, 1066
Sunscreen Products	15
<i>Sunscreen SPF 30</i>	1066
Supermarkets	945
Survey Responses	397

Table of Commodities - continued

Tamoxifen Citrate Oral Tablet, generic	563
Tobramycin Inhalant Solution, generic	563
Trimethoprim Oral Tablet, generic	563
Trimipramine Maleate Oral Capsule, generic	563
<i>Tri-Norinyl 28-Day</i> , generic	563
Triphasil-28, generic	563
Video Game	1040
Welding Gases, packaged, retail	141
<i>Yasmin-28</i> , generic	563