

**UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION**

**COMMISSIONERS:**      **Lina M. Khan, Chair  
Noah Joshua Phillips  
Rebecca Kelly Slaughter  
Christine S. Wilson**

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<b>In the Matter of</b>	)	
	)	
<b>ANI PHARMACEUTICALS, INC.,</b>	)	
<b>a corporation;</b>	)	<b>DECISION AND ORDER</b>
	)	
<b>NOVITIUM PHARMA LLC,</b>	)	<b>Docket No. C-4754</b>
<b>a limited liability company;</b>	)	
	)	
<b>and</b>	)	
	)	
<b>ESJAY LLC,</b>	)	
<b>a limited liability company.</b>	)	
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**DECISION**

The Federal Trade Commission initiated an investigation of Respondent ANI Pharmaceuticals, Inc.’s proposal to acquire the non-corporate interests of Respondent Novitium Pharma LLC, whose ultimate parent entity is Respondent Esjay LLC (collectively “Respondents”). The Commission’s Bureau of Competition prepared and furnished to each Respondent the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint 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 (collectively “Acts”).

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders (“Consent Agreement”) containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint; (2) 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 the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true; (3) waivers and other provisions as required by the Commission’s Rules; and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and 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. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings, and issues the following Decision and Order (“Order”):

1. Respondent ANI Pharmaceuticals, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 210 Main Street West, Baudette, Minnesota 56623.
2. Respondent Novitium Pharma LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 70 Lake Drive, East Windsor, New Jersey 08520.
3. Respondent Esjay LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 16732 Strasbourg Lane, Delray Beach, Florida 33446.
4. Prasco LLC is a limited liability company organized, existing and doing business under the laws of the State of Ohio with its executive offices and principal place of business located at 6125 Commerce Court, Mason, Ohio 45040.
5. 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. Definitions**

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

- A. “ANI” means ANI Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by ANI Pharmaceuticals, Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. “Novitium” means Novitium Pharma LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships,

divisions, groups, and affiliates controlled by Novitium Pharma LLC, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

- C. “Esjay” means Esjay LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, including Novitium Pharma LLC, partnerships, divisions, groups, and affiliates controlled by Esjay LLC, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- D. “Commission” means the Federal Trade Commission.
- E. “Respondents” means ANI, Novitium, and Esjay.
- F. “Acquirer(s)” means:
  - 1. Prasco; or
  - 2. Any other Person that the Commission approves to acquire Divestiture Assets pursuant to this Order.
- G. “Acquisition” means the proposed acquisition described in agreement titled the *Agreement and Plan of Merger* by and among ANI Pharmaceuticals, Inc., Nile Merger Sub LLC, Novitium Pharma LLC, Esjay LLC, Chali Properties LLC, Chad Gassert, Muthusamy Shanmugam, Thorappadi Vijayaraj, and Shareholder Representative Services LLC, dated as of March 8, 2021.
- H. “Acquisition Date” means the date of the closing on the above-referenced *Agreement and Plan of Merger*.
- 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 the FDA.
- J. “Biosimilar” means any biologic drug product that is highly similar to, and has no clinically meaningful difference from, an existing FDA-approved biologic drug product or that otherwise meets the FDA’s criteria for classification as a biosimilar.
- K. “Business Information” means all written information, wherever located or stored, relating to or used in a Divestiture Product Business, including documents, graphic materials, and data and information in electronic format. Business Information includes records and information relating to research and development (including copies of Product Development Reports), manufacturing, process technology, engineering, product formulations, production, sales, marketing (including Product Marketing Materials), logistics, advertising, personnel, accounting, business strategy, information technology systems, customers, customer purchasing histories, customer preferences, delivery histories, delivery routing information, suppliers and all other aspects of the Divestiture Product Business. For clarity, Business Information includes any Respondent’s rights and control over information and material provided by that Respondent to any other Person. Business Information includes Confidential Business Information.

- L. “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.
- M. “Confidential Business Information” means all Business Information that is not in the public domain.
- N. “Customer” means any Person that is either a direct purchaser or who negotiates price on behalf of a direct purchaser (*e.g.*, group purchasing organization) of any Divestiture Product from a Respondent or the Acquirer.
- O. “Development” means all research related to a Product, and all studies of the safety or efficacy of a Product, including: discovery or identification of a new chemical entity, test method development; toxicology; bioequivalency; bioavailability; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; stability testing; statistical analysis and report writing; conducting studies of the safety or efficacy of a Product in animals or humans 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, labeling, and sale of a Product(including any government price or reimbursement approvals). “Develop” means to engage in Development.
- P. “Dexamethasone Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to ANDA No. 080399, and any supplements, amendments, or revisions to this ANDA, and any other Products that are or were in Development or Developed by ANI as of March 8, 2021 (the date the Respondents signed the *Agreement and Plan of Merger*) that are orally administered tablets and contain, as the active pharmaceutical ingredient, dexamethasone at a 0.75mg strength.
- Q. “Dexamethasone Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to the Dexamethasone Products, including all of the Divestiture Assets related to the Dexamethasone Products.
- R. “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 shall not exceed then-current average hourly wage rate for such employee.
- S. “Divestiture Agreements” mean:
1. Asset Purchase Agreement by and between Prasco and ANI Pharmaceuticals, Inc. dated as of October 21, 2021; and all amendments, exhibits, attachments, agreements to the above-referenced agreement; and
  2. Any other agreement between a Respondent(s) and the Acquirer (or between a Divestiture Trustee and the Acquirer, or between Respondents for the benefit of the Acquirer) that has been approved by the Commission to accomplish the requirements of this Order.

- T. “Divestiture Assets” mean Respondents’ equitable and legal right, title, and interests in and to all tangible and intangible assets that are not Excluded Assets, wherever located, relating to a Divestiture Product Business, including the following:
1. All Product Approvals;
  2. All FDA Authorizations;
  3. All Product Development Reports;
  4. All Product Intellectual Property;
  5. At the option of the Acquirer, Product Manufacturing Equipment;
  6. All technological, scientific, chemical, biological, pharmacological, toxicological, regulatory materials and information, including studies of the safety, efficacy, stability, bioequivalency, bioavailability, and toxicology of a Product;
  7. All website(s), Domain Names, and social media sites related exclusively to the Divestiture Product and the content thereon related exclusively to the Divestiture Product, and the content related exclusively to the Divestiture Product that is displayed on any website that is not dedicated exclusively to the Divestiture Product;
  8. At the option of the Acquirer, Product Contracts;
  9. All Business Information;
  10. At the option of the Acquirer, all inventory and all ingredients, materials, or components used in the manufacture of the specified Divestiture Product in existence as of the Divestiture Date including, the active pharmaceutical ingredient(s), excipient(s), raw materials, packaging materials, work-in-process, and finished goods related to that Divestiture Product; and
  11. At the option of the Acquirer, the right to fill any or all unfilled Customer purchase orders for the specified Divestiture Product as of the Divestiture Date.
- U. “Divestiture Date” means the date on which a Respondent (or a Divestiture Trustee) closes on a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey rights or assets related to a Divestiture Product to the Acquirer as required by Section II of this Order.
- V. “Divestiture Products” means the:
1. Dexamethasone Products; and
  2. Sulfamethoxazole/Trimethoprim Products.
- W. “Divestiture Product Business” means the research, Development, manufacture, commercialization, distribution, marketing, advertisement, importation, and sale related to a Divestiture Product.
- X. “Divestiture Trustee” means any Person appointed by the Commission to serve as a divestiture trustee pursuant to the Orders.

- Y. “Domain Name” means the domain name(s) and the related uniform resource locator(s) and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration.
- Z. “Employee Information” means the following, for each Relevant Employee, as and to the extent permitted by law:
1. With respect to each such employee, the following information:
    - a. Name, job title or position, date of hire, and effective service date;
    - b. Specific description of the employee’s responsibilities;
    - c. Base salary or current wages;
    - d. Most recent bonus paid, aggregate annual compensation for the relevant Respondent’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); and
    - f. All other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
  2. At the option of the Acquirer, copies of all employee benefit plans and summary.
- AA. “Erythromycin/Ethylsuccinate Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to ANDA No. 211991, and any supplements, amendments, or revisions to this ANDA, and any other Products in Development or Developed, marketed or sold by any Person other than a Respondent that are orally administered granules (for suspension) and contain, as the active pharmaceutical ingredients, erythromycin and ethylsuccinate at the EQ 200mg, BASE 5ml strengths.
- BB. “Excluded Assets” mean:
1. Any real estate and the buildings and other permanent structures located on such real estate;
  2. Corporate names or corporate trade dress of a Respondent 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 a Respondent can be identified or defined;
  3. The portion of any Business Information that contains information about any of a Respondent’s business other than a Divestiture Product Business, in those cases in which the redaction does not impair the usefulness of the information related to the Divestiture Product Business;
  4. Any original document that a Respondent has a legal, contractual, or fiduciary obligation to retain the original; *provided, however*, that Respondents shall provide

copies of the document to the Acquirer and shall provide that Acquirer access to the original document if copies are insufficient for regulatory or evidentiary purposes;

5. Any tax asset relating to (a) the Divestiture Assets for pre-Divestiture Date tax periods or (b) any tax liability that any Respondent is responsible for arising out of the divestiture of the Divestiture Assets;
6. All accounts receivable, notes receivable, rebates receivable and other miscellaneous receivables of any Respondent that are related to the Divestiture Product Business and arising out of the operation of the Divestiture Product Business prior to the Divestiture Date;
7. All cash, cash equivalents, credit cards and bank accounts of any Respondent; and
8. Any records or documents reflecting attorney-client, work product or similar privilege of any Respondent or otherwise relating to the Divestiture Assets as a result of legal counsel representing any Respondent in connection with the divestiture of the Divestiture Assets pursuant to this Order or the Divestiture Agreements.

CC. “FDA” means the United States Food and Drug Administration.

DD. “FDA Authorization(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDAs”), 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. “FDA Authorization” 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. “FDA Authorization” also includes any Biologic License Application (“BLA”) filed or to be filed with the FDA pursuant to 21 C.F.R. 601.2, et seq., and Section 351 of the Public Health Service Act, and any NDA deemed to be a BLA by the FDA, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondents and the FDA or other government regulatory authority relative thereto.

EE. “Licensed Intellectual Property” means; (a) all Product Manufacturing Technology that is used (but not exclusively, predominantly, or primarily used) in the manufacture of a Divestiture Product, and (b) copyrights used (but not exclusively, predominantly, or primarily used), to commercialize, distribute, market, advertise, or sell any Divestiture Product as of the applicable Divestiture Date.

FF. “Manufacturing Designee” means any Person other than a Respondent that has been designated by the Acquirer to perform any part of the manufacturing process, including the finish or packaging of a Divestiture Product on behalf of that Acquirer.

- GG. “Monitor” means any Person appointed by the Commission to serve as a monitor pursuant to the Orders.
- HH. “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 and package size code for a specific Product.
- II. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- JJ. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- KK. “Orders” means this Decision and Order and the Order to Maintain Assets.
- LL. “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 Divestiture 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.
- MM. “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.
- NN. “Prasco” means Prasco, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Prasco, LLC, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- OO. “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, or that is the subject of an FDA Authorization.
- PP. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other regulatory 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, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any FDA Authorization related to that Product.
- QQ. “Product Contracts” means all contracts, agreements, mutual understandings, arrangements, or commitments related to the Divestiture Product Business, including those:
  1. Pursuant to which any third party, including a Customer, purchases, or has the option to purchase, a Product from a Respondent or negotiates the purchase price



- on behalf of another Customer;
2. Pursuant to which a Respondent had, or has as of the Divestiture 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 a Product;
  3. Relating to any study of the safety or efficacy of a Product;
  4. With universities or other research institutions for the use of a Product in scientific research;
  5. For the marketing of a Product or educational matters relating solely to the Products;
  6. Pursuant to which a third party manufactures or plans to manufacture a Product as a finished dosage form 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 or packaging of a Product on behalf of a Respondent;
  8. Pursuant to which a third party licenses any Product Intellectual Property or Product Manufacturing Technology related to a Product to a Respondent;
  9. Pursuant to which a third party is licensed by a Respondent to use any of the Product Intellectual Property or Product Manufacturing Technology;
  10. Constituting confidentiality agreements involving a Product;
  11. Involving any royalty, licensing, covenant not to sue, or similar arrangement related to a Product;
  12. Pursuant to which a third party provides any specialized services necessary to the research, Development, manufacture, or distribution of a Product to a Respondent including, consultation arrangements; and
  13. Pursuant to which any third party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of a Product.

RR. “Product Development Reports” means information related to the Development of a Product, including:

1. Pharmacokinetic study reports;
2. Bioavailability study reports;
3. Bioequivalence study reports;
4. All correspondence, submissions, notifications, communications, registrations, or other filings made to, received from, or otherwise conducted with the FDA relating to the FDA Authorization(s);

5. Annual and periodic reports related to the above-described FDA Authorization(s), including any safety update reports;
6. FDA approved labeling or other Agency-approved labeling;
7. Currently used or planned product package inserts (including historical change of controls summaries);
8. FDA approved patient circulars;
9. Adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy;
10. Summaries of complaints from physicians or other health care providers;
11. Summaries of complaints from ultimate users of the Product;
12. Summaries of complaints from Customers;
13. Product recall reports filed with the FDA or any other Agency, and all reports, studies, and other documents related to such recalls;
14. Investigation reports and other documents related to any out of specification results for any impurities or defects found in any Product;
15. Reports from any Person (e.g., 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 or defects;
16. Reports from vendors of the component(s), active pharmaceutical ingredient(s), excipient(s), packaging component(s), and detergent(s) used to produce any Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of any Product;
17. Analytical methods development records;
18. Manufacturing batch or lot records;
19. Stability testing records;
20. Change in control history; and
21. Executed validation and qualification protocols and reports.

SS. “Product Intellectual Property” means intellectual property of any kind (other than Licensed Intellectual Property), that is owned, licensed, held, or controlled by a Respondent as of the Divestiture Date, including Patents, patent applications, trademarks, service marks, copyrights, trade dress, commercial names, internet web sites, internet domain names, inventions, discoveries, know-how, trade secrets, and proprietary information.

TT. “Product Manufacturing Equipment” means equipment that is being used, or has been used to manufacture the specified Divestiture Product.

- UU. “Product Manufacturing Technology” means all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of a Product, including the following: all product specifications, processes, analytical methods, product designs, plans, 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 conformance of any Product Approvals, conformance with any Agency requirements, and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists.
- VV. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the United States as of the Divestiture Date that are owned or controlled by a Respondent, including, without 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 dollars and units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, website content, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.
- WW. “Product Releasee(s)” means any of the following Persons:
1. The Acquirer;
  2. Any Person controlled by or under common control with that Acquirer;
  3. Any Manufacturing Designee(s); and
  4. Any licensees, sublicensees, manufacturers, suppliers, marketers, distributors, and Customers of that Acquirer, or of such Acquirer-affiliated entities, in each such case, as related to each Divestiture Product acquired by that Acquirer.
- XX. “Relevant Employees” includes:
1. Manufacturing Employees means all employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition Date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: (a) Developing and validating the commercial manufacturing process, (b) formulating the manufacturing process performance qualification protocol, (c) controlling the manufacturing process to assure performance Product quality, (d) assuring that during routine manufacturing the process remains in a state of control, (e) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently delivering quality Products, (f)

managing the operation of the manufacturing process, or (g) managing the transfer of the Product Manufacturing Technology to a different facility; and

2. Marketing Employees means all management-level employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: sales management, brand management, sales training, market research, or marketing and contracting with any of the following: drug wholesalers or distributors, group purchasing organizations, pharmacy benefit organizations, managed care organizations, or hospitals, *excluding* administrative assistants.

- YY. “Retained Product(s)” means any Product(s) other than a Divestiture Product that is manufactured, in Development, marketed, sold, owned, controlled, or licensed by a Respondent anywhere in the world on or before the Acquisition Date and that has not been discontinued or permanently withdrawn from the market.
- ZZ. “Sulfamethoxazole/Trimethoprim Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorizations: ANDA No. 077612, and any supplements, amendments, or revisions to this ANDAs.
- AAA. “Sulfamethoxazole/Trimethoprim Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to the Sulfamethoxazole/Trimethoprim Products, including all of the Divestiture Assets related to the Sulfamethoxazole/Trimethoprim.
- BBB. “Supply Cost” means the actual cost of materials, ingredients, packaging, direct labor, and direct overhead *excluding* any allocation or absorption of costs for excess or idle capacity, and *excluding* any intracompany transfer profits *plus* the actual cost of shipping and transportation in cases in which those costs are incurred by a Respondent.
- CCC. “Technology Transfer Standards” mean requirements and standards sufficient to ensure that the information and assets required to be transferred and delivered are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, as related to the specified Divestiture Product(s), *inter alia*:
1. Designating employees or other Persons working on behalf of a Respondent knowledgeable about the Product Manufacturing Technology who will be responsible for communicating directly with the receiving Person, and a Monitor, 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 Product that are acceptable to the receiving Person;
  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 to the receiving Person;

4. For any part of the manufacturing process that is performed by a Respondent, permitting employees of the receiving Person to visit the Respondent's facility where that process occurs for the purposes of evaluating and learning that process or discussing the process with employees of the Respondent involved in that process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, and methods to ensure batch or lot consistency); and
5. Providing, in a timely manner, assistance and advice to enable the receiving Person to:
  - a. Manufacture the Product in the quality and quantities achieved by a Respondent prior to the Acquisition Date;
  - b. Obtain any Product Approvals necessary for the receiving Person to manufacture the Product for the Acquirer in a manner that allows that Acquirer to distribute, market, and sell the Product in commercial quantities and to meet all Agency-approved specifications for the Product; and
  - c. Receive, integrate, and use all Product Manufacturing Technology used in, and all Product Intellectual Property that is related to, the manufacture of the Product.

DDD. "Therapeutic Equivalent" means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product or that otherwise meets the FDA's criteria for such classification.

EEE. "United States" means the United States of America, and its territories, districts, commonwealths, and possessions.

## II. Divestitures

**IT IS FURTHER ORDERED** that:

- A. No later than 10 days after the Acquisition Date, Respondents shall, absolutely and in good faith, divest the Dexamethasone Divestiture Assets and the Sulfamethoxazole/Trimethoprim Divestiture Assets and grant a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to use the related Licensed Intellectual Property in the related Divestiture Product Business to Prasco.

*Provided, however,* that, if within 12 months after the Order Date, the Commission determines, in consultation with the Acquirer and a Monitor, the Acquirer needs one or more Excluded Assets to operate any of the Divestiture Product Businesses in a manner that achieves the purposes of this Order, Respondents shall divest or license (as applicable) absolutely and in good faith, the needed Excluded Assets to that Acquirer.

- B. If Respondents have divested any of the Divestiture Assets or granted or assigned rights

to the Divestiture Products to Prasco prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:

1. The named Acquirer is not an acceptable purchaser of any of the Divestiture Assets or rights related to the Divestiture Products, then Respondents shall immediately rescind the transaction with that Acquirer as directed by the Commission, and shall divest the respective Divestiture Assets or grant or assign the rights related to the Divestiture Products, as applicable, within 180 days after the Order Date, absolutely and in good faith, at no minimum price, to a different Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission; or
2. The manner in which the divestiture was accomplished is not acceptable, then Respondents shall make such modifications to the manner of divestiture of the Divestiture Assets or the grant or assignment of rights to the Divestiture Products, as applicable, to the Acquirer named in this Order (including, entering into additional agreements or arrangements) as the Commission determines are necessary to satisfy the requirements of this Order.

C. Prior to the Divestiture Date, Respondents shall provide the Acquirer with the opportunity to review Product Contracts related to each of the Divestiture Products so that the Acquirer can determine whether to assume each Product Contract;

*Provided, however,* that in cases in which any Product Contract also relates to a Retained Product the Respondent shall, at the option of that Acquirer, assign or otherwise make available to that Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.

D. Prior to the Divestiture Date, Respondents shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets and to grant or assign rights to the Divestiture Products to the Acquirer, and to permit that Acquirer to continue in the related Divestiture Product Business in the United States without interruption or impairment.

E. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, Respondents shall not enforce any agreement against a third party or the 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 a license or other right to the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product. Such agreements include agreements that might limit the ability of a third party to disclose Confidential Business Information related to such Product Manufacturing Technology to the Acquirer. No later than 10 days after the Divestiture Date, Respondents shall grant a release to each third party that is subject to any such agreement that allows the third party to provide the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product to

the Acquirer. Within 5 days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer;

*Provided, however,* Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant third parties.

- F. Respondents shall transfer the Product Manufacturing Technology related to the Divestiture Products to the Acquirer, or at the Acquirer's option, to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Respondents shall bear all costs related to these transfers.
- G. No later than 10 days after the Divestiture Date, Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.
- H. No later than 10 days after the Divestiture Date, Respondents shall provide the following to the relevant Acquirer of each of the Divestiture Products:
  - 1. A list of any finished batch or lot of the relevant Divestiture Product that any Respondent, any manufacturer for a Respondent, or regulatory Agency determined to be out-of-specification at any time during the three-year period immediately preceding the Divestiture Date, and, for each such batch or lot: (a) a detailed description of the known deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (b) the corrective actions taken to remediate any cGMP deficiencies in that Divestiture Product; and (c) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;
  - 2. A list by stock-keeping unit by Customer that contains the current net price per unit as packaged for sale (*i.e.*, the price net of all customer-level discounts, rebates, or promotions) for the relevant Divestiture Product for each order sold to that Customer during the two-year period prior to the Divestiture Date;
  - 3. A list of the inventory levels (weeks of supply) of the relevant Divestiture Product in the possession of each Customer to the extent known or available to any Respondent, as of the date prior to and closest to the Divestiture Date as is available;
  - 4. A list of any pending reorder dates for the relevant Divestiture Product by Customer as of the Divestiture Date to the extent known by any Respondent;
  - 5. A list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by law, to control, prohibit, or otherwise limit the use, including the use in Customer cross-referencing, of such NDC numbers by the Respondents, *unless* that Divestiture Product has not been marketed or sold in the United States prior to the Divestiture Date; and
  - 6. The quantity and delivery terms in all unfilled Customer purchase orders for the relevant Divestiture Product as of the Divestiture Date.

- I. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research and Develop, or manufacture anywhere in the world the Divestiture Product(s), or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.
- J. Upon reasonable written request from the Acquirer to a Respondent, that Respondent shall provide, in a timely manner, assistance of knowledgeable employees of that Respondent (*i.e.*, employees of that Respondent that were involved in the Development of the Divestiture Products) 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 for the Divestiture Products acquired by that Acquirer from a Respondent. A Respondent shall make its employees available to that Acquirer for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than Direct Cost.
- K. For any patent infringement suit that is filed or to be filed within the United States that is (x) filed by, or brought against, a Respondent prior to the Divestiture Date related to any Divestiture Product or (y) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of the Divestiture Date that is related to any Divestiture Product, that Respondent shall:
  - 1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;
  - 2. Waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any such patent infringement suit; and
  - 3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to such patent infringement suit.

### **III. Divestiture Agreements**

**IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreements shall be incorporated by reference into this Order and made a part hereof, and any failure by a Respondent to comply with any term of the Divestiture Agreements shall constitute a violation of this Order;  
*Provided, however,* that the Divestiture Agreements shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreements varies from or conflicts with any provision in this Order such that the Respondents cannot fully comply with both, Respondents shall comply with this Order.
- B. Respondents shall include in the Divestiture Agreements a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth



of the Respondents' obligations to the Acquirer pursuant to this Order.

- C. Respondents shall not modify or amend any of the terms of any 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).

#### **IV. Transition Services and Manufacturing by Respondents**

**IT IS FURTHER ORDERED** that:

- A. At the request of the Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the same manner that Respondents have operated that Business prior to the Acquisition Date.
- B. Upon reasonable written notice and request from the Acquirer, Respondents shall manufacture, deliver and supply, or cause to be manufactured, delivered, and supplied, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, that Acquirer's requested supply of each of the Divestiture Products and any of the active pharmaceutical ingredients used in the Divestiture Products that are made by a Respondent, as applicable, hereinafter "Supplied Products." The requested supply of Supplied Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement.
- C. The Respondents shall make representations and warranties to the Acquirer that the Supplied Products meet the relevant Agency-approved specifications and, with the consent of the Acquirer, shall amend any agreement between the Respondents and the Acquirer that is related to the quality controls of a Divestiture Product to address any necessary changes to the agreement in order to comply with relevant Agency regulations or recommendations.
- D. The Respondents 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 Supplied Products to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

*Provided, however,* that the Respondents 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 Respondents' responsibilities to supply the Supplied Products in the manner required by this Order;

*Provided further, however,* that this obligation shall not require the Respondents 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 Respondents to the Acquirer in a Divestiture Agreement.

- E. The Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Supplied Products to the Acquirer in a timely manner *unless* (1) Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents, and (2) Respondents are able to cure the supply failure no later than 30 days after the receipt of notice from that Acquirer of a supply failure.
- F. The Respondents shall give priority to supplying the Acquirer over the supplying of Products for any Respondent's own use or sale.
- G. During the term of any agreement for a Respondent to supply the Supplied Products, upon written request of the Acquirer or a Monitor, the Respondent shall make available to the supplied Acquirer and a Monitor all records generated or created after the Divestiture Date that relate directly to the manufacture of the applicable Supplied Products.
- H. The Respondents shall provide the Acquirer with the actual costs incurred or the price paid for active ingredients, components, and excipients the Respondents use to manufacture the applicable Supplied Products.
- I. During the term of any agreement for a Respondent to supply the Supplied Products, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of each of the Supplied Products.
- J. Respondents shall not be entitled to terminate any agreement to supply the Supplied Products due to (x) a breach by the Acquirer of a Divestiture Agreement, or (y) that 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 creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;  
*Provided, however,* that this Paragraph IV.J shall not prohibit a Respondent from seeking compensatory damages from the Acquirer for that Acquirer's breach of its payment obligations to the Respondent under the agreement.
- K. The Respondents shall permit the Acquirer to terminate the agreement for the supply of the Supplied Products on a product-by-product basis, at any time, upon commercially reasonable notice, and without cost or penalty (other than costs or penalties due by the Respondent to third parties pursuant to the termination of such agreement, which may be the responsibility of that Acquirer).
- L. In the event that that a Respondent becomes (x) unable to supply or produce a Supplied Product from the facility that has been supplying the Acquirer, and (y) any Respondent has a different facility that is listed on the FDA Authorization for that Supplied Product and is still suitable for use to manufacture the Supplied Product, or any Respondent has a facility that manufactures the Therapeutic Equivalent of such Supplied Product, then such Respondent shall, at the option of the supplied Acquirer, provide a supply of either the Therapeutic Equivalent or the Supplied Product from the other facility under the same

terms and conditions as contained in the Divestiture Agreement to supply.

- M. During the term of any agreement for a Respondent to supply the Supplied Products, the Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the supplied Acquirer and at a facility chosen by the supplied Acquirer, for the purposes of enabling that Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the applicable Supplied Products in final form in the same quality achieved by, or on behalf of, Respondents and in commercial quantities, in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of that Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the applicable Supplied Products.
- N. For any Supplied Product that is made in a facility owned by Respondents, Respondents shall transfer such manufacturing to a facility owned, controlled, or operated by the Acquirer or, at the option of the Acquirer, to its Manufacturing Designee. Respondents shall bear all costs for this transfer including the cost to validate the Supplied Products at the changed facility and the costs for any changes in the specifications for any Supplied Product required by the FDA prior to the FDA's granting approval to market such Product from the changed site of manufacture.
- O. For any Divestiture Product, at the Acquirer's option, Respondents shall bear the costs to qualify and obtain FDA regulatory approval to change the source of the active pharmaceutical ingredient(s).

## **V. Asset Maintenance**

**IT IS FURTHER ORDERED** that, until the Respondents have physically transferred the Dexamethasone Divestiture Assets and the Sulfamethoxazole/Trimethoprim Divestiture Assets to the Acquirer pursuant to Section II of this Order, Respondents shall operate and maintain each of the respective Divestiture Assets and each of the respective Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondents shall:

- A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses, to minimize the risk of loss of competitive potential of such Divestiture Product Businesses, to operate such Divestiture Product Businesses in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of any of the Divestiture Assets, except for ordinary wear and tear.
- B. Not sell, transfer, encumber, or otherwise impair such Divestiture Assets, or terminate any of the operations of such Divestiture Product Businesses, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.
- C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with such Divestiture Product Businesses.

- D. Provide such Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for such Divestiture Product Businesses.
- E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with such Divestiture Product Businesses.
- F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with such Divestiture Product Businesses, including by:
  - 1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and
  - 2. Not transferring any employees from such Divestiture Product Businesses to another of Respondents' businesses.
- G. Maintain and preserve the Business Information of such Divestiture Product Businesses.
- H. Provide the resources necessary for such Divestiture Product Businesses to respond to competition, prevent diminution in sales, and maintain its competitive strength.
- I. Continue providing customary levels of support services to such Divestiture Product Businesses.
- J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of such Divestiture Product Businesses, and operate such Divestiture Product Businesses in accordance and compliance with all regulatory obligations and requirements.
- K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with such Divestiture Product Businesses.

*Provided, however,* Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by a Monitor (in consultation with Commission staff), in all cases to facilitate that Acquirer's acquisition of the Divestiture Assets and rights in the Divestiture Products and consistent with the purposes of the Orders.

## **VI. Employees**

**IT IS FURTHER ORDERED** that:

- A. Until 2 years after the Divestiture Date, Respondents shall cooperate with and assist the Acquirer to evaluate independently and offer employment to the Relevant Employees for

the Divestiture Products acquired by that Acquirer.

B. Respondents shall:

1. No later than 10 days after a request from the Acquirer, provide to that Acquirer a list of all Relevant Employees and provide Employee Information for each Relevant Employee;
2. No later than 10 days after a request from the Acquirer, provide that Acquirer or its Manufacturing Designee an opportunity to meet individually and outside the presence or hearing of any employee or agent of Respondents with any of the Relevant Employees, and to make offers of employment to any of the Relevant Employees;
3. Remove any impediments within the control of Respondents that may deter Relevant Employees from accepting employment with the Acquirer or its Manufacturing Designee, 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 that Acquirer or its Manufacturing Designee, and shall not make any counteroffer to a Relevant Employee who receives an offer of employment from that Acquirer or its Manufacturing Designee;

*Provided, however,* that nothing in the Orders shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee; and

4. Not interfere, directly or indirectly, with the hiring or employing by that Acquirer or its Manufacturing Designee of any Relevant Employees, not offer any incentive to such employees to decline employment with that Acquirer or its Manufacturing Designee, and not otherwise interfere with the recruitment of any Relevant Employees by that Acquirer.

C. Respondents shall continue to provide Relevant Employees compensation and benefits, including regularly scheduled raises and bonuses, until the Divestiture Date or as may be necessary to comply with the provisions of the Orders to provide manufacturing and supply of Divestiture Products or transition services to the Acquirer.

D. Respondents shall provide reasonable financial incentives for Relevant Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Relevant Employees by the Acquirer.

E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and a Monitor, determines in its sole discretion that the Acquirer or its Manufacturing Designee should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Relevant Employees, but who either (1) were involved with any of the Divestiture Products, or (2) provided manufacturing and supply of Divestiture Products or transition services to the Acquirer, then the Commission may notify Respondents that such employees are to be designated as Relevant Employees, and Section VI of this Order shall apply to such

employees as of that notification date.

- F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate the employee's employment with the Acquirer or its Manufacturing Designee;

*Provided, however,* Respondents may:

1. Hire an employee whose employment has been terminated by the Acquirer;
2. 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 one or more of Relevant Employees; and
3. Hire an employee who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of Section VI.

## **VII. Business Information**

**IT IS FURTHER ORDERED** that:

- A. Respondents shall transfer and deliver all Business Information related to a Divestiture Product Business to the Acquirer pursuant to the following:
1. Respondents shall deliver the Business Information to that Acquirer, at Respondents' expense, in good faith, in a timely manner (*i.e.* as soon as practicable, avoiding any delays in transmission), and in a manner that ensures the completeness and accuracy of all information and ensures its usefulness;
  2. Pending complete delivery of all Confidential Business Information, Respondents shall provide that Acquirer with access to all Business Information and to employees who possess or are able to locate this information for the purposes of identifying the Business Information that contains Confidential Business Information and facilitating the delivery in a manner consistent with the Orders;
  3. Not use, directly or indirectly, any such Confidential Business Information other than as necessary to comply with the following:
    - a. The requirements of the Orders;
    - b. Respondents' obligations to that Acquirer under the terms of the related Divestiture Agreements; or
    - c. Applicable law;
  4. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (a) that Acquirer, (b) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services, manufacturing Divestiture Products, or who are engaged in the transfer and delivery of the Product Manufacturing Technology), (c) the Commission, or (d) a Monitor, and *except* to

the extent necessary to comply with applicable law;

5. Not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information to the employees associated with the business that is being retained, owned, or controlled by a Respondent, other than those employees specifically authorized as described above;
6. Institute procedures and requirements to ensure that those employees of a Respondent that are authorized by that Acquirer to have access to such Confidential Business information:
  - a. Do not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and
  - b. Do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose; and
7. Take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such Confidential Business Information by or to any Person(s) not authorized to access, receive, or use such information pursuant to the terms of the Orders or the Divestiture Agreements, including:
  - a. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;
  - b. To the extent practicable, maintaining such Confidential Business Information separate from other data or information of any Respondent; and
  - c. Ensuring by other reasonable and appropriate means that such Confidential Business Information is not shared with a Respondent's personnel engaged in any Business related to the same or substantially the same type of Business as the Divestiture Products, including a Respondent's personnel engaged in the marketing and sale within the United States of Products Developed or in Development for the same or similar indications as the Divestiture Products or that use the same active pharmaceutical ingredients as the Divestiture Products.

- B. As a condition of continued employment after the Divestiture Date, Respondents shall require each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one-year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as 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 such Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of any Respondent (other than as necessary to comply with the requirements of the

Orders).

- C. No later than 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent's personnel to all of its employees who (1) may be in possession of such Confidential Business Information or (2) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for 2 years after the Divestiture Date. Respondents shall provide a copy of their notifications to the Acquirer. Respondents shall maintain complete records of all such notifications at the respective Respondent's principal executive offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide that Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.
- D. Each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to that Acquirer, except under circumstances in which copies of documents are insufficient or otherwise unavailable, and for the following purposes:
1. To assure such Respondent's compliance with any Divestiture Agreement, the Orders, 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
  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 an Divestiture Product, the Divestiture Assets, or the Divestiture Product Business;

*Provided, however,* that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph VII.D pursuant to an appropriate confidentiality order, agreement, or arrangement;

*Provided further, however,* that pursuant to this Paragraph VII.D, a Respondent needing such access to original documents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

## **VIII. Monitor**

**IT IS FURTHER ORDERED** that:

- A. The Commission appoints Denise Smart of Smart Consulting Group, LLC as Monitor to



observe and report on Respondents' compliance with the terms of the Orders.

B. The Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement shall:

1. Be subject to the approval of the Commission;
2. Not limit, and the signatories shall not construe it to limit, the terms of this Section VIII or Section VII of the Order to Maintain Assets ("Monitor Sections") and to the extent any provision in the agreement varies from or conflicts with any provision in the Monitor Sections, Respondents and the Monitor shall comply with the Monitor Sections; and
3. Include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of the Orders in this matter, and to the extent any provision in the agreement varies from or conflicts with any provision in the Orders, Respondents and the Monitor shall comply with the Orders.

C. The Monitor shall:

1. Have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;
2. Act in consultation with the Commission or its staff;
3. Serve as an independent third party and not as an employee, or agent of the Respondents or of the Commission;
4. Shall serve without bond or other security;
5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into a non-disclosure or other confidentiality agreement with the Commission;
7. Notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional, or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;
8. Report in writing to the Commission concerning Respondents' compliance with the Orders 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission; and

9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until Commission staff determines that Respondents obligations to provide manufacturing and supply of Divestiture Products pursuant to this Order have expired or been terminated and files a final report.

D. Respondents shall:

1. Cooperate with and assist the Monitor in performing the Monitor's duties for the purpose of reviewing Respondents' compliance with their obligations under the Orders, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;
2. Not interfere with the ability of the Monitor to perform the Monitor's duties pursuant to the Orders;
3. Pay the Monitor's fees and expenses as set forth in an agreement approved by the Commission, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing the Monitor's duties under the Orders, including expenses of any consultants, accountants, attorneys, and other representatives and assistants that are reasonably necessary to assist the Monitor in carrying out the Monitor's duties and responsibilities;
4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Orders; and
5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under the Orders, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.

E. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement provided that such agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission, or otherwise observe and report on the Respondents' compliance with the Orders.

F. Respondents shall not require nor compel the Monitor to disclose to Respondents the substance of communications with the Commission, including the Monitor's written reports submitted to the Commission, or any other Person with whom the Monitor communicates in the performance of their duties.

G. If the Monitor resigns or the Commission determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of the Monitor Sections of the Orders. The Commission

shall select the substitute Monitor, subject to the consent of the Respondents.  
Respondents:

1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;
2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and
3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same terms as the Commission-approved agreement referenced in Paragraph B of the Monitor Sections; or (b) receives Commission approval.

H. The Commission may on its own initiative or at the request of a Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

### **IX. Divestiture Trustee**

**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 Assets or the rights to the Divestiture Products 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 Section IX 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 the Orders.
- 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 Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 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.

- C. No later than 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. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to Section IX, 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 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-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 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 divestitures. Any delays in divestiture caused by a Respondent shall extend the time for divestiture under Section IX 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 the Acquirer that receives the prior approval of the Commission 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 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, 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 or willful misconduct 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.
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 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,* 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 enter into a non-disclosure or other confidentiality agreement with the Commission 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 Section IX.
- 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.

#### **X. Prior Approval**

**IT IS FURTHER ORDERED** that each Respondent shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any rights or interests in the Dexamethasone Products, the Sulfamethoxazole/Trimethoprim Products, and the Erythromycin/Ethylsuccinate Products, or the Therapeutic Equivalent or Biosimilar of any of these Products without the prior approval of the Commission.

#### **XI. Prior Approval for Acquirer**

**IT IS FURTHER ORDERED** that:

- A. For a period of 3 years after the Divestiture Date, Prasco or any other Acquirer shall not sell or license, through subsidiaries or otherwise, without the prior approval of the Commission, any of the FDA Authorizations that were divested pursuant to Section II, to any Person; and
- B. For a period of 7 years after the term of Paragraph XI.A ends, Prasco or any other Acquirer shall not sell or license, through subsidiaries or otherwise, without the prior approval of the Commission, any FDA Authorizations that were divested pursuant to Section II, to any Person who owns, directly or indirectly, an FDA Authorization, or is seeking approval from the FDA for an FDA Authorization, to manufacture and sell a Therapeutic Equivalent of a Divestiture Product.

*Provided, however,* Prasco is not required to obtain prior approval of the Commission under this Section XI for a change of control, merger, reorganization, or sale of all or substantially all of its business, or for a non-exclusive license to a contract manufacturer for the purpose of manufacturing a Divestiture Product.

#### **XII. Compliance Reports**

**IT IS FURTHER ORDERED** that:

- A. Respondents shall:
  - 1. Notify Commission staff via email at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov) of the Acquisition Date and the Divestiture Dates no later than 5 days after the occurrence of each;

and

2. Submit the complete copies of each of the Divestiture Agreements to the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov) no later than 30 days after the Divestiture Date.

B. Respondents shall file verified written reports (“Compliance Reports”) in accordance with the following:

1. Respondents shall submit interim Compliance Reports within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter until Respondents have completed all of the following: (a) the transfer and delivery of the Divestiture Assets and the rights to the Divestiture Products to the Acquirer, (b) the transfer and delivery of all of the Product Manufacturing Technology related to the Divestiture Products to the Acquirer or the Acquirer’s Manufacturing Designee, (c) the transfer and delivery of all Business Information to the Acquirer, and (d) the Acquirer or the Acquirer’s Manufacturing Designee is FDA approved to manufacture each of the Divestiture Products at a facility that is not owned or controlled by Respondents; and Respondents shall submit annual Compliance Reports one year after the Order Date, and annually for the following 4 years on the anniversary of the Order Date; and additional Compliance Reports as the Commission or its staff may request;
2. Each Respondent’s Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether the Respondent is in compliance with the Orders. Conclusory statements that the Respondent has complied with its obligations under the Orders are insufficient. Respondents shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance:
  - a. A detailed description of all substantive contacts, negotiations, or recommendations related to the transfer and delivery to the Acquirer of (i) the Divestiture Assets and the rights to the Divestiture Products, (ii) the Business Information related to each of the Divestiture Product Businesses, and (iii) the provision of manufacturing and supply of Divestiture Products to that Acquirer;
  - b. A detailed description of the transfer of the Product Manufacturing Technology related to the Acquirer or the Acquirer’s Manufacturing Designee and progress toward the manufacturing of these products at a facility that is not owned or controlled by Respondents; and
  - c. A detailed description of the timing for the completion of such obligations.
3. Each annual Compliance Report shall include the previous year’s market information for each market alleged in the Complaint including the aggregate size of the market in units and in dollars; the monthly sales in units and in dollars for each market participant; the market share for each market participant calculated based on units and on dollars; and, to the extent known, an explanation of any

significant changes in the total size of the market and any significant adverse impacts to the manufacture or supply of competing products to the market;

4. For a period of 5 years after filing a Compliance Report, each Respondent shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondent's obligations under the Orders and provide copies of these documents to Commission staff upon request.
- C. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondent shall file its compliance reports with the Secretary of the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and the Compliance Division at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov), as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a). In addition, Respondent shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

### **XIII. Change in Respondents**

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

- A. The dissolution of: ANI Pharmaceuticals, Inc., Novitium Pharma LLC, and Esjay LLC;
- B. Any proposed acquisition, merger, or consolidation of ANI Pharmaceuticals, Inc., Novitium Pharma LLC, and Esjay LLC; or
- C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

### **XIV. Access**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with the Orders, subject to any legally recognized privilege, upon written request, and upon 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 the Orders, 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.



**XV. Purpose**

**IT IS FURTHER ORDERED** that the purpose of this Order is to remedy in a timely and sufficient manner the lessening of competition as alleged in the Commission's Complaint by:

- A. Ensuring that the Acquirer can continue to use the Divestiture Assets and rights in the Divestiture Products granted or assigned pursuant to this Order for the purposes of each of the respective Divestiture Product Businesses within the United States; and
- B. Creating a viable and effective competitor in the respective Divestiture Product Businesses within the United States.

**XVI. Term**

**IT IS FURTHER ORDERED** that this Order shall terminate 10 years from the date it is issued.

By the Commission.

April J. Tabor  
Secretary

SEAL  
ISSUED:

**NONPUBLIC APPENDIX I  
AGREEMENTS RELATED TO THE DIVESTITURES**

**[Redacted from the Public Record but Incorporated by Reference]**

**NONPUBLIC APPENDIX II  
MONITOR COMPENSATION**

**[Redacted from the Public Record but Incorporated by Reference]**



**PUBLIC APPENDIX  
MONITOR AGREEMENT**

**[cover page]**