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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

In the Matter of **Altria Group, Inc.** **a corporation;** **and** **JUUL Labs, Inc.** **a corporation.**	**DOCKET NO. 9393**

COMPLAINT COUNSEL'S MOTION REQUESTING OFFICIAL NOTICE OF FDA DECISION

Pursuant to Commission Rules 3.22 (16 C.F.R. § 3.22), 3.43 (16 C.F.R. § 3.43), and 3.54 (16 C.F.R. § 3.54), Complaint Counsel respectfully requests that the Commission take official notice of the Food and Drug Administration's ("FDA") March 24, 2022 decision to grant marketing authorization to certain e-cigarette devices ("FDA Decision"). The FDA Decision is relevant to Complaint Counsel's claims and Respondents' defenses. Specifically, the FDA Decision is material to Complaint Counsel's allegations that but for the transaction with JLI, Altria would be competing aggressively in the closed-system e-cigarette market on price, innovation, and other key dimensions of competition. The FDA Decision is also material to Respondents' argument that Altria would be unable to secure FDA approval of its products, including the MarkTen cigalike. Moreover, there can be no reasonable dispute about the existence, wide availability, and

accuracy of this information. Indeed, this information is publicly available and included in a statement by a government agency.

I. FACTS

FDA regulations govern participation in the U.S. e-cigarette market. In 2016, the FDA issued regulations requiring that manufacturers of new e-cigarette products submit a Premarket Tobacco Application ("PMTA") and obtain a marketing authorization before they can sell their products. Complaint Counsel's Post-Trial Findings of Fact and Conclusions of Law ("CCFF") ¶197. The FDA looks at several factors in making its PMTA determinations, including conversion potential and initiation. CCFF ¶¶1323-27, 1912-17. The FDA has explained that "[u]nder the Premarket Tobacco Product Application (PMTA) pathway, manufacturers or importers must demonstrate to the agency, among other things, that marketing of a new tobacco product would be appropriate for the protection of the public health."[1] As part of its evaluation of a PMTA for an e-cigarette product, the FDA must "consider the risks and benefits to the population as a whole, including users and non-users of tobacco products."[2] The agency must take into account "the likely impact of the products on people's behavior—specifically, the likelihood that existing users will stop using such products and the likelihood that those who do not use tobacco products will start using such products. **This is especially important for youth** (emphasis added)."[3]

Prior to its exit, Altria was marketing, developing, and selling multiple e-cigarette products, including the MarkTen cigalike, MarkTen Bold (a cigalike with nicotine salts), and MarkTen Elite (a pod-based e-cigarette). CCFF ¶¶130, 138. JLI has never marketed, developed, or sold a cigalike, and has focused solely on pod-based e-cigarettes. CCFF ¶¶30, 65. Importantly, Altria

[1] Exhibit B (FDA, Press Release, *FDA Issues Decisions on Additional E-Cigarette Products* (Mar. 24, 2022), https://www.fda.gov/news-events/press-announcements/fda-issues-decisions-additional-e-cigarette-products) at 2.
[2] *Id.*
[3] *Id.*

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only pulled its pod-based e-cigarette devices under the guise of a youth concern. CCFF ¶¶812, 987. Altria never gave this excuse for pulling its cigalike devices from the market. *See* CCFF ¶¶989-91. Further, Altria executives were aware that JLI's JUUL product had significant appeal among non-smokers, and among youth in particular. CCFF ¶¶1248-52.

On March 24, 2022, the FDA issued "Marketing Granted Orders" to Logic Technology Development LLC ("Logic") authorizing Logic to market several e-cigarette products, including the Logic Power and Logic Pro devices and associated e-liquids.[4] None of these products are pod-based e-cigarettes, and to date, the FDA has not granted PMTA approval to any pod-based e-cigarettes.[5] The Logic Power is a cigalike product and Logic Pro is a cylindrical hybrid product.[6] The FDA posted the letter informing Logic of the approvals to its website (Exhibit A) and issued a concurrent press release (Exhibit B).[7]

According to the press release, the FDA concluded that "the likely benefit [of the approved products] for adult smokers who significantly reduce their cigarette use (or who switch completely and experience cigarette use cessation) outweighs the risk to youth, provided that the company follows postmarketing requirements to reduce youth access and youth exposure to their marketing."[8] At the same time, "[t]he agency also issued marketing denial orders to Logic for multiple other ENDS products."[9]

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[4] Exhibit A (FDA, *Premarket Tobacco Product Marketing Granted Orders*, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders (last visited March 31, 2022)).
[5] In addition to certain Logic e-cigarettes, the FDA has also issued a Marketing Granted Order for Reynolds' Vuse Solo cigalike product. Initial Decision Finding 261.
[6] Complaint Counsel's Post-Trial Reply Findings of Fact and Conclusions of Law ("CCRRFF") ¶¶262-63.
[7] Exhibit B at 2.
[8] *Id.* at 1.
[9] *Id.*

II. THE COMMISSION SHOULD TAKE OFFICIAL NOTICE OF THE FDA'S DECISION

Commission Rule 3.43(f) provides in relevant part that "official notice may be taken of any material fact that is not subject to reasonable dispute in that it is either generally known within the Commission's expertise or capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Commission Rule 3.43(f) (internal quotation marks omitted). Further, Commission Rule 3.54(a) provides that "[u]pon appeal from or review of an initial decision, the Commission will consider such parts of the record as are cited or as may be necessary to resolve the issues presented *and, in addition, will, to the extent necessary or desirable, exercise all the powers which it could have exercised if it had made the initial decision.*" Commission Rule 3.54(a) (emphasis added). Thus, the Commission may take official notice of material facts not subject to reasonable dispute even though the evidentiary record is closed.

The FDA Decision is appropriate for official notice: It is the public statement of a government agency and widely available on the FDA's website. Under Commission precedent, official notice may be taken of references "generally accepted as reliable." *In re Basic Research, LLC*, No. 9318, 2006 WL 271518, at *1 (F.T.C. Jan. 23, 2006) (citing *In re Thompson Medical Co.*, 104 F.T.C. 648, 790 (1984)). "Matters of official notice include those contained in public records, such as judicial decisions, statutes, regulations, and 'records and reports of administrative bodies.'" *In re S.C. State Bd. of Dentistry*, 138 F.T.C. 229, 240 (2004) (citing *United States v. Ritchie*, 342 F.3d 903, 909 (9th Cir. 2003)); *see also In re Rambus Inc.*, No. 9302, 2003 WL 22064718, at *2 (F.T.C. Aug. 27, 2003) (taking official notice of the existence of patents and information contained on the face of the patent); *In re Kentucky Household Goods Carriers Ass'n*, No. 9309, 2004 WL 2068008, at *21 n.47 (F.T.C. Aug. 31, 2004) (information

contained in documents from Oregon Public Utilities Commission and Department of Transportation was appropriate for official notice).

Similarly, federal courts have applied Federal Rule of Evidence 201, the federal rule upon which Commission Rule 3.54 is based,[10] to allow judicial notice (a close analogue to official notice) of government documents available from reliable sources. *See, e.g.*, *Cannon v. District of Columbia*, 717 F.3d 200, 205 n.2 (D.C. Cir. 2013) (taking judicial notice of the contents of a District of Columbia Retirement Board document); *Oran v. Safford*, 226 F.3d 275, 289 (3d Cir. 2000) (taking judicial notice of SEC filings). Exhibits A and B are public statements made by the FDA which are readily available on the FDA's official website. The reliability of this information cannot reasonably be called into question.

The FDA Decision is also material to Complaint Counsel's claims and Respondents' defenses. Much like Altria's discontinued MarkTen cigalike product, the newly approved Logic products do not contain nicotine salts nor are they pod-based products. *See* Respondents' Post-Trial Proposed Findings of Fact ¶¶262, 1332. In its Initial Decision, the Court held that Altria was not competitively significant based almost entirely on its conclusion that Altria's products lacked conversion potential and would therefore have been unlikely to receive PMTA approval. Initial Decision ("ID") 96-97. The Court relied on this flawed conclusion in holding that Complaint Counsel failed to meet its burden of showing reasonably likely competitive effects from the transaction. ID27, 30, 97, 112-13; Initial Decision Finding ("IDF") 262-70, 413-30. In reaching this conclusion, the Court (1) credited testimony from an Altria executive that the cigalike format of Altria's MarkTen products would not appeal to a sufficiently broad and deep pool of smokers to generate sufficient conversion potential (IDF291); (2) cited Respondents'

[10] *See e.g.*, *In re Rambus*, 2003 WL 22064718, at *1-2.

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argument that MarkTen cigalikes' purported lack of conversion potential raised serious doubts for receiving FDA approval (ID27); (3) credited testimony from Altria executives that Altria's MarkTen Elite lacked conversion potential because the product lacked nicotine salts (IDF452, 455); and held that Elite's lack of conversion potential was a serious hurdle to it securing FDA approval. ID27. However, the FDA's ultimate decision to approve two Logic products that lacked nicotine salts, one of which is a cigalike, severely undercuts Respondents' claims that Altria's existing products would have been unable to obtain FDA approval. In fact, it reinforces Complaint Counsel's argument that but for the transaction, Altria would have been a competitively significant player in the closed-system e-cigarette market. The FDA Decision demonstrates that conversion is only one factor the FDA considers in in granting PMTA approval, and that cigalikes and e-cigarettes without nicotine salts can in fact be granted PMTA approval. The Commission should consider the FDA's most recent actions with respect to PMTAs for e-cigarettes when it evaluates Respondents' claims. In light of the importance of the FDA approval process to the claims and defenses at issue in this case, the agency's recent approval of the Logic e-cigarette products satisfies the standard for materiality under Commission Rule 3.43(f).

Based on the reliability of this information and its materiality, the FDA Decision is appropriate for official notice by the Commission.

CONCLUSION

For the foregoing reasons, Complaint Counsel respectfully requests that the Commission grant its Motion for Official Notice of FDA Decision.

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Dated: March 31, 2022

Respectfully submitted,

s/ Frances Anne Johnson

Frances Anne Johnson
Stephen Rodger
Peggy Bayer Femenella
James Abell
Jeanine Balbach
Michael Blevins
Erik Herron
Joonsuk Lee
Meredith Levert
Nicole Lindquist
Michael Lovinger
David Morris
Kristian Rogers
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Federal Trade Commission
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Counsel Supporting the Complaint

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BEFORE THE FEDERAL TRADE COMMISSION

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[PROPOSED] ORDER GRANTING COMPLAINT COUNSEL'S MOTION REQUESTING OFFICIAL NOTICE OF FDA DECISION

Upon consideration of Complaint Counsel's Motion Requesting Official Notice of FDA Decision, it is hereby ORDERED that the motion is GRANTED.

ORDERED By the Commission:

April J. Tabor
Secretary

Dated:

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina Khan, Chair**
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STATEMENT OF CONFERENCE
PURSUANT TO PARAGRAPH 4 OF THE SCHEDULING ORDER

In a telephone conversation at 6:00 p.m. on March 29, 2022, Complaint Counsel Stephen Rodger and James Abell and Respondents' counsel Beth Wilkinson and David Gelfand met and conferred in an effort in good faith to resolve by agreement the issues raised by the attached motion and were unable to reach an agreement.

Dated: March 31, 2022

By: *s/ James Abell*
James Abell

Counsel Supporting the Complaint

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EXHIBIT A

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

MARKETING GRANTED ORDERS

Logic Technology Development LLC
Attention: Emil H. Weiss, Regulatory Affairs Manager
300 Frank W Burr Boulevard, Suite 70
Teaneck, NJ 07666

FDA Submission Tracking Numbers (STNs): Multiple STNs**,** see Appendix A

Dear Emil Weiss:

We completed review of your PMTAs[1] and are issuing marketing granted orders for the tobacco products identified in Appendix A.

Based on our review of your PMTAs, we determined that permitting the marketing of the new tobacco products, as described in your applications and specified in Appendix A, is appropriate for the protection of the public health (APPH). It should be noted that our determination that the marketing of these products is APPH is based in part on the submitted microbial stability data[2]. The issuance of these marketing granted orders confirms that you have met the requirements of section 910(c) of the FD&C Act and authorizes marketing of your new tobacco products. Under the provisions of section 910, you may introduce or deliver for introduction into interstate commerce the tobacco products, in accordance with the marketing order requirements outlined in these orders, including all appendices.

The authority to market the new tobacco products under these orders is also contingent upon the conditions listed in these orders and subject to the requirements in the enclosed appendices.

The requirements in these orders are intended to help ensure that the marketing of your products will continue to be appropriate for the protection of the public health, taking into account, among other factors, initiation among non-users, particularly youth. However, compliance with these requirements alone is not a guarantee that the marketing of the products will remain appropriate for the protection of the public health, particularly if, despite these measures, there is a significant uptake in youth initiation, for example. FDA will continue to monitor the marketing of your products.

[1] Premarket Tobacco Product Applications (PMTAs) submitted under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

[2] The data provided support microbial stability of the products over 12 months for PM0000529.PD1 and PM0000531.PD1, and over 15 months for PM0000535.PD1 – PM0000537.PD1, PM0000540.PD1, and PM0000541.PD1. The stability data for 12 months (for PM0000529.PD1 and PM0000531.PD1), and 15 months (for PM0000535.PD1 – PM0000537.PD1, PM0000540.PD1, and PM0000541.PD1) is acceptable and there are no other stability concerns. If you would like FDA to evaluate additional microbial stability data for a longer period, submit this information in a post-market report.

Based on our review of your PMTAs, the marketing restrictions in Appendix D are necessary to our conclusion that permitting the marketing of the new tobacco products is appropriate for the protection of public health. Absent these restrictions, a marketing granted order for these applications could not issue consistent with the requirements of section 910(c) of the FD&C Act. Relatedly, we support certain aspects of your marketing practices, as described in your PMTAs, that are intended to help address the potential for youth use of your products. Specifically, you stated you eliminated all social media accounts as of September 28, 2020; are not currently paying social media or any other influencers to market or promote your products; do not employ social media bots to market your products; only use models over the age of 30 in your consumer marketing materials; do not use characterizing words such as sweet, fruity, candy, juicy, iced, soda, mouthwatering, sugary, gummy, sour, tart, cool, or naturally flavored; do not use cartoon imagery or images of foods marketed to youth; require adult consumers to confirm they are current tobacco or vapor users and to participate in mandatory age verification before any in-person interactions with Logic products; provide your retail partners with the most advanced and up-to-date training to ensure only adult consumers can access your products; and support the We Card program as a member of the Manufacturers' Advisory Council. Additionally, as of March 16, 2021, you have discontinued online sales of all Logic products via your website. We encourage you to continue these measures because they are likely to help further mitigate risks to youth. We also recommend that you take additional steps to limit youth exposure to your print and point-of-sale advertising, including, for example, limiting advertising to print publications where 85% or more of the readership is 21 years of age or older and/or selecting publications that do not over-index for youth.

Additionally, these orders are conditioned upon the products conforming with any applicable current or future tobacco product standards, unless specifically exempted under these orders or the product standard(s).

Our finding that permitting the marketing of the new products is APPH does not mean FDA has "approved" the new tobacco products specified in Appendix A; therefore, you may not make any express or implied statement or representation in a label, labeling, or through the media or advertising, that the new tobacco products specified in Appendix A are approved by FDA (see Section 301(tt) of the FD&C Act). In addition, the issuance of marketing granted orders for your products does not mean FDA has made a determination on whether the statements or representations[3] on your products' labels, labeling or advertising, do or do not convey modified risk.[4]

The products subject to these marketing granted orders are subject to withdrawal or temporary suspension as described in section 910(d) of the FD&C Act.

You may be eligible to submit a supplemental PMTA, in accordance with 21 C.F.R. § 1114.15, for modification(s)[5] made to tobacco products that received marketing granted orders, by cross-referencing content in the PMTA and postmarket reports for the original tobacco products subject to

[3] For example, in STNs PM0000529-PM0000531, the leaflet and user guide provide the following description for the new products, "A unique combination of vapor technology and real tobacco provides satisfying taste and no smoke smell and no ash." Point-of-sale advertisement states "Real Tobacco. No Smoke Smell. No Ash." Labeling for the cartridge and capsules states "No Ash, No Smoke Smell."

[4] No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to Section 911(g) in the FD&C Act is effective with respect to such product.

[5] We note that any modifications made to a tobacco product would render it a new tobacco product that would be subject to the premarket review requirements under section 910 of the FD&C Act.

this letter. Applicants that have questions about whether it would be appropriate to submit a supplemental PMTA for modification(s) they are seeking to implement should contact their Regulatory Health Project Manager (RHPM) within the Office of Science for more information.

We remind you that all regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. These requirements include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, packaging, labeling, and advertising requirements. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

If you discontinue the manufacture, preparation, compounding or processing for commercial distribution of these tobacco products and later decide to reintroduce the products into the market, please contact the Office of Science prior to reintroduction.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[6,7] using eSubmitter.[8] Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date[9]; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

[6] https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal
[7] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.
[8] https://www.fda.gov/industry/fda-esubmitter
[9] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

If you have any questions, please contact Carlos Suarez, MPH, Regulatory Health Project Manager, at (301) 796 - 5453 or Carlos.Suarez@fda.hhs.gov.

If you have any questions regarding postmarket activities for the tobacco products subject of these orders, please contact Lillian Ortega, Director, Division of Enforcement and Manufacturing, at CTP-OCE-Postmarket@fda.hhs.gov.

Sincerely,

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New Tobacco Products Subject of This Letter
Appendix B – Postmarket Recordkeeping and Retention
Appendix C – Postmarket Reporting
Appendix D – Marketing Restrictions

Appendix A[10]

New Tobacco Products Subject of This Letter

Common Attributes of PMTA	
Submission date	August 19, 2019
Receipt date	August 19, 2019
Applicant	Logic Technology Development LLC
Product manufacturer	Logic Technology Development LLC
Product category	ENDS (VAPES)
Attributes	**New Tobacco Product**
STN	**PM0000529.PD1**
Product Name	Logic Vapeleaf Regular Cartridge/Capsule Package [11]
Product Subcategory	ENDS Other
Package Type	Blister Pack
Package Quantity	5 Capsules
Characterizing Flavor	None
Additional Properties	Mass of flavored tobacco granules per capsule: 310 mg Nicotine Content: < 39.8 mg-dry base/g
STN	**PM0000530.PD1**
Product Name	Logic Vapeleaf Cartridge/Capsule Package[11]
Product Subcategory	Closed E-Liquid
Package Type	Cartridge[12]
Package Quantity	1 Cartridge
Characterizing Flavor	None
Nicotine Concentration	0 mg/mL
E-liquid Volume	1.125 mL
PG/VG Ratio	50/50
Additional Properties	Contains an atomizer
STN	**PM0000531.PD1**
Product Name	Logic Vapeleaf Tobacco Vapor System[11]
Product Subcategory	Closed E-Cigarette
Package Type	Box
Package Quantity	1 Battery Unit
Characterizing Flavor	Not Provided
Additional Properties	Diameter: 9.2 mm, Length: 69.4 mm, Battery Capacity: >210 milliAmpere hours (mAh), Wattage: Ranges from 3.5 to 3.0 watts over the course of approximately 300 puffs, Universal Serial Bus (USB) Charger

[10] Brand/sub-brand or other commercial name used in commercial distribution.
[11] This product contains properties of ENDS and Heated Tobacco Products (HTPs). As such, it may be considered an HTP in the future.
[12] Contains U-plugs on either end of cartridge.

Attributes	New Tobacco Product
STN	**PM0000535.PD1**
Product Name	Logic Pro Tobacco e-Liquid Package
Product Subcategory	Closed E-Liquid
Package Type	Blister Pack
Package Quantity	2 Cartridges
Characterizing Flavor	Tobacco
Nicotine Concentration	20.0 mg/mL
E-liquid Volume	1.5 mL
PG/VG Ratio	69/25
STN	**PM0000536.PD1**
Product Name	Logic Pro Capsule Tank System
Product Subcategory	ENDS Other
Package Type	Box
Package Quantity	1 Capsule Case
Characterizing Flavor	Not Provided
Additional Properties	Diameter: 14.1 mm, Length: 65.5 mm
STN	**PM0000537.PD1**
Product Name	Logic Pro Capsule Tank System
Product Subcategory	Closed E-Cigarette
Package Type	Box
Package Quantity	1 Battery Unit
Characterizing Flavor	Not Provided
Additional Properties	Diameter: 14.1 mm, Length: 78.2 mm, Battery Capacity: 650 mAh, Wattage: Ranges from 5 to 4.5 watts over the course of approximately 520 puffs, USB Charger
STN	**PM0000540.PD1**
Product Name	Logic Power Tobacco e-Liquid Package
Product Subcategory	Closed E-Liquid
Package Type	Blister Pack
Package Quantity	2 Cartridges
Characterizing Flavor	Tobacco
Nicotine Concentration	27.0 mg/mL
E-liquid Volume	1.2 mL
PG/VG Ratio	68/25
STN	**PM0000541.PD1**
Product Name	Logic Power Rechargeable Kit
Product Subcategory	Closed E-Cigarette
Package Type	Box
Package Quantity	1 Battery Unit
Characterizing Flavor	Not Provided
Additional Properties	Diameter: 9.2 mm, Length: 82.6 mm, Battery Capacity: 340 mAh, Wattage: Ranges from 5.25 to 4 watts over the course of approximately 300 puffs, USB Charger

Appendix B

Postmarket Recordkeeping and Retention

Under section 910(f) of the FD&C Act, this order requires that you establish and maintain the records listed below. At any time during the retention period described in this order, FDA may request that you provide any of the documents described below. In addition, under section 704 of the FD&C Act, FDA may inspect your establishment(s) and request to inspect any record(s) described below.

The following records must be retained according to the retention periods described below. These records must be legible, in English, and available for inspection and copying by officers or employees duly designated by the Secretary, upon request.

Record	Description	Retention Period
Prior PMTAs	Each PMTA submitted prior to marketing orders	4 years from the date that FDA issues the marketing order
Postmarket reports	Postmarket reports, including periodic and adverse experience reports as described in this order	4 years from the date the report was submitted to FDA or until FDA inspects the records, whichever occurs sooner
Correspondence with FDA	Correspondence with FDA pertaining to each authorized product	4 years from the date of distribution of the last batch of each product subject to this order
Study data	Nonclinical or clinical study documentation including: • Source data; • Study protocols (including statistical analysis plan) and amendments showing the dates and reasons for each protocol revision; • Institutional Review Board (IRB) or Independent Ethics Committee (IEC) approvals; • Informed consent forms; • Correspondence with study monitors/investigators/contract research organizations/sponsors/IRB/IEC; • Investigator financial disclosure statements; • Progress reports; • Monitoring reports; • Adverse experience reports; • Case report forms/subject diaries/medical records/laboratory reports; • Subject data line listings/observations records; • Test article accountability records; • Study results/protocol summaries/study reports; and • Certifications and amendments to certifications	4 years from the date of the order or 4 years from the conclusion of the study, whichever occurs later

Record	Description	Retention Period
Manufacturing records	Records pertaining to the manufacture, in process and release testing, production process (including any changes to the process, facility, or controls), packaging, storage, and stability monitoring and testing (including protocol and results) Records and reports of all manufacturing deviations, investigations, and corrective and preventive actions including, but not limited to, those deviations associated with processing, testing, packing, labeling, storage, holding and distribution; and any deviation that may affect the characteristics of each final product	4 years from the date of distribution of each batch of each product subject to this order
Sales and/or distribution records	A list of distributors and retailers of the products, including brick-and-mortar and digital[13] (including internet/online and mobile) Any available information (not to include personally identifiable information) about product purchasers, such as purchasers' demographics (e.g., age, gender, race/ethnicity, geographic region) and previous or current use of other tobacco products (i.e., dual use) With respect to individuals under the federal minimum age of sale of tobacco products, policies and procedures regarding restrictions on access to the products, including purchaser age and identity verification processes	4 years from the date of distribution of each batch of each product subject to this order
Complaints	Records pertaining to any and all complaints associated with the tobacco product that is the subject of this order; such records may also include your analysis of those complaints	4 years from the date of distribution of each batch of each product subject to this order
Health hazard analysis	Health hazard analyses, if performed voluntarily or directed by FDA	4 years from the date of distribution of each batch of each product subject to this order
Labeling	Specimens of all labeling (including all labeling variations, such as those reflecting different required warnings), labels, inserts/onserts, instructions, and other accompanying information	4 years from the date of initial dissemination to the public
Advertising, marketing and promotional materials and plans	Copies of all advertising, marketing, and/or promotional materials published, disseminated to consumers, or for use in engaging or communicating with consumers	4 years from the date of initial dissemination to the public or implementation

[13] For the purposes of this order, here and throughout the document, "digital" includes internet/online and mobile.

Record	Description	Retention Period
	Copies of all advertising and marketing plans including strategic creative briefs and paid media plans, by channel and by product, and the details, dollar amount(s) and flighting of such plans, by channel and by product, including any: • Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys; • Targeting of specific group(s) by age-range(s), including young adults, ages 21-24, and other demographic or psychographic characteristics that reflect your intended audience(s), including the source(s) of such data; • With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict access to the products and limit exposure to the products' labeling, advertising, marketing, and/or promotion; • Use of owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products; • Use of broadcast, satellite, or cable TV media, or broadcast or satellite radio media, including copies of media buy schedules pre-launch, program lists, projected percent audience compositions by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, projected audience indices by age breakouts (i.e., 2-11, 12-17, 18-24, 25-54, 55+) by program, reach and frequency goals, and any other targeting or purchasing parameters; • Use of partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, and/or promote the products; • Consumer engagements – whether conducted by you, on your behalf, or at your direction -including events at which the products will be demonstrated and how access will be restricted to individuals at or	

Record	Description	Retention Period
	above the federal minimum age of sale of tobacco products; or • Use of public relations or other communications outreach to create labeling for, advertise, market, and/or promote the products Copies of all records pertaining to the actual delivery of advertising impressions, including media tracking and optimization, by channel, by product (if applicable), by program (where applicable), and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), media buy summaries, program lists, number of units by program, impressions by program, percent audience compositions by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, audience indices by age breakouts (i.e., 2-11, 12-17, 18-24, 25-54, 55+) by program, reach and frequency, any other parameters purchased against the buying demographics, post-logs that verify TV/radio ads ran within the approved parameters, and all post-launch delivery-verification reports for other paid media submitted to you or entities working on your behalf or at your direction from an accredited source Policies and procedures for real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products, including documentation of such monitoring activities and implementation of corrective and preventive measures	
Formative consumer research	Copies of any formative research studies conducted among any audiences, in the formation of the labeling, advertising, marketing, and/or promotional materials, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing	4 years after the studies are completed
Consumer evaluation research	Copies of any consumer evaluation research studies conducted among any audiences to determine the effectiveness of the labeling, advertising, marketing, and/or promotional materials and any shifts in consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including copies of the stimuli used in testing	4 years after the studies are completed

Record	Description	Retention Period
Contractual agreements	Copies of any contractual agreements regarding the creation or dissemination of the products' labeling, advertising, marketing, and/or promotional materials, including, for example, in print media, online or through digital platforms (e.g., social media and mobile applications), such as influencers, bloggers, and ambassadors, on your behalf, or at your direction	4 years from the date of the contract or until the contract expires, whichever is later

Appendix C
Postmarket Reporting

I. Annual Reporting

Under section 910(f) of the FD&C Act, these orders require that you submit the following postmarket reports to FDA on an annual basis, beginning twelve months from the date of the order to help FDA determine whether continued marketing of each new tobacco product is appropriate for the protection of public health or whether there is or may be other grounds for withdrawing or temporarily suspending such order. For each 12-month reporting period, the report must include:

1. A single submission with a cover letter that includes the following subject line: **ANNUAL REPORT for PM0000529.PD1 - PM0000531.PD1, PM0000535.PD1 - PM0000537.PD1, PM000040.PD1 - PM0000541.PD1.** The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of report, reporting period, and marketing status outside the United States;

2. All final printed labeling (including all variations, such as those reflecting different required warnings) not previously submitted (e.g., if previously submitted under section 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), including the date the labeling was first disseminated and the date when the labeling was discontinued, and a description of all changes to the labeling. The labeling must include all the panels and be presented in the actual size and color with legible text. The labeling must include labels, inserts/onserts, instructions, and any other accompanying information or materials for the products;

3. All final full-color advertising, marketing, and/or promotional materials, published, disseminated to consumers, or for use in engaging or communicating with consumers not previously submitted (e.g., if previously submitted under 905(i) or previously submitted at the last reporting period and no changes were made, please list the date and manner of submission), along with the original date such materials were first disseminated and the date they were discontinued, and a description of all changes to the materials. The materials must be legible, include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5” x 11” piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read lettering clearly. If resizing the advertisement does not allow for text to be read easily, the complete text must be provided separately and clearly referenced. Digital media, such as videos and animations must be submitted in a format that FDA is able to open and review;

4. A description of each change made to the manufacturing, facilities, or controls during the reporting period, including:
    a. A comparison of each change to what was described in the PMTAs;
    b. The rationale for making each change and, if any, a listing of any associated changes; and
    c. The basis for concluding that each change does not result in a new tobacco product that is outside the scope of the marketing granted order.

5. A summary of any stability monitoring, and testing of the products, including the monitoring and testing protocol(s) (including batch/lot sampling) and results;

6. A complete list of ongoing and completed studies about the tobacco products conducted by, or on your behalf, that have not been previously reported;

7. Full reports of information published or known to you, or which should be reasonably known to you, concerning scientific investigations and literature about the tobacco products that have not been previously reported, as well as significant findings from publications not previously reported;

8. A summary and analysis of all serious and unexpected adverse experiences associated with the tobacco products that have been reported to you or that you are aware of, accompanied by a statement of any changes to the overall risk associated with the tobacco products, and a summary of any changes in the health risks, including the nature and frequency of the adverse experience, and potential risk factors; a separate summary of all adverse experiences related to liver abnormalities, seizures or neurological symptoms, and respiratory symptoms characteristic of EVALI;

9. A summary, full reports, and analysis of all user complaints of Logic Pro (PM0000535) product leakage;

10. A summary of sales and distribution of the tobacco products for the reporting period, to the extent that you collect or receive such data, including:
    a. Total U.S. sales reported in dollars, units, and volume with breakdowns by U.S. census region, major retail markets, and channels in which the products are sold;
    b. The Universal Product Code that corresponds to the products identified in the PMTA; and
    c. Demographic characteristics of products purchasers, such as age, gender, race/ethnicity, geographic region, and tobacco use status;

11. A summary of the implementation and effectiveness of your policies and procedures regarding verification of the age and identity of purchasers of the products;

12. A summary of the implementation and effectiveness of your policies and procedures regarding restrictions on access to the products for individuals under the federal minimum age of sale of tobacco products;

13. A summary of all formative consumer research studies conducted– whether by you, on your behalf, or at your direction -among any audiences, in the formation of new labeling, advertising, marketing, and/or promotional materials, not previously submitted, including qualitative and quantitative research studies used to determine message effectiveness, consumer knowledge, attitudes, beliefs, intentions and behaviors toward using the products, and including the findings or these studies and copies of the stimuli used in testing;

14. A summary of all consumer evaluation research studies conducted – whether by you, on your behalf, or at your direction - among any audiences, not previously submitted, to determine the effectiveness of labeling, advertising, marketing, and/or promotional materials and shifts in

consumer knowledge, attitudes, beliefs, intentions, and behaviors toward using the products, and including the findings of these studies and copies of the stimuli used in testing;

15. A summary of the creation and dissemination of the products' labeling, advertising, marketing, and/or promotional materials – whether conducted by you, on your behalf, or at your direction – including a list of all entities involved and a description of their involvement, including a description of contractual agreements with such entities;

16. A description of the implementation of all advertising and marketing plans – whether conducted by you, on your behalf, or at your direction - not previously submitted, including strategic creative briefs and paid media plans by channel and by product, and the details, dollar amount(s) and flighting of such plans, by channel and by product, including a description of any:
    a. Use of competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;
    b. Targeting of specific group(s) by age-range(s), including young adults, ages 21-24, and other demographic or psychographic characteristics that reflect the intended audience(s), including the source(s) of such data;
    c. With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict access to the products and limit exposure to the products' labeling, advertising, marketing, and/or promotion;
    d. Use of owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products;
    e. Use of broadcast, satellite, or cable TV media, or broadcast or satellite radio media, including media buy summaries, program lists, number of units by program, program and network TRPs, impressions by program, percent audience compositions by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, audience indices by age breakouts (i.e., 2-11, 12-17, 18-24, 25-54, 55+) by program, reach and frequency, any other parameters purchased against the buying demographics;
    f. Use of partners, influencers, bloggers, and/or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
    g. Consumer engagements – whether conducted by you, on your behalf, or at your direction – including events at which the products were demonstrated and how access was restricted to individuals at or above the federal minimum age of sale of tobacco products; or
    h. Use of public-relations or other communications outreach to create labeling for, advertise, market, and/or promote the products; including the original date such plans were first used and the date they were discontinued, and a description of all changes to such plans since the last periodic report, by channel and by product;

17. A summary of media tracking and optimization, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region), including a summary of real-time digital media monitoring to identify, correct, and prevent delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products, and

including a summary of implementation of any corrective and preventive measures, not previously submitted;

18. An analysis of the actual delivery of advertising impressions, by channel, by product (if applicable), by program (where applicable), and by audience demographics, (e.g., age, gender, race/ethnicity, geographic region), not previously submitted, and verified against post-logs (for TV/radio) and post-launch delivery-verification reports for other paid media submitted to you or entities working on your behalf or at your direction from an accredited source; and

19. An overall assessment of how the marketing of the tobacco products continues to be appropriate for the protection of public health.

The products subject to these marketing granted orders are subject to withdrawal or temporary suspension as described in section 910(d) of the FD&C Act. Grounds that FDA will consider for withdrawal under section 910(d) of the FD&C Act include scenarios in which FDA finds that the continued marketing of the product is no longer APPH. These scenarios may include, but are not limited to, certain changes in product use behaviors that were not expected in FDA's assessment of the PMTA (e.g., increases in the percentage or number of youth and young adults who report use of your products, fewer users of potentially more harmful products switching to your products than anticipated), changes in FDA's understanding of the net effects of your products on the population as a whole, or new scientific evidence that demonstrates that the products present a greater risk to health than FDA understood during the review process.

II. Serious and Unexpected Adverse Experiences Reporting and Reporting of Certain Manufacturing Deviations

Under section 910(f) of the FD&C Act, these orders require that you report to the FDA all adverse experiences that are both serious and unexpected and your analysis of the association between the adverse experience and each new tobacco product **within 15 calendar days** after the report is received by you. These experiences may become known to you through any source including a customer complaint, request, or suggestion made as a result of an adverse experience, a manufacturing deviation analysis, tobacco product defect, or failure reported to you; or identified in the literature or media. Your information should be submitted with a cover letter that includes the following subject line: **SERIOUS UNEXPECTED ADVERSE EXPERIENCE REPORT for PM0000529.PD1 - PM0000531.PD1, PM0000535.PD1 - PM0000537.PD1, PM000040.PD1 - PM0000541.PD1**.

For purposes of reporting under these orders, serious adverse experience means an adverse experience that results in any of the following outcomes:

- Death;
- A life-threatening condition or illness;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption in the ability to conduct normal life functions;
- A congenital anomaly/birth defect; or
- Any other adverse experience that, based upon appropriate medical judgment, may jeopardize the health of a person and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

For purposes of reporting under these orders, unexpected adverse experience means an adverse experience occurring in one or more persons in which the nature, severity, or frequency of the experience is not consistent with:

- The known or foreseeable risks of adverse experiences associated with the use or exposure to each tobacco product as described in the PMTA and other relevant sources of information, such as postmarket reports and studies;
- The expected natural progression of any underlying disease, disorder, or condition of the persons(s) experiencing the adverse experience and the person's predisposing risk factor profile for the adverse experience; or
- The results of nonclinical laboratory studies.

For products that have been distributed, if a manufacturing deviation occurs that you determine presents a reasonable probability that the tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death you are required to report the deviation to FDA within 15 calendar days of identification.

III. Notifications

Under sections 910(c)(1)(B) and 910(f) of the FD&C Act, these orders also requires that, as of the authorization date of your marketing granted orders, you submit the following notifications of your marketing plans and materials to FDA. This requirement to submit the product's labeling, advertising, marketing, and promotional materials and plans in advance of their use is not for pre-approval – that is, FDA is not requiring that it review and approve such materials or plans before they may be used. Rather, such advance notification will provide FDA timely access to such materials and plans and, if needed, allow FDA to provide advisory comments, including any concerns about their possible impact on youth appeal and tobacco use initiation. You may begin disseminating the materials 30 days after providing notification to FDA.

This notification must be received by FDA **at least 30 days** prior to dissemination, which includes but is not limited to the publication, dissemination to consumers, or use in engaging or communicating with consumers of such materials. The duration of these notification requirements is as follows:

- On an ongoing basis, provide notification of any labeling, advertising, marketing or promotion in broadcast, satellite, or cable TV media or broadcast or satellite radio media; and
- For a period of six months starting with the initial dissemination of the materials, provide notification of all other labeling, advertising, marketing, and promotion.

Each 30-day notification must include:

1. A single submission with a cover letter that includes the following subject line: **30-DAY NOTIFICATION for PM0000529.PD1 - PM0000531.PD1, PM0000535.PD1 - PM0000537.PD1, PM000040.PD1 - PM0000541.PD1.** The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of notification, and planned dissemination date;

2. Full-color copies of all such labeling, advertising, marketing, and promotional materials for the products. The materials must be legible, include all panels where applicable (e.g., print ads, point of sale signs) and reflect the actual size and colors used. For any materials that would not fit on an 8.5" x 11" piece of paper, you may resize and submit electronic versions of such materials in a format that FDA can review and with sufficient resolution to allow FDA to read all lettering clearly. If resizing the advertisement does not allow for text to be read easily, the complete text must be provided separately and clearly referenced; and

3. All advertising and marketing plans, including strategic creative briefs and paid media plans, by channel and by product, and the details, dollar amount(s) and flighting of such plans, by channel and by product, including any plans to:
    a. Use competent and reliable data sources, methodologies, and technologies to establish, maintain, and monitor highly targeted advertising and marketing plans and media buys, including a list of all data sources used to target advertising and marketing plans and media buys;
    b. Targeting specific group(s) by age-range(s), including young adults, ages 21-24, and other demographic or psychographic characteristics that reflect your intended audience, including the source(s) of such data;
    c. With respect to individuals below the federal minimum age of sale of tobacco products, actions taken to restrict access and exposure to the products' labeling, advertising, marketing, and/or promotion;
    d. Use owned, earned, shared, or paid media to create labeling for, advertise, market, and/or promote the products;
    e. Use broadcast, satellite, or cable TV media, or broadcast or satellite radio media, including copies of media buy schedules pre-launch, program lists, projected percent audience compositions by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, projected audience indices by age breakouts (i.e., 21+, 2-11, 12-17, 18-24, 25-54, 55+) by program, reach and frequency goals, and any other targeting or purchasing parameters;

f. Use partners, influencers, bloggers, or brand ambassadors to create labeling for, advertise, market, and/or promote the products;
g. Conduct consumer engagements – whether by you, on your behalf, or at your direction – including events at which the products will be demonstrated and how access will be restricted to individuals at or above the federal minimum age of sale of tobacco products; or
h. Use public-relations or other communications outreach to create labeling for, advertise, market, and/or promote the products.

Appendix D
Marketing Restrictions

Under section 910(c)(1)(B) of the FD&C Act, these orders requires you to:

- For any **digital sales** – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare customer information against independent, competent, and reliable data sources, such as public records, to prevent the sale of the products to individuals who are under the federal minimum age of sale of tobacco products.

- For any of the products' labeling, advertising, marketing, and/or promotion appearing in your **owned digital properties** (e.g., your company-owned, consumer-directed, product-branded website(s) and/or mobile applications) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of independent age- and identity-verification service(s) that compare customer information against independent, competent, and reliable data sources, such as public records, at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or promotion to only individuals who are at or above the federal minimum age of sale of tobacco products.

- For any of the products' labeling, advertising, marketing, and/or promotion appearing in any **shared digital properties** (e.g., your product-branded social media accounts, pages and associated content; content promoting your products on your behalf disseminated through another entity's social media accounts) – whether conducted by you, on your behalf, or at your direction – establish, maintain, and monitor use of the available site-, platform- and content-(e.g., post, video) specific age-restriction controls (e.g., age-restrict an entire product-branded account and all associated content disseminated through such account; ensure age-restriction of a specific video disseminated by an influencer promoting the products on your behalf through the influencer's account), at the first point of access to such properties, to restrict access to such labeling, advertising, marketing, and/or such promotion to only individuals who are at or above the federal minimum age of sale of tobacco products.

- For any of the products' labeling, advertising, marketing, and/or promotion appearing in **paid digital media** (e.g., paid digital banner advertisements for the products running on another company's website; paid advertising for the products running in social media; paid distribution of influencer content; paid advertising in streaming/Over-The-Top video programming; paid advertising in streaming/internet radio content) – whether conducted by you, on your behalf, or at your direction:

    - Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies to precisely target delivery of such labeling, advertising, marketing, and/or promotion to only individuals who are or above the federal minimum age of sale of tobacco products. Such targeting must use only first- and/or second-party age-verified data, where:

        - "First-party" age-verified data is data owned by you (e.g., your customer registration data collected via site traffic to your company-owned website; data you use in direct

marketing to your adult smoking customers) that you have age-verified through independent, competent, and reliable data sources; and

- "Second-party" age-verified data is first-party data owned and age-verified by another competent and reliable entity (e.g., another company's first-party user registration data) to which you have access. Such data must be age-verified by the second party.

- "First-party" and "second-party" data does not include data obtained from data aggregators who categorize consumers based on trackable activities and inferred interests (e.g., internet search terms, video interactions, browsing history, purchasing behaviors) to create demographic and psychographic profiles marketers may use to enhance audience targeting. Such data is not considered age-verified and can only be used in combination with first- and/or second-party age-verified data.

- For any of the products' labeling, advertising, marketing, and/or promotion appearing **in broadcast, satellite, or cable TV media, and/or broadcast or satellite radio media** (e.g., video advertisements for the products airing during broadcast cable television programming; audio advertisements for the products airing through radio media channels; ads airing via multichannel video programming distributors; ads airing during Video on Demand/Full Episode Player extensions to network buys; addressable TV ads) – whether conducted by you, on your behalf, or at your direction:

  - Establish, maintain, and monitor use of independent, competent, and reliable data sources, methodologies, and technologies to target delivery of such labeling, advertising, marketing, and/or promotion to individuals who are at or above the federal minimum age of sale of tobacco products. Such targeting must adhere to the following requirements, at a minimum:

    - All TV and radio programs must have reported audience compositions of 85% or more adults who are at or above the federal minimum age of sale of tobacco products;

    - All TV and radio programs must have reported audience indices of 99 or lower for youth aged 2-11; and

    - All TV and radio programs must have reported audience indices of 99 or lower for youth aged 12-17.

- Establish, maintain, and monitor use of competent and reliable data sources, methodologies, and technologies (e.g., using an embedded tracking pixel in all digital advertising) – whether conducted by you, on your behalf, or at your direction – to **track and measure actual delivery of all advertising impressions**, by channel, by product, and by audience demographics (e.g., age, gender, race/ethnicity, geographic region). Such monitoring requires real-time digital media tracking, and identifying, correcting, and preventing delivery of advertising impressions to individuals under the federal minimum age of sale of tobacco products. Such monitoring also requires post-logs that verify TV/radio ads fan within the approved parameters and post-launch delivery verification reports for other paid media be submitted to you or entities working on your behalf or at your direction from an accredited source.

- For any use of **partners, influencers, bloggers, and/or brand ambassadors** to create labeling for, advertise, market, and/or promote the products – whether conducted by you, on your behalf, or at your direction – disclose to consumers or viewers, via the use of statements such as "sponsored by [firm name]" in such labeling, advertising, marketing, and/or promotional materials, any relationships between you and entities that create labeling for, advertise, market, and/or promote the products, on your behalf, or at your direction.

The marketing restrictions in these orders were determined based on review of the information submitted in your PMTAs, including information about how you intend to advertise and market the products, and in consideration of other marketing restrictions that currently apply to and/or affect the marketing of your products, including policies and practices of media entities (e.g., no broadcast TV network currently accepts tobacco advertising). Any change in the policies or practices of media entities that has the effect of expanding opportunities for manufacturers of tobacco products to reach youth and any subsequent changes in your use of such media entities may, in turn, affect the APPH analysis of your products, based on our obligation to consider how products are likely to be used, including by youth.

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EXHIBIT B

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FDA NEWS RELEASE

FDA Issues Decisions on Additional E-Cigarette Products

Agency Permits Marketing of Certain Tobacco-Flavored Products, Denies Other Products; Additional Decisions on Popular Products Expected Soon

For Immediate Release:

March 24, 2022

Today, the U.S. Food and Drug Administration took additional actions as part of the agency's work to ensure any electronic nicotine delivery system (ENDS) products available for sale have demonstrated that marketing of the products is appropriate for the protection of the public health.

What You Need to Know

- The FDA authorized several tobacco-flavored ENDS products (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders) from Logic Technology Development LLC (Logic) under the Logic Vapeleaf, Logic Power and Logic Pro brands, including devices. These products were authorized after the agency's review of the product applications concluded, among other things, that the likely benefit for adult smokers who significantly reduce their cigarette use (or who switch completely and experience cigarette use cessation) outweighs the risk to youth, provided that the company follows postmarketing requirements to reduce youth access and youth exposure to their marketing. While today's action permits these specific products to be sold in the U.S., it does not mean these products are safe nor are they "FDA approved." All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start.
- The agency also issued marketing denial orders to Logic for multiple other ENDS products. Any of those products currently on the market must be removed or FDA may take enforcement action. Retailers should contact Logic with any questions about products in their inventory. Applications for Logic's additional products, including menthol, remain under FDA review.
- The FDA has taken action on approximately 99% of the nearly 6.7 million ENDS products submitted for premarket authorization, including issuing marketing denial orders for more than 1 million ENDS products.
- The agency is close to making additional (/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders) decisions on applications for

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popular ENDS products that account for a large part of the market. The continued marketing of these products has the potential to have a substantial public health impact—either positively or negatively—as they hold an overall large market share and are used by a lot of people.

"As a cardiologist, I've personally seen the devastating health effects of tobacco use, so I'm highly motivated for the FDA to help reduce death and disability caused by these products," said FDA Commissioner Robert M. Califf, M.D. "We know that there is a demand among adult smokers to use e-cigarette products to try to switch from more harmful combusted cigarettes, but millions of youth are using these products and getting addicted to nicotine. The balance of these issues was considered by the agency's career scientists when evaluating the potential marketing of e-cigarette products. They have made great progress and I know they will use the best available evidence with the most robust methods to ensure that products that continue to be marketed are appropriate for the protection of the public health."

Under the Premarket Tobacco Product Application (PMTA) pathway (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications), manufacturers or importers must demonstrate to the agency, among other things, that marketing of a new tobacco product would be appropriate for the protection of the public health. That statutory standard requires the FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products. The FDA must also consider the likely impact of the products on people's behavior—specifically, the likelihood that existing users will stop using such products and the likelihood that those who do not use tobacco products will start using such products. This is especially important for youth. Before a product is authorized under the PMTA pathway, the agency reviews a tobacco product's components, ingredients, additives, constituents and health risks, as well as how the product is manufactured, packaged and labeled.

"Ensuring new tobacco products undergo premarket evaluation by the FDA is a critical part of our work to reduce tobacco-related disease and death," said Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products. "For the authorized products, the manufacturer demonstrated that possible benefits to adult smokers outweigh the risk of youth possibly initiating. We are making progress in our review of flavored ENDS, and we will continue to deny marketing of products where the applicant hasn't provided enough evidence to show that the potential benefit to adult smokers outweighs the considerable risk to youth. We are committed to continuing to take the appropriate actions to protect our nation's youth from the dangers of all tobacco products, including e-cigarettes, which remain the most commonly used tobacco product by youth in the United States."

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Logic Authorizations

The FDA's review of the applications for the products authorized today determined that the marketing of the tobacco-flavored products and associated components is appropriate for the protection of the public health. The FDA authorized these tobacco-flavored ENDS products because, among several key considerations, the data submitted by the company and the available evidence show that marketing these products may help addicted adult smokers transition away from combusted cigarettes and reduce their risk of exposure to harmful and potentially harmful toxins compared to combusted cigarettes. At the same time, the data showed there was low risk for non-users, including youth, to use the products. The risk was also low for non-users, including youth, to progress to regular use of the products.

Specifically, available data showed that current tobacco users who used these tobacco-flavored products were more likely to significantly decrease their use of combusted cigarettes and that those who don't smoke are unlikely to start using these products. Most study subjects decreased the number of combusted cigarettes they smoked each day by greater than 80%, from an average of 13-16 cigarettes per day at screening to 1-2 by day 59. The data also showed that the products produce fewer or lower levels of some toxins, like carbon monoxide, than combustible cigarettes and the products' abuse liability, or their ability to encourage continued tobacco use, addiction or dependence, was lower than combusted cigarettes.

Additionally, today's authorization imposes strict marketing restrictions on the company to greatly reduce the potential for youth exposure to tobacco advertising for these products. The FDA will closely monitor how these ENDS products are marketed and will act as necessary if the company fails to comply with any applicable statutory or regulatory requirements, or if there is a notable increase in the number of non-smokers—including youth—using these products.

As evidenced through data collected via the National Youth Tobacco Survey (/news-events/press-announcements/youth-e-cigarette-use-remains-serious-public-health-concern-amid-covid-19-pandemic), compared to users of non-tobacco-flavored ENDS products, young people are less likely to start using tobacco-flavored ENDS products. The data also suggest that most youth and young adults who use ENDS begin with flavors such as fruit, candy or mint, and not tobacco flavors. These data reinforce the FDA's decision today, consistent with past decisions, to authorize the marketing of the tobacco-flavored ENDS products in part because they are not significantly appealing to youth and authorizing these products may be beneficial for individual adult combusted cigarette users who completely switch to ENDS or significantly reduce their cigarette consumption.

The FDA may suspend or withdraw a marketing order issued under the PMTA pathway for a variety of reasons, including if the agency determines the continued marketing of a product is no longer "appropriate for the protection of the public health," such as if there is a notable increase

in youth initiation.

Related Information

- Premarket Tobacco Product Marketing Orders (/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders)
- Premarket Tobacco Product Applications (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications)

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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888-INFO-FDA

More Press Announcements (/news-events/newsroom/press-announcements)

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CERTIFICATE OF SERVICE

I hereby certify that on March 31, 2022, I caused a true and correct copy of the foregoing to be filed electronically using the FTC's E-Filing System, which will send notification of such filing to:

April J. Tabor
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I also certify that I caused the foregoing document to be served via email to:

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