UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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

COMPLAINT COUNSEL'S SECOND 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") May 12, 2022, decision to grant marketing authorization to certain Vuse-branded e-cigarette products sold by R.J. Reynolds Vapor Company ("FDA Decision"). The FDA Decision is similar to the one that was the subject of Complaint Counsel's prior motion for official notice,[1] as well as those that are the subject of Respondents' pending motion for official notice (which Complaint Counsel does not oppose).[2]

[1] *See* Complaint Counsel's Motion Requesting Official Notice of FDA Decision, dated March 31, 2022.
[2] *See* Respondents' Motion for Official Notice of Recent FDA Decisions, dated May 16, 2022; Complaint Counsel's Response to Respondents' Motion for Official Notice of Recent FDA Decisions, dated May 24, 2022. Although the FDA Decision was issued before Respondents' filed their motion, they chose not to seek official notice of this

Like the other FDA decisions for which the parties have sought official notice, the instant 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. As the Commission itself has noted, there can be no reasonable dispute about the existence, wide availability, and accuracy of the FDA's decisions.[3] 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 PMTA pathway, the applicant 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."[4] As part of its evaluation, "the FDA consider[s] the risks and benefits to the population

particular FDA decision. Unlike Respondents—who would have the Commission afford some, but not all, of the recent FDA decisions official notice—Complaint Counsel maintains that all of the FDA decisions that have been the subject of the parties' recent motion practice should be granted official notice under the Commission's rules.

[3] Order Extending Time for Ruling on Motion for Official Notice of FDA Decision, dated May 13, 2022.

[4] Exhibit B (FDA, Press Release, *FDA Issues Decisions on Additional E-Cigarette Products* at 1 (May 12, 2022), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-decisions-vuse-vibe-and-vuse-ciro-e-cigarette-products.

as a whole, including users and non-users of tobacco products, and **importantly, youth**. (emphasis added)."[5]

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 pulled its pod-based e-cigarette devices under the guise of a youth concern, CCFF ¶¶ 812, 987, but never offered 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 May 12, 2022, the FDA issued "Marketing Granted Orders" to R.J. Reynolds Vapor Company ("RJR") for its Vuse Vibe e-cigarette device and accompanying tobacco-flavored closed e-liquid pod, as well as for its Vuse Ciro e-cigarette device and accompanying tobacco flavored closed e-liquid pod.[6] Both Vuse Vibe and Vuse Ciro are cigalike products that contain nicotine salts. CCFF ¶ 167.[7] The FDA posted the letter informing RJR of the approvals to its website (Exhibit A) and issued a concurrent press release (Exhibit B).[8]

According to the press release, the FDA concluded that "the potential benefit to adult smokers who switch completely or significantly reduce their cigarette use would outweigh the risk to youth – provided that the company follows post-marketing requirements to reduce youth access and youth exposure to their marketing."[9]

---

[5] *Id.*at 2.
[6] Exhibit A (FDA, *Premarket Tobacco Product Marketing Granted Orders*, https://www.fda.gov/media/158373/download (last visited May 23, 2022)).
[7] *FAQs*, Vuse, https://vusevapor.com/faqs (last visited May 24, 2022).
[8] Exhibit B at 1.
[9] *Id.* at 2.

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 Ky. 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 products, the newly approved Vuse products are not pod-based products. *See* CCFF ¶ 167. Indeed, Altria's MarkTen Bold product was nearly identical to Vuse Vibe and Vuse Ciro—all three are cigalike products that contain nicotine salts. *See* CCFF ¶¶ 81, 167.

In its Initial Decision, the Court held that Altria was not competitively significant based in part on its conclusion that Altria's products would have been unlikely to receive PMTA approval. Initial Decision ("ID") 96-97. In reaching this conclusion, the Court credited testimony from an Altria executive that the cigalike form factor of Altria's MarkTen products would not appeal to a sufficiently broad and deep pool of smokers. IDF 291.

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

But the FDA's decision to approve three Vuse cigalike products[11] severely undercuts Respondents' claims that Altria's cigalike 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 form is only one factor that the FDA considers in evaluating PMTA approval, and that cigalikes can in fact receive PMTA approval.[12] The Commission should consider the FDA's recent PMTA decisions when it evaluates Respondents' assertions on the future viability of cigalikes. In light of the importance of the FDA approval process to the claims and defenses at issue in this case, the FDA's recent approval of the Vuse 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 Second Motion Requesting Official Notice of FDA Decision.

[11] In addition to the Vuse Vibe and Vuse Ciro products that received marketing authorization in the FDA Decision, the FDA had previously authorized RJR's Vuse Solo cigalike device and tobacco flavored cartridges. IDF 261.
[12] Although both Vuse Vibe and Vuse Ciro contain nicotine salts—much like Altria's discontinued MarkTen Bold product—the FDA has also recently granted PMTA approval to a cigalike that does *not* contain nicotine salts, the Logic Power. *See* Complaint Counsel's Motion Requesting Official Notice of FDA Decision at 5, dated March 31, 2022.

Dated: May 24, 2022

Respectfully submitted,

s/ Erik Herron

Erik Herron
Stephen Rodger
Peggy Bayer Femenella
James Abell
Jeanine Balbach
Michael Blevins
Frances Anne Johnson
Joonsuk Lee
Meredith Levert
Nicole Lindquist
Michael Lovinger
David Morris
Kristian Rogers
Eric Sprague

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
Telephone: (202) 326-3535
Email: eherron@ftc.gov

Counsel Supporting the Complaint

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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

REQUESTING OFFICIAL NOTICE OF FDA DECISION

Upon consideration of Complaint Counsel's Second 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 M. Khan, Chair**
Noah Joshua Phillips
Rebecca Kelly Slaughter
Christine S. Wilson
Alvaro Martín Bedoya

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

STATEMENT OF CONFERENCE

In a conversation over the course of May 23, 2022, Complaint Counsel Stephen Rodger and James Abell and Respondents' counsel Jonathan Moses conferred in a good faith effort to resolve by agreement the issues raised by the attached motion and were unable to reach an agreement.

Dated: May 24, 2022

By: *s/ James Abell*
James Abell
Counsel Supporting the Complaint

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

R.J. Reynolds Vapor Company
Attention: Aaron P. Williams, Ph.D.
Senior Vice President, Scientific & Regulatory Affairs
RAI Services Company
401 North Main Street
Winston-Salem, NC 27101

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

Dear Dr. Williams:

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, are 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 are 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] For PM0000636 and PM0000712, you stated that the shelf life of the subject products is (b) (4) but did not provide data that would allow FDA to evaluate whether the products are microbially stable over (b) (4) . The data provided support microbial stability of the products over (b) (4) . The stability data for (b) (4) is acceptable and there are no other stability concerns, so the lack of stability data for (b) (4) does not preclude an APPH finding for the subject products. 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 the 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 intend to use the following measures to help reduce youth appeal of your marketing materials: "Not use any social media platforms (e.g., Facebook, Instagram, Twitter) or social media influencers for marketing and promotional purposes; No testimonials by sports figures or celebrities or any person with special appeal to persons under 21 years of age; No person appearing in any advertising materials shall be under age 25 or be styled to look under age 25; Content shall not include characters, images, or themes designed to target youth; Content shall not be related to youth or youth-oriented activities; Content shall not suggest that use of R.J. Reynolds Vapor Company's ("RJRV") products is essential to social prominence, distinction, success or sexual attraction, nor shall any content picture a person using any RJRV products in an exaggerated manner; and Content shall not depict persons participating in, or obviously just having participated in, a physical activity requiring stamina or athletic conditioning beyond that of normal recreation." We also support your proposed efforts to ensure responsible retailing practices intended to prevent underage sales to minors, plans to age-verify tobacco consumers opting-in to receive direct mail/e-mail marketing, and plans to conduct age- and identity-verification of consumers participating in engagement events. We encourage you to implement 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 that do not over-index for youth, requiring advertising to be placed inside the store, and placing product displays near other age-restricted products and away from products appealing to youth like toys and candy.

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).

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)[3] 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 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.

[3] 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.

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[4,5] using eSubmitter.[6] 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[7]; 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.

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

If you have any questions, please contact Sequoia Bacon, Regulatory Health Project Manager, at (301) 796-0736 or Sequoia.Bacon@fda.hhs.gov.

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

Sincerely,

/S/

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[8]

New Tobacco Products Subject of This Letter

Common Attributes of PMTAs	
Applicant	R.J. Reynolds Vapor Company
Product manufacturer	R.J. Reynolds Vapor Company
Product category	ENDS (VAPES)
Attributes	**New Tobacco Product**
STN	**PM0000635**
Submission date	April 2, 2020
Receipt date	April 2, 2020
Product name	Vuse Vibe Power Unit
Product subcategory	Closed E-Cigarette
Package type	Paperboard Carton
Package quantity	1 Power Unit
Characterizing flavor [9]	Unflavored
Additional properties	Length: 82.5 mm Diameter: 13.0 mm Wattage:[10] (b) (4) W Battery capacity: (b) (4) milliAmpere hour (mAh) Universal Serial Bus (USB) Charger Battery Manufacturer: (b) (4)
STN	**PM0000636**
Submission date	April 2, 2020
Receipt date	April 2, 2020
Product name	Vuse Vibe Tank Original 3.0%
Product subcategory	Closed E-Liquid
Package type	Paperboard Carton/Blister Pack
Package quantity	2 Cartridges
Characterizing flavor	Tobacco[11]
E-liquid volume	1.9 mL per cartridge
Nicotine concentration	36.0 mg/mL
PG/VG ratio	20/80
Additional properties	Length: 59.0 mm Diameter: 13.0 mm Nicotine content: 3.0% w/w

[8] Brand/sub-brand or other commercial name used in commercial distribution.

[9] Provided as part of product label.

[10] The applicant states the wattage listed represents the nominal operating range; the upper and lower wattages have a variation of (b) (4) %.

[11] Labels may contain descriptive term such as "Original."

Attributes	New Tobacco Product
STN	**PM0000646**
Submission date	April 15, 2020
Receipt date	April 15, 2020
Product name	Vuse Ciro Power Unit
Product subcategory	Closed E-Cigarette
Package type	Paperboard Carton
Package quantity	1 Power Unit
Characterizing flavor[9]	Unflavored
Additional properties	Length: 83.5 mm Diameter: 9.2 mm Battery Capacity: (b) (4) milliAmpere hour (mAh) Wattage:[12] Expected High: (b) (4) W Expected Low: (b) (4) W Universal Serial Bus (USB) Charger Battery Manufacturer: (b) (4)
STN	**PM0000712**
Submission date	April 15, 2020
Receipt date	April 15, 2020
Product name	Vuse Ciro Cartridge Original 1.5%
Product subcategory	Closed E-Liquid
Package type	Paperboard Carton/Blister Pack
Package quantity	3 Cartridges
Characterizing flavor	Tobacco[11]
Nicotine concentration	17.7 mg/ml
PG/VG ratio	29/71
E-liquid volume	0.9 ml per cartridge
Additional properties	Length: 50.0 mm Diameter: 9.2 mm Nicotine Content: 1.5%
STN	**PM0004287**
Submission date	April 2, 2020
Receipt date	April 2, 2020
Product name	Vuse Vibe Power Unit
Product subcategory	Closed E-Cigarette
Package type	Paperboard Carton
Package quantity	1 Power Unit
Characterizing flavor[9]	Unflavored
Additional property	Length: 82.5 mm Diameter: 13.0 mm Wattage:[10] (b) (4) W Battery capacity: (b) (4) milliAmpere hour (mAh) Universal Serial Bus (USB) Charger Battery Manufacturer: (b) (4)

[12] The wattages listed represent the average of 15 samples ± 95% confidence interval.

Attributes	New Tobacco Product
STN	**PM0004293**
Submission date	April 15, 2020
Receipt date	April 15, 2020
Product name	Vuse Ciro Power Unit
Product subcategory	Closed E-Cigarette
Package type	Paperboard Carton
Package quantity	1 Power Unit
Characterizing flavor[9]	Unflavored
Additional property	Length: 83.5 mm Diameter: 9.2 mm Wattage:[12] Expected High: (b) (4) W Expected Low: (b) (4) W Battery capacity: (b) (4) milliAmpere hour (mAh) Universal Serial Bus (USB) Charger Battery Manufacturer: (b) (4)

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;	4 years from the date of the order or 4 years from the conclusion of the study, whichever occurs later

Record	Description	Retention Period
	• 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	
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

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

Record	Description	Retention Period
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 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	4 years from the date of initial dissemination to the public or implementation

Record	Description	Retention Period
	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 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	

Record	Description	Retention Period
	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
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	4 years from the date of the contract or until the contract expires, whichever is later

Record	Description	Retention Period
	as influencers, bloggers, and ambassadors, on your behalf, or at your direction	

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 products is appropriate for the protection of public health or whether there are 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 PM0000635, PM0000636, PM0000646, PM0000712, PM0004287, PM0004293.** The cover letter should include the STN(s) and corresponding tobacco product name(s), applicant name, date of report, and 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 seizures or neurological symptoms, and respiratory symptoms characteristic of EVALI;

9. 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;

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

11. 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;

12. 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;

13. 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;

14. 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;

15. 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;

16. 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;

17. 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

18. 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 PM0000635, PM0000636, PM0000646, PM0000712, PM0004287, PM0004293**.

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 require 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.

These notifications 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, please 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/or 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 PM0000635, PM0000636, PM0000646, PM0000712, PM0004287, PM0004293.** 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 require 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 at 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.

EXHIBIT B

FDA Issues e ing Decisions on Vuse Vibe nd Vuse Ci o E-Cig e e P oduc s

On May 1 , the FDA issued decisions on several Vuse Vibe and Vuse Ciro e-cigarette products (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders), including the authorization of six new tobacco products through the Premarket Tobacco Product Application (PMTA) pathway. The FDA issued marketing granted orders (MGO) (https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Premarket% oTobacco% oProduct% oApplications% o(PMTA)) to R.J. Reynolds Vapor Company for its Vuse Vibe e-cigarette device and accompanying tobacco-flavored closed e-liquid pod, as well as for its Vuse Ciro e-cigarette device and accompanying tobacco-flavored closed e-liquid pod. For each device, two versions of the Power Units were authorized to reflect 2 different battery manufacturers described in the company's applications. In total, the products receiving MGOs include:

- Vuse Vibe Power Units
- Vuse Vibe Tank Original 3.0%
- Vuse Ciro Power Units
- Vuse Ciro Cartridge Original 1.5%

This authorization allows these products to be legally marketed in the U.S. While this 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 FDA also issued marketing denial orders to R.J. Reynolds Vapor Company for multiple other Vuse Vibe and Vuse Ciro e-cigarette products. Any of those products currently on the market must be removed or FDA may take enforcement action. Retailers should contact R.J. Reynolds Vapor Company with any questions about products in their inventory.

Under the PMTA pathway (/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications), the applicant must demonstrate to the agency, among other things, that marketing of the new tobacco product would be appropriate for the protection of the public health. The authorized Vuse products were found to meet this standard because, among several key considerations, chemical testing was sufficient to determine that overall harmful and potentially harmful constituent (HPHC) levels in the aerosol of these products is lower than in combusted cigarette smoke. Further, data provided by the 2

applicant n trat that participant wh ha u nly th auth riz Vu Vib an Vu Cir pr uct ha l w r l v l f xp ur t n n-nic tin HPHC c ar p th ual u r f th n w pr uct an c u t bcigar tt . Th r f r th pr uct hav th p t ntial t b n fit a ult k r wh witch c l t lyp r ignificantly r uc th ir cigar tt c n u ti n.p,

A iti nally th FDA c n i r th ri k an b n fit t th p pulati n a a wh l inclu ing u r an n n-u r f t bacc pr uct an i rtantptly y uth. Thi inclu r vi w f availabl ata n th lik lih f u f th pr uct by y ung p pl . F r th auth riz pr uct th FDA t r n thiat th p t ntial b n fit t a ult k r wh witch c l t lyp r ignificantly r uc th ir cigar tt u w ul utw igh th ri k t y uth – pr vi that th c any fpll w p t- rk tiag r quir nt t r uc y uth acc an y uth xp ur t th ir rk tiag.

Thi auth rizati n i pric t rk ting r tricti n n th c any tp gr atly r uc th p t ntial f r y uth xp ur t t bacc a v rti ing f r th pr uct . Th FDA will cl ly nit r h w th pr uct ar rk t a an will act a n c ary if th c any fpil t c ly wiph any applicabl tatut ry r r gulat ry r quir nt r if th r i a n tabl incr a in th nu r f n n- k r —inclu ing y uth—u ing th pr uct . ,

Th FDA y u p n r with raw a rk tiag grant r r i u un r th PMTA pathway f r a vari ty f r a n if th ag ncy t r n thi c ntinu rk tiag f a pr uct i n l ng r “appr priat f r th pr t cti n f th public h alth” uch a if th r i a n tabl incr a in y uth initiati n. ,

B f r king a rk tiag ci i n cu nt availabl t th public FDA t r uact tra cr t an c nfi ntial c rcial inf r ti n (CCI) an n ur cu nt p t t th FDA w b it ar acc ibl t v ry n . F r th r a n th full m cinia n u ry f r rk tiag auth rizati n y n tab p t t th Pr rk t Ti bacc Pr uct Mark ting Grant Or r w bpag (/t bacc -pr uct /pr rk t-ta bacc -pr uct-applicati n /pr rk t-ta bacc - pr uct- rk tiag-grant - r r) until aft r th r r i uanc at . In th int ri t pr vi a ch infi r ti n a p ibl at th ti f r r i uanc th FDA i aking r act v r i n f th r r l tt r an th “Ex cutiv Su ry” cti n af th ci i n u ry availabl at br a ly xplain th public h alth rati nal f r auth rizati n f th pr uct . ,

CERTIFICATE OF SERVICE

I hereby certify that on May 24, 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:

Debbie Feinstein
Robert J. Katerberg
Justin P. Hedge
Francesca M. Pisano
Adam Pergament
Tanya Freeman
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave, NW
Washington, DC 20001
Telephone: (202) 942-5000
debbie.feinstein@arnoldporter.com
robert.katerberg@arnoldporter.com
justin.hedge@arnoldporter.com
francesca.pisano@arnoldporter.com
adam.pergament@arnoldporter.com
tanya.freeman@arnoldporter.com

David I. Gelfand
Jeremy Calsyn
Matthew I. Bachrack
Linden Bernhardt
Jessica Hollis
Cleary Gottlieb Steen & Hamilton LLP
2112 Pennsylvania Avenue, NW
Washington, DC 20037
Telephone: (202) 974-1500
dgelfand@cgsh.com
jcalsyn@cgsh.com
mbachrack@cgsh.com
lbernhardt@cgsh.com
jhollis@cgsh.com

Counsel for Juul Labs, Inc.

Beth Wilkinson
James Rosenthal
Hayter Whitman
Megan Braun
Alysha Bohanon
Wilkinson Stekloff LLP
2001 M Street NW, 10th Floor
Washington, DC 20036
Telephone: (202) 847-4000

bwilkinson@wilkinsonstekloff.com
jrosenthal@wilkinsonstekloff.com
hwhitman@wilkinsonstekloff.com
mbraun@wilkinsonstekloff.com
abohanon@wilkinsonstekloff.com

Moira Penza
Ralia Polechronis
Meghan Cleary
Wilkinson Stekloff LLP
130 West 42nd Street, 24th
FloorNew York, NY 10036
Telephone: (212) 294-8910
mpenza@wilkinsonstekloff.com
rpolechronis@wilkinsonstekloff.com
mcleary@wilkinsonstekloff.com

Jonathan M. Moses
Kevin S. Schwartz
Adam L. Goodman
Wachtell, Lipton, Rosen & Katz
51 West 52nd Street
New York, NY 10019
Telephone: (212) 403-1000
JMMoses@wlrk.com
KSchwartz@wlrk.com
ALGoodman@wlrk.com

Counsel for Respondent Altria Group, Inc.

By: *s/ James Abell*
James Abell, Attorney

Counsel Supporting the Complaint