PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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

RESPONDENTS' MOTION FOR OFFICIAL NOTICE OF RECENT FDA DECISIONS

Respondents Altria Group, Inc. ("Altria") and Juul Labs, Inc. ("JLI") respectfully request that the Commission take official notice of the Food and Drug Administration ("FDA")'s (1) April 8, 2022 decision to deny Premarket Tobacco Application ("PMTA") authorization for several myBlu e-vapor products, and (2) April 26, 2022 decision to grant PMTA authorization for several NJOY Ace e-vapor products ("FDA Decisions"). Each decision is publicly available, and neither their accuracy nor existence can be reasonably disputed. *See* Order, No. 9393 (May 13, 2022) at 2 (finding "FDA Decision to be not subject to reasonable dispute").

To the extent the Commission intends to consider any FDA marketing order issued many years after the transaction at issue as bearing on the "PMTA approval prospects for Altria's . . . former products," *id.*, these recent FDA Decisions are material to the claims and defenses in this case and should also be considered. An important issue here is whether Altria's decision to withdraw its own products was based in part on the view of its scientists and regulatory personnel that those products would not obtain FDA authorization, rather than, as Complaint Counsel ("CC") contends, pretextual. The FDA Decisions provide further context about the

rigorous standard FDA applies in evaluating PMTAs, show that the judgment of Altria's scientists and regulatory personnel based on the information available at the time was well founded, and illustrate why, as the Court found, CC's argument that Altria's products would have obtained PMTA authorization rests on "unacceptable and unfair speculation," ID108.

CC previously requested notice of FDA's authorization of certain Logic e-vapor products, which Respondents opposed. The situation there was different because CC had denied Respondents the opportunity to develop a record about the Logic products, such that the Commission has no basis on which to assess the relevance of the FDA's action there. *See* Opposition to CC's Motion 1-2 ("Respondents ordinarily would not oppose notice of an official document from a government agency, such as FDA. But here, granting the Motion would prejudice Respondents, who were never afforded the opportunity to examine an executive of the parent company that owns Logic."). Both Respondents and CC had ample opportunity to and did in fact develop a record regarding the myBlu and NJOY Ace products that are the subject of the present motion. *Cf.* Order, No. 9393 (May 13, 2022) at 2 (acknowledging "Respondents' concerns about the scope of discovery taken of Logic").

The recent FDA Decisions are thus properly subject to notice under Commission Rules 3.43(f) (16 C.F.R. §3.43(f)) and 3.54(d) (16 C.F.R. §3.54(d)).

BACKGROUND

FDA's regulatory regime was at the heart of the trial in this matter. Congress expressly found that "[n]either the Federal Trade Commission nor any other Federal agency except [FDA] possesses the scientific expertise needed to" regulate tobacco products, Pub. L. No. 111-31, §2(45), 123 Stat. 1776, 1781 (2009), and thus granted FDA broad power to regulate tobacco products, including to issue regulations deeming additional categories of tobacco products subject to its authority, IDF189-192. Pursuant to that authority, FDA began regulating e-vapor in 2016, through what is known as the Deeming Rule. IDF194-98. As the Court found, the Deeming Rule, which became effective on August 8, 2016, "fundamentally changed the e-vapor

industry." IDF199. Among many other things, it meant that all e-vapor manufacturers would have to file a PMTA for on-market e-vapor products and ultimately receive FDA authorization to stay on the market. IDF196-99.

The PMTA process is "expensive" and "time-consuming," IDF215, requiring years, specific expertise, and tens of millions of dollars, IDF221-48. In addition, the standard is "rigorous," IDF220, as it requires that a manufacturer demonstrate that a tobacco product is "appropriate for the protection of the public health." IDF216. In deciding whether this standard is satisfied, FDA weighs: (1) "the risks and benefits to the population as a whole, including users and nonusers of tobacco products," (2) the "likelihood that existing users of tobacco will stop using such products," and (3) the "likelihood that those who do not use tobacco products will start using such products." IDF218. In other words, the manufacturer must show that the product reduces the constituents of harm that smokers are taking in when they're smoking (known as a "harmful and potentially harmful constituents" ("HPHCs")), reduces that risk relative to *other* tobacco products, including other e-vapor products, and converts smokers, balanced against risks to the non-tobacco-using population. IDF219.

"FDA has not provided clear guidance on the criteria or thresholds it [would] use when reviewing PMTAs to assess whether e-vapor products have adequate conversion potential to be considered appropriate for the protection of public health." IDF269. Over the course of 2017 and 2018, however, it repeatedly advised manufacturers that its goal was to facilitate "access" to products that provided "satisfying levels of nicotine" and could "move adult smokers down the ladder of harm" on which "tobacco products exist." IDF208-214; RX1921 (Sept. 11, 2018 Statement from FDA Commissioner) at 8. Manufacturers and their regulatory experts and scientists thus understood that "[d]emonstrating conversion capability" would be "a critical part of the evidence" for their PMTA applications. IDF262-70. FDA also made clear the risks posed by "flavors/designs that appeal to youth" in pod-based and non-tobacco or menthol flavored e-vapor products. IDF214, 273-77; RX1921 (Sept. 11, 2018 Statement from FDA Commissioner) at 1, 3-5.

Given the "kind of investment" necessary to meet FDA's requirements, e-vapor manufacturers tried to identify products that "have a good chance" of getting "approved." RX0091 Eldridge (ITG) Dep. 97:22-98:2. The consensus among Altria's scientists and regulatory experts was that its MarkTen cig-a-like product was unlikely to get FDA authorization because it could not be shown to reduce risks of exposure to formaldehyde relative to cigarettes or other e-vapor products, and it had little conversion potential. IDF541, 573, 593. The same consensus and conclusion was reached with respect to Altria's MarkTen Elite pod product, whose "primary benefit" centered on "good tasting flavors," and which, in addition to numerous other design defects, entirely lacked nicotine salts. IDF317, 380-85, 573.

In contrast, Imperial Tobacco Group ("ITG"), which markets the myBlu pod product through an e-vapor subsidiary, Fontem, believed that its product would survive the PMTA process, and, on the basis of that belief, made a "big investment" to prepare an application for myBlu. *Id.* at 93:5-14; 97:10-12. NJOY similarly prepared an application for its NJOY Ace pod product. RX0094 Farrell (NJOY) Dep. 90:3-11; IDF238. As NJOY's Chief Revenue Officer testified, NJOY had other products for which it could have submitted a PMTA application but decided against doing so. RX0094 Farrell (NJOY) Dep. at 102:7-14.

After nearly two years, on April 8, 2022, FDA denied the application for myBlu on the basis that it "did not demonstrate that the potential benefit to smokers who switch completely or significantly reduce their cigarette use would outweigh the risk to youth." Ex. A at 1-2. As of mid-to-late 2020, myBlu held a 3% market share. IDF1017. By virtue of FDA's decision, ITG will be required to stop selling these products. Ex. A at 2; *see also* IDF207.

Weeks later, on April 26, 2022, FDA authorized NJOY Ace on the basis that the "overall [HPHC] levels in the aerosol of the[] product[] is lower than in combusted cigarette smoke," that users "had lower levels of exposure to HPHCs compared to the dual users of the new products and combusted cigarettes," and that "the potential benefit to adult smokers who switch completely or significantly reduce their cigarette use[] would outweigh the risk to youth." Ex. C at 1-2. FDA only authorized the "Classic" and "Rich Tobacco" flavored NJOY Ace pods,

however. *Id.* at 1. It explained that it was still reviewing the application for NJOY Ace's "menthol-flavored" pods but outright denied the application for all other flavored Ace pods. *Id.*

ARGUMENT

The Commission may take official notice of any material fact, even after the evidentiary record is closed, 16 C.F.R. §§3.43(f), 3.54(a), provided that the fact is "not subject to reasonable dispute," *In re Polypore Int'l, Inc.*, 2010 WL 1249875, at *1 (F.T.C. Feb. 16, 2010); *see also* Order, No. 9393 (May 13, 2022) at 2 ("[O]fficial notice may be taken of references 'generally accepted as reliable.'" (citation omitted)). Applying these principles, the Commission routinely takes official notice of matters "contained in public records, such as judicial decisions, statutes, regulations, and records and reports of administrative bodies." *Id.* at *2 (internal quotation marks omitted); *see also In re Ethyl Corp.*, 101 F.T.C. 425, 1983 WL 486336, at *121 n.12 (Mar. 22, 1983) (noticing presidential economic report); *In re Beauty-Style Modernizers, Inc.*, 83 F.T.C. 1761, 1974 WL 175318, at *14 n.7 (June 11, 1974) (noticing Federal Reserve Board publication); *In re Avnet, Inc.*, 82 F.T.C. 391, 1973 WL 165042, at *46 n.31 (Feb. 16, 1973) (noticing U.S. Census Data). Like the records at issue in those instances, the "fact of the FDA Decision[s], as reported in FDA documents, is not subject to reasonable dispute," and thus suitable for official notice. *See* Order, No. 9393 (May 13, 2022) at 2.

To the extent the Commission intends to consider FDA marketing orders as bearing on the "PMTA approval prospects for Altria's . . . former products," *id.*, these recent FDA Decisions are material to the claims and defenses in this case and should also be considered. In concluding that CC had failed to prove that Altria withdrew its e-vapor products from the market because of an agreement with JLI, the Court relied, among other things, on contemporaneous documents and witness testimony showing Altria had determined that its own e-vapor products would not obtain FDA authorization. ID80-85. As the Court found, Altria believed that its own products had poor regulatory prospects because, among other reasons, the products emitted higher levels of formaldehyde than other e-vapor products and were unsuccessful at converting

adult smokers due to their lack of nicotine salts or, in the case of one cig-a-like product line, its lack of an effective nicotine salt formulation. IDF380-85, 442-43, 464, 572-73. The Court rejected CC's unsupported suggestion that Altria's products would have in fact overcome these issues and obtained FDA authorization, determining that any prediction that a product will survive the PMTA standard is "unacceptable and unfair speculation." ID108, IDF220.[1]

On appeal, CC argues that the Court erred in these factual findings and that Altria's products were in fact "well-positioned for PMTA approval." Opening Br. ("OB") 22. Indeed, CC even suggests that Altria's lack of a pod product with nicotine salts was actually a competitive advantage, contending that "a product without nicotine salts may be *more likely* to win PMTA approval." *Id*. The recent FDA Decisions further undermine these arguments, in three critical respects.

First, ITG testified that it was willing to devote substantial resources to its myBlu application because it believed its product had "a good chance" of getting "approved." RX0091 Eldridge (ITG) Dep. 97:22-98:2. Yet FDA nonetheless denied the applications, demonstrating that predicting that a product will obtain PMTA approval is an entirely speculative inquiry. ID108.

Second, FDA's authorization of NJOY Ace—a pod product with the same nicotine content and a similarly optimal nicotine salt formulation to JUUL's, *see* IDF1000-01, 1016; RFF1332-34—undercuts CC's suggestion that "a product without nicotine salts may be *more likely* to win PMTA approval," OB22, and further underscores the importance of conversion and of a product having "an optimal formulation of nicotine salts," IDF473.

[1] FDA recently advised in a court-ordered status report that it does not "expect" to finish reviewing "applications from manufacturers with the greatest market share" until over a year from now, on June 30, 2023, further underscoring the time and rigor of the process and that premising any predictions on FDA's approach to date remains speculative. *See* Status Report at 3, *American Academy of Pediatrics, et al.* v. *FDA*, No. 18-CV-883 (D. Md. May 13, 2022), Dkt. No. 205.

Third, the decisions altogether reinforce the reasonableness of the contemporaneous judgments of Altria's scientists and regulatory personnel that its own products would not obtain authorization. FDA predicated its authorization of NJOY Ace (1) had "lower levels of exposure to HPHCs compared to" other e-vapor products and to cigarettes and (2) could convert adult smokers to a degree that "would outweigh the risk to youth." Ex. C at 1-2. Moreover, FDA has required manufacturers to remove all flavored e-vapor products other than tobacco or menthol that have not yet obtained PMTA authorization, IDF289-90, and, to date, has not granted PMTA authorization to any such flavored e-vapor product, cig-a-like or pod, *e.g.*, IDF261, CC Notice Motion Ex. B at 1, 3; *infra* n.3. Per these recent FDA Decisions, the only pod-based product FDA has authorized thus far is one with tobacco flavors—"Tobacco" or "Rich Tobacco"—that contains a nicotine salt formulation proven to convert smokers to a degree that outweighs the risk pod-based products pose to youth, *supra.* This record is further proof that Altria's decision to not invest in a PMTA for its pod-based MarkTen Elite product, the "primary benefit" of which centered on "good tasting flavors,"[2] and the "[p]rimary drawbacks" of which included "lack of nicotine satisfaction," was prescient, not pretextual. IDF317.

Against this backdrop, CC's wishful assertion that Altria's products were "well-positioned" to survive FDA scrutiny, despite higher levels of exposure to HPHCs and little evidence of conversion, deserves no weight.[3] Such predictions are entirely speculative and in no

[2] MarkTen Elite had five cartridge offerings, four of which—"Strawberry Brulee, Apple Cider, Hazelnut Cream, and Glacier Mint"—are inarguably non-tobacco or menthol flavors, and the last of which, "Sweet Original," was described as having "a balanced tobacco blend with honeysuckle fruit flavors," and thus might also have been viewed as a non-tobacco flavor. RFF ¶1474. Furthermore, "Sweet Original" "constituted less than one-quarter of MarkTen Elite sales." *Id*.

[3] FDA also recently announced PMTA authorizations for RJ Reynolds' two nicotine salt-based cig-a-like products, Vuse Vibe and Vuse Ciro. FDA, *FDA Issues Marketing Decisions on Vuse Vibe Ciro E-Cigarette Products* (May 12, 2022), https://tinyurl.com/mpkfnamn. The products have even less market share than Vuse Solo, PX8008 Huckabee (RJ Reynolds) Decl. ¶19, which was authorized by FDA during post-trial briefing and which the Court addressed in its opinion as further evidencing the "lack of competitive significance of cig-a-likes," ID96. As with Vuse Solo, the authorization was based on the products demonstrating "lower levels of exposure to

way undermine the reasonableness of the judgments of Altria's scientists and other regulatory personnel at the time. The recent FDA Decisions thus satisfy the standard for materiality under Commission Rule 3.43(f), are noticeable, and should be considered by the Commission to the extent it intends to consider any recent FDA marketing orders.

CONCLUSION

For the foregoing reasons, Respondents respectfully request that the Commission grant their Motion for Official notice of the FDA Decisions.

Dated: May 16, 2022

Respectfully submitted,

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non-nicotine HPHCs compared" to other e-vapor products and "combusted cigarettes." FDA, *supra*.

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[PROPOSED] ORDER GRANTING RESPONDENTS' MOTION FOR OFFICIAL NOTICE OF RECENT FDA DECISIONS

Upon consideration of Respondents' Motion Requesting Official Notice of FDA Decisions, it is hereby ORDERED that the motion is GRANTED.

ORDERED By the Commission:

_____
April J. Tabor
Secretary

Dated:

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STATEMENT OF CONFERENCE
PURSUANT TO PARAGRAPH 4 OF SCHEDULING ORDER

In a conversation over the course of May 10-12, 2022, Respondents' counsel Jonathan Moses and Complaint Counsel Stephen Rodger and James Abell 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: May 16, 2022

By: *s/ Jonathan Moses*
Jonathan M. Moses

EXHIBIT A

PUBLIC

FDA Issues Marketing Denial Orders to Fontem US for myblu Products

On April 8, FDA issued marketing denial orders (MDOs) to Fontem US, LLC for several myblu electronic nicotine delivery system (ENDS) products after determining their applications lacked sufficient evidence to show that permitting the marketing of these products would be appropriate for the protection of the public health. The currently marketed products receiving MDOs include:

- myblu Device Kit
- myblu Intense Tobacco Chill 2.5%
- myblu Intense Tobacco Chill 4.0%
- myblu Intense Tobacco 2.4%
- myblu Intense Tobacco 3.6%
- myblu Gold Leaf 1.2%
- myblu Gold Leaf 2.4%

Generally, the submission of a premarket application and intent to commercially market a new tobacco product that has never been marketed would be considered confidential commercial information (CCI) that the FDA would not disclose. However, FDA determined that these products are currently marketed based on communication with the applicant during the development of the publicly available Deemed New Tobacco Product Application List (/tobacco-products/market-and-distribute-tobacco-product/deemed-new-tobacco-product-applications-lists), and therefore the applicant has acknowledged the submission of these premarket applications. Please note that FDA has not independently verified the information provided by applicants about the marketing status of their products.

FDA is issuing MDOs for additional myblu products that do not appear on the publicly available list. FDA has publicly named only products that the FDA or the manufacturer have confirmed to be currently marketed to avoid potential CCI issues. Therefore, FDA recommends contacting the company with questions about their products that may have received MDOs but are not listed above.

In reviewing premarket applications for tobacco products, FDA evaluates the risks and benefits of those tobacco products to the population as a whole, including users and nonusers of the tobacco product, and takes into account, among other things, the likelihood that those who do not currently use tobacco products will start using those tobacco products. Based on the

information provided in the applications submitted by Fontem US, LLC for these myblu products and the available evidence, the applications lacked sufficient evidence regarding design features, manufacturing, and stability. Additionally, the applications did not demonstrate that the potential benefit to smokers who switch completely or significantly reduce their cigarette use would outweigh the risk to youth.

Tobacco products subject to a negative action regarding a premarket submission, including those subject to an MDO, may not be offered for sale, distributed or marketed in the US. Such products may not be introduced or delivered for introduction into interstate commerce, and if the product is already on the market, the product must be removed from the market. Currently, FDA's highest enforcement priorities are ENDS products for which no application is pending, including, for example, those with an MDO or those for which no application was submitted.

Today's actions move FDA one step closer toward ensuring all deemed new tobacco products have undergone science-based review and received marketing authorization by FDA before they can be legally marketed. FDA has completed the review of and made determinations on more than 99 percent of the nearly 6.7 million products for which applications were submitted by the Sept. 9, 2020 deadline. More information about FDA's tobacco product authorizations and marketing denial orders can be found on FDA's website (/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders).

EXHIBIT B

U.S. FOOD & DRUG ADMINISTRATION

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

PUBLIC

MARKETING GRANTED ORDERS

NJOY LLC
Attention: David Graham, Chief Impact Officer and Executive Vice President of Regulatory Affairs
635 15th Street, Suite 100
Baraboo, WI 53913

FDA Submission Tracking Numbers (STNs): PM0000613.PD1 – PM0000615.PD1 and PM0000622.PD1**,** see Appendix A

Dear David Graham:

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 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.

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

[2] In your PMTAs, 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 for (b) (4) (PM0000622.PD1) and (b) (4) (PM0000614.PD1 and PM0000615.PD1). FDA determined this timeframe is acceptable and there are no other stability concerns. 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 postmarket 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 be issued consistent with the requirements of section 910(c) of the FD&C Act. We support certain aspects of your marketing plan, 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, restrict youth access to your products, and limit youth exposure to your labeling, advertising, marketing, and promotion:

- Not utilizing the following marketing practices:
  - Broadcast or digital radio advertising,
  - Television advertising,
  - Outdoor advertising,
  - Print advertising,
  - Direct mail advertising,
  - Search engine advertising,
  - Online display advertising,
  - Paid or unpaid product placements,
  - Public relations or earned media,
  - In-person engagements or activations,
  - Social media promotion,
  - Partners, sponsors, influencers, bloggers, or brand ambassadors,
  - Referral or affiliate programs, or
  - Product sampling;
- Prohibiting the use of cartoon images or characters, fruit or food-related images, or imagery of any kind that is intended, designed, or otherwise likely to appeal to minors;
- Limiting human portrayals to only depictions of models who are or appear to be over age 45;
- Limiting the use of NJOY-owned social media properties to the sole purpose of receiving inbound customer service communications and utilizing all available platform-native age-gating functionality to restrict access to adults;
- Maintaining Distributor and Retailer Policies that govern the selection and oversight of tobacco retailers that carry NJOY ACE products;
- Prohibiting the sale of NJOY ACE products on third-party websites;
- Limiting the number of products that can be purchased in a given time period or transaction;
- Using competent and reliable third-party sources to verify the age and identity of users against public records before granting access the product website or conducting online sales;
- Requiring retailers to only place NJOY ACE products in non-self-service areas of the store; and
- Conducting quarterly audits of point-of-sale signage located in retail chains that carry NJOY to determine whether only NJOY-approved trade marketing materials are being utilized.

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 point-of-sale advertising (e.g., requiring advertising to be placed inside the store, placing displays near other age-restricted products and away from 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.

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, and 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.

[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 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.

If you have any questions, please contact Kristopher VanAmburg, Regulatory Health Project Manager, at (301) 348-3032 or Kristopher.VanAmburg@fda.hhs.gov.

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

Sincerely,

/S/

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

Enclosures (if provided electronically, the Appendix is not included in physical mail):

Appendix A – New Tobacco Products Subject to This Letter
Appendix B – Required Postmarket Recordkeeping and Retention
Appendix C – Postmarket Reporting
Appendix D – Marketing Requirements

[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

Appendix A
New Tobacco Products Subject to This Letter

Common Attributes of PMTAs	
Submission date	March 10, 2020
Receipt date	March 10, 2020
Applicant	NJOY LLC
Product manufacturer	NJOY LLC
Product category	ENDS (Electronic Nicotine Delivery System)
Attributes	**New Tobacco Product**
STN	**PM0000613**
Static Product ID	PD1
Product name	NJOY ACE Device[8]
Product subcategory	Closed E-Cigarette
Package type	Box
Package quantity	1 E-Cigarette
Characterizing flavor	None
Length	74.12 mm
Diameter	29.8 mm
Wattage	6.5 W
Battery Capacity	400 mAh
E-liquid volume	Not applicable
Nicotine concentration	Not applicable
PG/VG Ratio	Not applicable
Additional Properties	Thickness: 13.5 mm Universal Serial Bus (USB)
STN	**PM0000614**
Static Product ID	PD1
Product name	NJOY ACE POD Classic Tobacco 2.4%[8]
Product subcategory	Closed E-Liquid
Package type	Cartridge
Package quantity	2 Cartridge
Characterizing flavor	Tobacco
E-Liquid Volume	1.9 mL
Nicotine Concentration	2.4% w/w
PG/VG Ratio	0.83[9]
Additional Properties	Length: 34.75 mm Thickness: 11.57 mm Width: 29.59 mm

[8] Brand/sub-brand or other commercial name used in commercial distribution.
[9] Applicant provided value. Additionally, applicant provided PG and VG values as percentages of ingredient formula for each product.

Attributes	New Tobacco Product
STN	**PM0000615**
Static Product ID	PD1
Product name	NJOY ACE POD Classic Tobacco 5%[8]
Product subcategory	Closed E-Liquid
Package type	Cartridge
Package quantity	2 Cartridge
Characterizing flavor	Tobacco
E-Liquid Volume:	1.9 mL
Nicotine Concentration:	5% w/w
PG/VG Ratio:	0.75[9]
Additional Properties	Length: 34.75 mm Thickness: 11.57 mm Width: 29.59 mm
STN	**PM0000622**
Static Product ID	PD1
Product name	NJOY ACE POD Rich Tobacco 5%[8]
Product subcategory	Closed E-Liquid
Package type	Cartridge
Package quantity	2 Cartridge
Characterizing flavor	Tobacco
E-Liquid Volume:	1.9 mL
Nicotine Concentration:	5% w/w
PG/VG Ratio:	0.77[9]
Additional Properties	Length: 34.75 mm Thickness: 11.57 mm Width: 29.59 mm

Appendix B

Required 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 issued 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
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)	4 years from the date of distribution of each batch of each product subject to this order

	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	
Sales and/or distribution records	A list of distributors and retailers of the products, including brick-and-mortar and digital[10] (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 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;	4 years from the date of initial dissemination to the public or implementation

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

	• 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 of such data; • With respect to individuals under the federal minimum age of sale of tobacco products, actions taken to restrict access to the product 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 directions - 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 • 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
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, this order requires that you submit the following periodic reports to FDA on an annual basis, beginning twelve months from the date of these orders 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 PM0000613.PD1 - PM0000615.PD1 and PM0000622.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 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 PM0000613.PD1 – PM0000615.PD1 and PM0000622.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 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, 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 PM0000613.PD1 – PM0000615.PD1 and PM0000622.PD1**. The cover letter should include the STN(s), static product ID if applicable, 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/or 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.

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 a list of all data sources used to target advertising and marketing plans and media buys;
c. With respect to individuals below the minimum purchasing age, 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 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 ran 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 C

PUBLIC

FDA Issues Marketing Decisions on NJOY Ace E-Cigarette Products

On April 26, the FDA issued decisions on multiple NJOY Ace e-cigarette products, including the authorization of four new tobacco products through the Premarket Tobacco Product Application (PMTA) pathway. The FDA issued marketing granted orders (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders) to NJOY LLC for its Ace closed e-cigarette device and three accompanying tobacco-flavored e-liquid pods, specifically:

- NJOY Ace Device
- NJOY Ace Pod Classic Tobacco 2.4%
- NJOY Ace Pod Classic Tobacco 5%
- NJOY Ace Pod Rich Tobacco 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 NJOY for multiple other Ace e-cigarette products. Any of those products currently on the market must be removed or FDA may take enforcement action. Retailers should contact NJOY with any questions about products in their inventory. Applications for two menthol-flavored Ace e-liquid pods remain under FDA review.

Under the PMTA pathway, 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 NJOY 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 applicant demonstrated that participants who had used only the authorized NJOY Ace products had lower levels of exposure to HPHCs compared to the dual users of the new products and combusted cigarettes. Therefore, these products have the potential to benefit adult smokers who switch completely or significantly reduce their cigarette consumption.

Additionally, the FDA considered the risks and benefits to the population as a whole, including users and non-users of tobacco products, and importantly, youth. This included review of available data on the likelihood of use of the product by young people. For the authorized products, the FDA determined 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.

Additionally, this 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 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.

The FDA may suspend or withdraw a marketing granted order issued under the PMTA pathway for a variety of reasons 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.

Before making marketing decision documents available to the public, FDA must redact trade secret and confidential commercial information (CCI) and ensure documents posted to the FDA website are accessible to everyone. For these reasons, the full decision summary for marketing authorizations may not be posted to the Premarket Tobacco Product Marketing Granted Orders webpage (/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders) until after the order issuance date. In the interim, to provide as much information as possible at the time of order issuance, the FDA is making redacted versions of the order letter and the "Executive Summary" section of the decision summary available to broadly explain the public health rationale for authorization of these products.

CERTIFICATE OF SERVICE

I hereby certify that on May 16, 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:

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Washington, DC 20580
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The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
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I also certify that I caused the foregoing document to be served via email to:

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