APPENDIX

APPENDIX

TABLE OF CONTENTS

Appendix A Opinion in the United States Court of Appeals for the Ninth Circuit (July 7, 2023). . . . . App. 1

Appendix B Order Denying Petition for Panel Rehearing in the United States Court of Appeals for the Ninth Circuit (September 14, 2023) . . . . . App. 47

Appendix C Mandate in the United States Court of Appeals for the Ninth Circuit (September 22, 2023) . . . . . App. 48

Appendix D Marketing Denial Order in the U.S. Food & Drug Administration with Fold-Out Exhibit (September 17, 2021) . . . . . App. 49

Appendix E Technical Project Lead (TPL) Review of PMTAs in the U.S. Food & Drug Administration with Fold-Out Exhibit (September 17, 2021) . . . . . App. 57

Appendix F Relevant Statutory Provisions . App. 103
5 U.S.C. § 706(2) . . . . . App. 103
21 U.S.C. § 387j. . . . . App. 103
21 U.S.C. § 387*l*(b) . . . . . App. 105

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

[Filed July 7, 2023]

No. 21-71328

LOTUS VAPING TECHNOLOGIES, LLC,
Petitioner,

v.

U.S. FOOD & DRUG ADMINISTRATION,
Respondent.

No. 21-71321

NUDE NICOTINE INC.,
Petitioner,

v.

U.S. FOOD & DRUG ADMINISTRATION,
Respondent.

App. 2

OPINION

On Petition for Review of an Order of the
Food & Drug Administration

Argued and Submitted August 11, 2022
San Francisco, California

Filed July 7, 2023

Before: Johnnie B. Rawlinson, Bridget S. Bade, and Daniel A. Bress, Circuit Judges.

Opinion by Judge Bade

SUMMARY[*]

Food and Drug Administration

The panel denied petitions for review challenging the denial of Petitioners' premarket tobacco product applications seeking Food and Drug Administration ("FDA") authorization to sell nicotine-containing e-liquids in the United States.

The FDA issued marketing denial orders for Petitioners' flavored products, finding that Petitioners' applications lacked sufficient evidence showing that their flavored products would provide a benefit to adult users that outweighs the risks such products pose to youth.

The panel held that the text of the Family Smoking Prevention and Tobacco Control Act (the "Tobacco

[*] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

Control Act") plainly authorizes the FDA to require that manufacturers submit comparative health risk data, which necessarily includes comparisons of flavored e-liquids to tobacco-flavored e-liquids. The panel also held that the FDA did not arbitrarily or capriciously deny Petitioners' applications, and that any error the agency committed by failing to consider Petitioners' marketing plans was harmless.

First, Petitioners contended that the FDA exceeded its statutory authority by requiring comparative efficacy studies to demonstrate that their flavored products—electronic nicotine delivery systems ("ENDS")—better promote smoking cessation than comparable tobacco-flavored products. The panel joined the Second, Third, Fourth, Seventh, and D.C. Circuits in holding that the FDA had statutory authority to regulate as it did. The Tobacco Control Act expressly authorized the FDA's consideration of comparative evidence.

Second, Petitioners argued that that the FDA acted arbitrarily and capriciously by denying their applications to market flavored e-liquids. The panel rejected Petitioner's first argument that the FDA unfairly surprised them by demanding that they compare their flavored e-liquids to *tobacco*-flavored ones. Considering the Tobacco Control Act's purpose and the FDA's concern regarding the substantial increase in youth initiation prompted by *flavored* ENDS products, Petitioners cannot plausibly contend that the agency led them to believe a flavor-to-flavor comparison would meet the Act's requirements. The panel also rejected Petitioner's second argument—that

the FDA purportedly stated that it would accept single-point-in-time studies, like consumer surveys, but ultimately required studies that followed consumers over long time periods. The panel held that the FDA did not introduce a new evidentiary standard; rather, it consistently required evidence that evaluated the impacts of flavored versus non-flavored products on initiation and cessation. The FDA acted in conformity with its previous guidance and reasonably rejected Petitioners' applications because their other proffered evidence was not sufficiently reliable and robust. The panel held the agency did not act arbitrarily or capriciously by concluding that Petitioners' evidence fell short.

The panel next turned to Petitioners' contentions that the FDA's failure to consider their marketing and sales-access-restrictions plans was arbitrary and capricious. The panel assumed, without deciding, that the FDA erred in ignoring Petitioners' marketing plans, but concluded that any error was harmless. The Tobacco Control Act incorporates the Administrative Procedures Act's harmless error rule. Petitioners do not identify how their marketing measures were materially different from those the FDA had already said are insufficient. At the time the FDA reviewed Petitioners' applications, it had already concluded that eliminating marketing aimed at youth users and monitoring retailers' sales were ineffective in preventing youth use because children maintained a steady stream of access to the flavored products they desired through alternate means, like their friends and social networks. Accordingly, the panel concluded that, even if the agency erred by failing to consider Petitioners'

marketing plans, any error was harmless, and it would not remand on this basis.

Finally, the panel addressed Petitioners' post-argument motions to supplement the administrative record and file supplemental briefing, and seeking judicial notice of a premarket tobacco product application deficiency letter, FDA internal memoranda, and FDA press releases. The panel denied the motions to supplement the administrative record and file supplemental briefing and granted the motions for judicial notice.

COUNSEL

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OPINION

BADE, Circuit Judge:

Congress has authorized the United States Food and Drug Administration ("FDA") to regulate the manufacture, marketing, and distribution of tobacco products. 21 U.S.C. § 387a. Exercising that authority, the FDA promulgated a final rule in 2016 that subjects e-cigarettes and their component e-liquids to the requirements outlined in the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or the "Act"). *Id.* §§ 387–387t. The Act requires manufacturers to apply for authorization to sell new tobacco products, which the FDA permits only if the marketing of such products would be "appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A).

Petitioners Lotus Vaping Technologies, LLC, and Nude Nicotine Inc. each submitted premarket tobacco product applications seeking FDA authorization to sell nicotine-containing e-liquids in the United States. The FDA issued marketing denial orders for Petitioners' flavored products, finding that Petitioners' applications lacked sufficient evidence showing that their flavored products would provide a benefit to adult users that

outweighs the risks such products pose to youth. Petitioners seek review of these denial orders.[1]

We are asked to decide whether the FDA has statutory authority to require manufacturers to demonstrate that their flavored electronic nicotine delivery systems ("ENDS") better promote smoking cessation than comparable tobacco-flavored products, and whether the agency arbitrarily or capriciously denied Petitioners' applications. We hold that the text of the Tobacco Control Act plainly authorizes the FDA to require that manufacturers submit comparative health risk data, which necessarily includes comparisons of flavored e-liquids to tobacco-flavored e-liquids. We also hold that the FDA did not arbitrarily or capriciously deny Petitioners' applications and that any error the agency committed by failing to consider Petitioners' marketing plans is harmless. In so holding, we join the majority of our sister circuits that have addressed the merits of the same issues in materially identical cases. *See Magellan Tech., Inc. v. FDA*, No. 21-2426, 2023 WL 4035722 (2d Cir. June 16, 2023); *Liquid Labs LLC v. FDA*, 52 F.4th 533 (3d Cir. 2022); *Avail Vapor, LLC v. FDA*, 55 F.4th 409 (4th Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022); *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022). We deny the petitions for review.

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[1] We consolidated these cases for oral argument, and we keep them consolidated for disposition.

I

A

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301–399i, as amended by the Tobacco Control Act, *id.* §§ 387–387t, authorizes the Secretary of Health and Human Services to regulate the manufacture, marketing, and distribution of "tobacco products" through the FDA. *Id.* § 387a(a), (e). Congress's stated purpose in enacting the Tobacco Control Act was to, among other things, "ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco" and "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases." Tobacco Regulation, Federal Retirement Reform, Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781–82 (2009); *see also Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 444 (5th Cir. 2020) ("Obviously, the [Tobacco Control Act's] purpose sounds in (1) protecting public health and (2) preventing young people from accessing (and becoming addicted to) tobacco products."). Congress immediately subjected "cigarettes, cigarette tobacco, roll-your-own tobacco," "smokeless tobacco," and "any tobacco product containing nicotine that is not made or derived from tobacco" to the FDA's tobacco-product authorities. 21 U.S.C. § 387a(b). But Congress delegated to the Secretary the power to determine whether "any other tobacco products" should be covered by the Act. *Id.* § 387a(b); *see id.* § 321(d).

Exercising this authority, the FDA promulgated a final rule in 2016 that extended the Tobacco Control Act to all products meeting the FDCA's definition of "tobacco product" under 21 U.S.C. § 321(rr)(1).[2] *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,973-01 (May 10, 2016) ("Deeming Rule"). The parties agree that ENDS generally, and Petitioners' products specifically, satisfy that statutory definition. *Id.* at 28,975–76.

Thus, under the Deeming Rule, Petitioners must comply with the Tobacco Control Act. This includes § 387j, which requires that manufacturers obtain FDA authorization to market "new tobacco product[s]" in interstate commerce. 21 U.S.C. § 387j(a)(1)–(2). Premarket authorization can be obtained in three ways. Only one is relevant here: A manufacturer may submit a premarket tobacco product application ("PMTA") showing that the "product to be marketed would be appropriate for the protection of the public health." *Id.* § 387j(a)(2)(A), (c)(2)(A).

"The PMTA process is onerous, requiring manufacturers to gather significant amounts of information." *Big Time Vapes*, 963 F.3d at 439. Congress requires that applications include "full reports . . . concerning investigations which have been

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[2] Under that definition, a "tobacco product" is "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr)(1).

made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products," a full statement of the ingredients, and a full description of the manufacturing process, among other information. *See* 21 U.S.C. § 387j(b)(1).

When evaluating an application, the FDA must examine "the risks and benefits to the population as a whole, including [to] users and nonusers of the tobacco product." *Id.* § 387j(c)(4). This includes "the increased or decreased likelihood that existing users of tobacco products will stop using such products," and "the increased or decreased likelihood that those who do not use tobacco products will start using such products." *Id.* The Tobacco Control Act instructs that the FDA "shall deny" an application "if, upon the basis of the information submitted . . . and any other information before [the FDA]," the application does not show that the marketing of the product "would be appropriate for the protection of the public health."[3] *Id.* § 387j(c)(2)(A). Otherwise, and if all other statutory requirements are

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[3] In addition, the FDA must deny an application if: (1) "the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of [the Tobacco Control Act]"; (2) "based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular"; or (3) "such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of [the Tobacco Control Act], and there is a lack of adequate information to justify the deviation from such standard." 21 U.S.C. § 387j(c)(2)(B)–(D).

met, the FDA must issue a marketing granted order. *Id.* § 387j(c)(1)(A).

When the Deeming Rule was promulgated, ENDS products were widely available in the United States. *See* Deeming Rule, 81 Fed. Reg. at 28,982. The FDA recognized that manufacturers of these products would need time to gather data and prepare the documents needed to receive market authorization.[4] *Id.* at 29,010–11. Thus, the FDA announced staggered compliance deadlines for newly deemed products that were marketed in the United States as of August 8, 2016. *Id.* at 28,974, 29,011.

The Deeming Rule originally set the PMTA submission deadline for August 8, 2018. *Id.* The FDA later extended the deadline to August 8, 2022. FDA, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry 5 (2020) ("2020 Guidance"). But, after a successful challenge by the American Academy of Pediatrics and other interested entities, a district court accelerated the deadline to May 11, 2020, *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 480–81, 487 (D. Md. 2019), and then adjusted it to September 9, 2020 in response to the COVID-19 pandemic, *see* Order, *Am. Acad. of Pediatrics v. FDA*, No. 8:18-CV-883, Dkt. 182 (D. Md. Apr. 22, 2020); *id.*, Dkt. 201 at 1 (D. Md. April 15, 2022).

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[4] Tobacco products that were on the market on or before February 15, 2007 were "grandfathered" and did "not require premarket authorization." Deeming Rule, 81 Fed. Reg. at 29,009.

The FDA also implemented a twelve-month grace period after the PMTA submission deadline to afford the agency time to review the applications and issue appropriate orders. Deeming Rule, 81 Fed. Reg. at 28,978. The agency did not "intend to initiate enforcement action for failure to have premarket authorization" until after the entire compliance period expired on September 9, 2021. *Id.* at 29,011; Center for Tobacco Products, Deemed Product Review: A Conversation with the Office of Science 4 (June 11, 2021).

B

In advance of the submission deadline, the FDA issued nonbinding guidance and a proposed rule to assist ENDS-product manufacturers with their applications.

1

In June 2019, the FDA issued guidance outlining its then-current "thinking on the types of information an applicant should include in a PMTA to help show that permitting the new tobacco product to be marketed would be [appropriate for the protection of the public health]." FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry 46 (2019) ("2019 Guidance"). That information included "well-controlled investigations"—i.e., investigations that "are designed and conducted in such a way that minimizes or controls for bias, confounding variables, and other factors that may render the results unreliable"—or "other 'valid

scientific evidence' if found sufficient to evaluate the tobacco product." *Id.* at 12 & n.21.

For example, the FDA "intend[ed] to review" "information on other products (e.g., published literature, marketing information)" if applicants provided "appropriate bridging studies." *Id.* at 12.[5] But the FDA cautioned that published literature reviews "are considered a less robust form" of evidence, *id.* at 47, and that "[n]onclinical studies alone are generally not sufficient to support" marketing authorization, *id.* at 12 & n.22, 46. Nonetheless, given the relative newness of the products, the FDA did "not expect that applicants [would] need to conduct long-term studies to support an application."[6] *Id.* at 13.

The 2019 Guidance also encouraged applicants to submit "data that adequately characterizes the potential impact of the new tobacco product on the

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[5] The FDA further explained: "For clinical assessments, instead of conducting clinical studies that span months or years to evaluate potential clinical impact, applicants could demonstrate possible long-term health impact by including existing longer duration studies in the public literature with the appropriate bridging information (i.e., why the data used are applicable to the new tobacco product) and extrapolating from short-term studies." 2019 Guidance at 13; *see also id.* at 50.

[6] The 2019 Guidance mirrored the assertions made by the FDA at a public meeting in October 2018. *See* Center for Tobacco Products, Premarket Tobacco Product Application Content Overview 26 (Oct. 23, 2018) (stating that "[n]o specific studies are required for a PMTA" and that "it may be possible to support a marketing order for an ENDS product without conducting new nonclinical or clinical studies").

health of both users and nonusers." *Id.* at 37. To that end, the FDA advised that applicants include "[e]valuations of the likelihood of initiation among never-users and former users of tobacco products and cessation among current tobacco users." *Id.* at 38. Those behaviors could be addressed in "randomized clinical trials," but the FDA "believe[d] this would also be true of observational studies (perception, actual use, or both) examining cessation behaviors." *Id.*

Relatedly, the 2019 Guidance conveyed the FDA's recommendation that applicants compare their products to other tobacco products to demonstrate the risks and benefits of marketing. *Id.* at 13–14, 23–24. The FDA explained that, as part of its determination under § 387j(c)(4), it would "review[] the health risks associated with changes in tobacco product use behavior (e.g., initiation, switching, dual use, cessation) that are likely to occur with the marketing of the new tobacco product." *Id.* at 13. Thus, the FDA urged applicants to "compare the health risks of [their] product[s] to both products within the same category and subcategory, as well as products in different categories as appropriate." *Id.*

For e-liquids, the FDA recommended that "the product's health risks be compared to those health risks presented by other e-liquids used in a similar manner" and that manufacturers "include those characteristics (materials, ingredients, design, composition, heating source, or other features) that contribute to the new product presenting the same, less, or different health risks than other tobacco products of similar category and subcategory." *Id.* at

14. "This comparative health risk data," the FDA advised, would be "an important part of the evaluation of the health effects of product switching." *Id.* at 13.

2

In September 2019, the FDA issued a proposed rule to help "ensure that PMTAs contain sufficient information for [the] FDA to determine whether a marketing order should be issued." Premarket Tobacco Product Applications and Recordkeeping Requirements, 84 Fed. Reg. 50,566-01, 50,566 (Sept. 25, 2019) ("Proposed Rule"). The focus of the Proposed Rule's "content requirements [was] the threshold amount of information necessary for application filing" because the FDA was "still gaining experience in applying the authorization standard to PMTAs" and it believed that applicants had "some flexibility in the types of scientific information they [could] submit." *Id.* at 50,567.

The threshold information included a marketing plan "concerning at least the first year of marketing after an applicant receives a marketing order." *Id.* at 50,580. The Proposed Rule advised that marketing plans would aid the agency in assessing "whether permitting the marketing of the new tobacco product would be [appropriate for the protection of the public health] because they . . . provide input that is critical to [the] FDA's determination of the likelihood of changes in tobacco product use behavior, especially when considered in conjunction with other information contained in the application." *Id.* at 50,581.

Like the 2019 Guidance, the Proposed Rule did "not set requirements for specific studies that must be contained in every single PMTA." *Id.* at 50,599. The FDA similarly recognized that "long-term data is not available for all categories of products," and thus, it did "not expect that long-term clinical studies . . . [would] need to be conducted for each PMTA." *Id.* at 50,619. The Proposed Rule reinforced, however, that the FDA would rely "upon only valid scientific evidence to determine whether the marketing of the new tobacco product would be [appropriate for the protection of the public health]." *Id.*

In addition, the Proposed Rule reiterated the FDA's "recommend[ation]" that an "applicant compare the health risks of its product to both products within the same category and subcategory, as well as products in different categories as appropriate." *Id.* at 50,600. And, echoing the 2019 Guidance, the Proposed Rule underscored that "comparative health risk data is an important part of the evaluation." *Id.*

3

In April 2020, the FDA issued guidance conveying its enforcement priorities for ENDS products. 2020 Guidance at 9. Relevant here, the FDA announced that it would prioritize enforcement against "flavored, cartridge-based ENDS products" to counteract "an alarming increase in the use of ENDS products by middle and high school students" driven by the "extraordinary popularity" of flavored products with minors and their "overwhelming[] prefer[ence]" for cartridge-based devices. *Id.* at 3, 6, 13, 15, 19–22.

Notably, the 2020 Guidance also compiled a list of measures that manufacturers had proposed as safeguards to limit youth access to ENDS products for both brick and mortar and online stores. *Id.* at 7. The safeguards included (1) age-verification requirements and technology; (2) contractual penalties for retailers that sold tobacco products to minors; and (3) restrictions on the quantity of ENDS products that consumers could purchase. *Id.* But the FDA reported that youth e-cigarette use continued to increase, *id.* at 8–9, and that youth continued to have access to such products even when those safeguards were in place, *id.* at 8–9, 21. Thus, the FDA concluded "that focusing on how the product was sold would not appropriately address youth use of . . . flavored, cartridge-based products," *id.* at 21, and it advised the industry that "age verification alone" would not adequately address youth use of tobacco products "given the many sources of products available for youth access," *id.* at 44.

C

Lotus Vaping Technologies, LLC is an Idaho-based manufacturer of tobacco products. Lotus's nicotine-containing e-liquids are designed to be used in open-system devices[7] and come in a variety of flavors.

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[7] E-cigarettes come in "open" and "closed" forms. Premarket Tobacco Product Applications & Recordkeeping Requirements, 86 Fed. Reg. 55,300-01, 55,317 (Oct. 5, 2021). An open device "includes a reservoir that a user can refill with an e-liquid of their choosing." *Id.* A closed device, by contrast, "includes an e-liquid reservoir that is not refillable . . . or that uses e-liquid contained in replaceable cartridges or pods that are not intended to be refillable." *Id.*

Although such flavors include tobacco and menthol, Lotus's other flavored products[8]—e.g., "apple," "cinnamon candy," "juicy fruit," and "rootbeer"—are the ones at issue here.

Nude Nicotine Inc. is a California-based manufacturer of nicotine-containing e-liquids. Like Lotus's products, Nude Nicotine's e-liquids are also designed to be used in open-system devices. But unlike Lotus's products, Nude Nicotine's e-liquids are not sold with added flavors. Nevertheless, Nude Nicotine's products constitute "flavored products" because they are designed to be suitable for flavor addition.

1

In September 2020, Lotus and Nude Nicotine submitted applications seeking marketing authorization for their flavored products. Lotus supported its application with a scientific literature review, a customer survey, and a coalition survey of thousands of participants. Nude Nicotine submitted product testing, an e-liquid stability study, and scientific literature.

Each Petitioner also submitted a marketing plan to describe the steps it would take to minimize unauthorized use of their products. Both Petitioners proposed age verification for sales of their products and

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[8] We use the term "flavored products" to refer to products other than tobacco- or menthol-flavored products, which includes nonflavored products that are designed to have flavor added to them. Our definition is consistent with the nomenclature used by the FDA.

age gating to restrict youth access to advertisements on outlets such as social media. Lotus also proposed individual purchase limits for online sales and maintained that product demonstrations or sampling would occur only at age-gated industry trade shows. Nude Nicotine outlined a program that would purportedly bind its retailers to comply with age gating requirements, certain marketing procedures, and other post-market monitoring practices. Petitioners also emphasized their commitment to post-market surveillance to ensure appropriate marketing of their products.

2

In July 2021, a few months before the FDA issued decisions on Petitioners' applications, the FDA circulated an internal memorandum that announced "a new plan to effectively manage" a subset of applications for flavored ENDS products and to "take final action on as many applications as possible by September 10, 2021."[9] Under this new plan, the agency would conduct

[9] The FDA initially believed that it would receive applications for a few thousand ENDS products. *See* FDA, Final Regulatory Impact Analysis Final Regulatory Flexibility Analysis Unfunded Mandate Reform Act Analysis 48 (May 2016). The agency ultimately received applications for more than 6.5 million newly deemed tobacco products, and the majority of those applications were for ENDS. *See* News Release, FDA, FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health (Aug. 26, 2021); Center for Tobacco Products, Deemed Product Review: A Conversation with the Office of Science 17 (June 11, 2021); Statement, FDA, FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action

a "simple" fatal flaw review to identify whether the application contained "either a randomized controlled trial (RCT) or a longitudinal cohort study." If those studies were lacking, the application would "likely receive a marketing denial order."

One month later, the FDA circulated another internal memorandum that explained that the agency would broaden its inquiry to consider evidence from other types of studies if such studies "reliably and robustly assess behavior change." The memorandum cautioned that cross-sectional surveys, consumer perception studies, and general scientific literature would "not likely be sufficiently robust or direct in providing evidence as to the impact of the new ENDS on adult switching or cigarette reduction." The memorandum also advised that the FDA would not evaluate marketing plans "for the sake of efficiency." The FDA rescinded this memorandum within days of its circulation.

In late August 2021, the FDA announced that it had issued the first marketing denial orders for ENDS products "after determining the applications for about 55,000 flavored ENDS products . . . lacked sufficient evidence that they have a benefit to adult smokers sufficient to overcome the public health threat posed by the well-documented, alarming levels of youth use of such products." News Release, FDA, FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence

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on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted (Sept. 9, 2021).

They Appropriately Protect Public Health (Aug. 26, 2021). Within a matter of weeks, then-Acting Commissioner of the FDA, Janet Woodcock, issued a statement conveying that the agency had acted on applications for over 6 million ENDS products. Statement, FDA, FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted (Sept. 9, 2021). This action included the issuance of marketing denial orders "for more than 946,000 flavored ENDS products." *Id.*

3

In September 2021, the FDA issued marketing denial orders to Lotus and Nude Nicotine for their flavored e-liquids. The "key basis" for both orders was that Petitioners' applications did not include "a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of [Petitioners'] flavored ENDS products over an appropriate comparator[:] tobacco-flavored ENDS," *and* that the applications otherwise lacked "reliabl[e] and robust[]" forms of "other evidence . . . evaluat[ing] the impact of the new flavored [versus] tobacco-flavored products on adult smokers' switching or cigarette reduction over time."

Along with the orders, the FDA provided each Petitioner with a Technical Project Lead review ("TPL") that described the agency's reasoning in greater detail. The TPLs, which are materially identical, stressed the "exponential growth in youth ENDS use" and the "enduring prevalence of youth ENDS use in the U.S."

The FDA found that "[t]he role of flavors in increasing the appeal of tobacco products to youth . . . is well-established in the literature." And although the agency acknowledged that "there is variability in the popularity of device types among youth," it determined that "the role of flavor is consistent." For example, the FDA pointed to a "substantial rise in use of *disposable* flavored ENDS" after it "changed its enforcement policy to prioritize *pod-based* flavored ENDS." Thus, in the FDA's view, the data established "that the removal of one flavored product option prompted youth to migrate to another ENDS type that offered the desired flavor options, underscoring the fundamental role of flavor in driving appeal."

In addition, the TPLs described the types of evidence capable of showing that flavored products are appropriate for the protection of the public health. For flavored products, "the magnitude of the likely benefit [to adult smokers] would have to be substantial enough to overcome the significant risk of youth uptake and use posed by [those] products." Thus, "strong direct evidence" demonstrating the potential benefit was required. Randomized controlled trials and longitudinal cohort studies were "most[] likely to demonstrate such a benefit," but "other types of evidence could be adequate if sufficiently reliable and robust." The FDA explained that evidence must be product specific, and the agency concluded that cross-sectional surveys (entailing "a one-time assessment of self-reported outcomes"), consumer perception studies (evaluating intentions but not actual product use or behavior), and general scientific literature would not suffice.

The TPLs advised that the FDA had reviewed Petitioners' applications to assess whether they contained "a randomized controlled trial, longitudinal cohort study, or other evidence regarding the impact of the ENDS on switching or cigarette reduction that could potentially demonstrate the benefit of their flavored ENDS over tobacco-flavored ENDS" and concluded they did not. Because that "key evidence" was missing, the FDA did not "assess other aspects of the applications," including Petitioners' marketing plans.

Petitioners timely sought review in this court. *See* 21 U.S.C. § 387l(a).

II

"Under the Tobacco Control Act's judicial review provision, a party subject to a marketing denial order may petition for review either in [the D.C. Circuit] or in the circuit in which its principal place of business is located." *Prohibition Juice*, 45 F.4th at 17 (citing 21 U.S.C. § 387*l*(a)(1)(B)). We review such orders in accordance with the Administrative Procedure Act ("APA"), which requires us to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Under this "narrow standard of review," we do not substitute our own judgment for that of the agency. *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020). Instead, we assess only "whether the decision was based on a consideration of the relevant

factors and whether there has been a clear error of judgment." *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989) (quotation omitted). Agency action must "be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). And an agency "must defend its actions based on the reasons it gave when it acted," not with post hoc rationalizations. *Regents*, 140 S. Ct. at 1909.

III

Petitioners primarily assert two arguments on appeal. First, they contend that the FDA exceeded its statutory authority by requiring comparative efficacy studies. Second, Petitioners argue that the FDA's denial of their PMTAs was arbitrary, capricious, or otherwise unlawful. We begin with the FDA's statutory authority.

A

Petitioners maintain that the FDA exceeded the scope of its statutory authority by requiring applicants to demonstrate that their flavored products better promote smoking cessation than comparable tobacco-flavored products. We disagree and join the Second, Third, Fourth, Seventh, and D.C. Circuits in holding that the FDA had statutory authority to regulate as it did.[10] *See, e.g.*, *Magellan Tech., Inc.*, 2023 WL 4035722 at *7 ("The TCA expressly contemplates a comparative

[10] Because the Tobacco Control Act "is best read to support the FDA's action, we need not consider whether or how much deference to accord its interpretation." *Prohibition Juice*, 45 F.4th at 18.

analysis among tobacco products in the context of evaluating whether the products are Appropriate."); *Liquid Labs*, 52 F.4th at 542 (explaining that the Act "expressly asks for evidence concerning whether an applicant's tobacco product presents less risk than other tobacco products" (internal quotation marks and citations omitted)); *Avail Vapor*, 55 F.4th at 427 ("The [Act] explicitly contemplates that [the] FDA must embark on a comparative inquiry before allowing any marketing of a new tobacco product."); *Gripum*, 47 F.4th at 555 (explaining that the FDA is required under the Act to "weigh a product's risks of hooking new users (typically youth) into the world of tobacco, broadly defined, against its potential to help existing users (typically adults) wean themselves from tobacco's unhealthier forms (namely, combustible cigarettes)"); *Prohibition Juice*, 45 F.4th at 19 (concluding that the Act "not only allows but expressly instructs the FDA" to compare a flavored ENDS product's effectiveness at promoting cessation of combustible cigarette use).

We start with the text of the Tobacco Control Act. *See Van Buren v. United States*, 141 S. Ct. 1648, 1654 (2021). The Act permits the FDA to authorize the marketing of a new tobacco product only if the manufacturer has established that it "would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). In making that determination, the FDA must consider "the *increased or decreased likelihood* that existing users of tobacco products will *stop* using such products," as well as "the *increased or decreased likelihood* that those who do not use tobacco products will *start* using such products." *Id.* § 387j(c)(4)

(emphases added). These considerations are inherently comparative. *See Avail Vapor*, 55 F.4th at 428.

The textual support for the FDA's authority does not end there. Congress also directed applicants seeking to market a new tobacco product to include in their applications "full reports of all information . . . concerning investigations which have been made to show the health risks of such tobacco product and *whether such tobacco product presents less risk than other tobacco products*." 21 U.S.C. § 387j(b)(1)(A) (emphasis added). Section 387j(c) provides, in turn, that the FDA "shall deny an application . . . if, upon the basis of the information submitted"—which would necessarily include any comparative reports submitted in accordance with § 387j(b)(1)(A)—"and any other information before the [FDA]," the agency finds that the applicant did not show "that permitting [the] tobacco product to be marketed would be appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A). Put differently, the FDA must weigh the risk of hooking new users on tobacco products against a product's potential to help existing users switch from unhealthier forms of tobacco—i.e., combustible cigarettes. *See Gripum*, 47 F.4th at 555.

Perhaps realizing that the Tobacco Control Act expressly authorizes the FDA's consideration of comparative evidence,[11] Petitioners contend that the

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[11] Indeed, Nude Nicotine "acknowledged fully" at oral argument that "it is a fair application of the statutory standard" for the FDA to require that manufacturers of flavored ENDS compare their products to tobacco-flavored products to obtain marketing authorization.

term "risk," as used in § 387j(b)(1)(A), refers only to "physiological *health* risks" and "not some broader concept of risk that encompasses initiation and cessation behaviors." We find this contention wholly unpersuasive. As the D.C. Circuit aptly explained: "The degree to which a harmful product entices and addicts new users is inarguably a component of the 'health risk' it poses." *Prohibition Juice*, 45 F.4th at 19–20.

We therefore conclude that the Tobacco Control Act expressly authorizes the FDA to consider comparative evidence, and we agree with our sister circuits that "[t]he FDA acted well within [Congress's] statutory directive when it compared the claimed cessation benefits of flavored and non-flavored products."[12] *Id.* at 19; *Gripum*, 47 F.4th at 558 ("Th[e] [statutory] language expressly orders the agency to conduct the described balancing process and to consider both the risks and benefits attendant to each application that it adjudicates."); *Liquid Labs*, 52 F.4th at 543 (finding that "the statute and June 2019 Guidance are clear about comparative analysis"); *Avail Vapor*, 55 F.4th at 427–28 (same); *Magellan Tech., Inc.*, 2023 WL 4035722 at *7 (same).

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[12] We reject Petitioners' arguments premised on 21 U.S.C. §§ 355 and 387k for the same reasons articulated by the D.C. Circuit in *Prohibition Juice*, 45 F.4th at 20. Similarly, we need not evaluate whether injunctive relief is appropriate because we deny the petitions for review.

B

We turn now to Petitioners' remaining challenge: that the FDA acted arbitrarily and capriciously by denying their applications to market flavored e-liquids.

In their opening briefs, Petitioners advance virtually identical arguments to those asserted by the ENDS manufacturers in *Prohibition Juice*, *Gripum*, *Liquid Labs*, *Avail Vapor*, and *Magellan*. Petitioners insist that the FDA pulled a "surprise switcheroo" by requiring manufacturers to submit evidence of comparative efficacy through a randomized controlled trial, longitudinal cohort study, or other long-term study, while also rejecting evidence that the agency had previously recommended manufacturers submit, including published scientific literature and observational studies. Petitioners also maintain that the FDA acted arbitrarily and capriciously by ignoring their marketing plans, rejecting the evidence they submitted in support of their applications, "imposing an evidentiary double standard," failing to consider allegedly material distinctions between different kinds of ENDS products, and failing to offer less drastic alternatives to marketing denial orders. Nude Nicotine additionally contends that the FDA's review resulted in disparate outcomes for similarly situated applicants. The D.C. Circuit rejected each of these arguments days before we held oral argument in these consolidated cases. *See Prohibition Juice*, 45 F.4th at 20–24.

Ostensibly in response to our sister circuit's decision, Petitioners refocused their arbitrary and capricious challenge at oral argument, advocating primarily that the FDA did not provide sufficient notice

of the "substantive evidentiary standard" governing PMTAs.[13] We therefore take Petitioners to raise two principal arguments in support of their arbitrary and capricious claim. We find neither persuasive.

1

The first argument proceeds as follows: Although the 2019 Guidance informed ENDS manufacturers to "compare the health risks of [their] product[s] to both products within the same category and subcategory, as well as products in different categories," 2019 Guidance at 13, Petitioners believed that they had unfettered discretion to choose a relevant comparator. Under Petitioners' theory, it would have been adequate for a manufacturer of flavored ENDS to, for example, compare its flavored e-liquids to other flavored e-liquids. Petitioners thus contend that the FDA unfairly surprised them by demanding that they compare their flavored e-liquids to *tobacco*-flavored ones.

We, like the D.C. Circuit, find this argument to be "far off base." *Prohibition Juice*, 45 F.4th at 23. As discussed, the FDA may authorize the marketing of a new tobacco product only if an applicant demonstrates that it "would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). To facilitate that inquiry, Congress directed manufacturers to include in their applications reports concerning

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[13] Petitioners were likely also influenced by the Fifth Circuit's rejection of these arguments, also shortly before argument in these cases. *See Wages & White Lion Invs., LLC v. FDA* (*Triton II*), 41 F.4th 427 (5th Cir. 2022), *reh'g en banc granted*, *vacated by* 58 F.4th 233 (5th Cir. 2023).

"whether [the] tobacco product presents less risk than other tobacco products." *Id.* § 387j(b)(1)(A). And, as Petitioners admitted at oral argument, the FDA told ENDS manufacturers to compare the health risks of their products to "products within the same category and subcategory, as well as products in different categories." 2019 Guidance at 13.

Moreover, as the D.C. Circuit explained, "[a] core objective of the Tobacco Control Act is to 'ensure' tobacco products will not be 'sold or accessible to underage purchasers,'" *Prohibition Juice*, 45 F.4th at 12 (quoting P.L. No. 111-31, § 3(7)), and at the time Petitioners were preparing their PMTAs, they knew the FDA was focusing on the desirability of flavored products to youth users. *See, e.g.*, 2019 Guidance at 42; 2020 Guidance at 11–17. Considering the Act's purpose and the FDA's concern regarding the substantial increase in youth initiation prompted by *flavored* ENDS products, Petitioners cannot plausibly contend that the agency led them to believe a flavor-to-flavor comparison would meet the Act's requirements.

Indeed, Petitioners do not explain how a flavor-to-flavor comparison would provide any meaningful information to the FDA. For example, demonstrating that "apple" flavored ENDS products are less risky than "cinnamon candy" flavored products would not provide the FDA with useful information about whether Petitioners' flavored tobacco products on the whole are less harmful to existing users than their tobacco-flavored counterparts, or whether flavored products draw existing users away from combustible cigarettes or help them otherwise quit smoking—

benefits that could counterbalance the risk of youth use. We therefore conclude that the FDA did not act arbitrarily or capriciously in requiring a comparison between flavored products and tobacco-flavored products. *See Prohibition Juice*, 45 F.4th at 23 (because the FDA had identified flavor as a driver of youth use, "Petitioners' own unflavored or tobacco-flavored e-liquids were an obvious, otherwise-similar comparator against which to gauge whether the added risks of their flavored e-liquids are overcome by those products' added benefits to adult smokers").[14]

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[14] After oral argument and in subsequent motions to this court, Petitioners have seemingly attempted to renew their contention that the FDA failed to meaningfully consider the distinction between cartridge-based or disposable ENDS products and bottled e-liquids. We join our sister circuits in rejecting this argument. First, the FDA acknowledged that "there is variability in the popularity of device types among youth, suggesting there may be differential appeal of certain product styles," but "reasonably explained that it nonetheless found the scientific literature about public health risks to youth applicable to petitioners' products, because 'across these different device types, the role of flavor is consistent.'" *Prohibition Juice*, 45 F.4th at 26 (citation omitted). The "FDA's original focus on *enforcement* against cartridge-based ENDS products did not foreclose it from denying a marketing order for [Petitioners'] e-liquids, especially in light of the growing evidence that the role of flavors in driving youth initiation was consistent across products." *Avail Vapor*, 55 F.4th at 427; *see also Liquid Labs*, 52 F.4th at 544–45 (same). The FDA supported its determination with evidence including "large, national surveys and longitudinal cohort studies" that "consistently demonstrated" the "preference for use of flavored ENDS among youth." Thus, the FDA did not arbitrarily disregard distinctions between open and closed ENDS products.

Petitioner's second argument—that the FDA purportedly stated that it would accept single-point-in-time studies, like consumer surveys, but ultimately required studies that followed consumers over long time periods—fares no better.

Again, we agree with our sister circuits who have held that the FDA did not introduce a new evidentiary standard; rather, it consistently required evidence that evaluated the impacts of flavored versus non-flavored products on initiation and cessation. The FDA repeatedly used conditional language indicating that it *might* accept evidence other than long term studies *if* such evidence was sufficiently reliable and robust. *See, e.g.*, *Gripum*, 47 F.4th at 559–60 (explaining that the FDA stated that "'in some cases, it may be possible to support a marketing order for an [e-cigarette] product without conducting new nonclinical or clinical studies,' though that depends on whether 'an established body of evidence . . . can be adequately bridged to [the] product such as data from the published literature or government-sponsored databases'" (quoting 2019 Guidance at 46) (alterations in original)); *Prohibition Juice*, 45 F.4th at 21 (explaining that the FDA provided that "randomized controlled trials or longitudinal studies would not be necessary if applicants submitted similarly rigorous 'valid scientific evidence'" and "[t]he FDA nowhere guaranteed that unspecified other forms of evidence would necessarily be sufficient—only that they might be" (quoting 2019 Guidance at 12–13)); *Magellan Tech., Inc.*, 2023 WL 4035722 at *5 (same).

As the Fourth Circuit explained: the "FDA never guaranteed that manufacturers could carry their evidentiary burden under the [Act] without providing long-term data." *Avail Vapor*, 55 F.4th at 422. And by focusing on isolated statements in the 2019 Guidance that the FDA did not expect applicants would need to conduct long-term studies, Petitioners "failed to look at the 2019 guidance in any depth," as "[t]he agency made quite clear that it was interested in receiving information about long-term *impact*, even if that information did not necessarily come from a long-term *study*." *Id.* at 422–23.

Here, the FDA acted in conformity with its previous guidance and reasonably rejected Petitioners' applications because their other proffered evidence was not sufficiently reliable and robust. *See id.* at 422 (concluding that the FDA "did not reject Avail's application because it failed to include certain long-term studies, but rather due to a lack of *any* 'valid scientific evidence' substantial enough to outweigh the known risks to youth of flavored products"). Specifically, Petitioners stumbled at the initial hurdle of providing useful comparative evidence demonstrating the risks and benefits of initiation and cessation. Lotus failed to even include product-specific evidence. And, although Nude Nicotine offered some product-specific evidence—for example, in the form of a Harmful and Potentially Harmful Constituents analysis—the FDA adequately explained that such evidence did not, standing alone, "demonstrate that current smokers are likely to start using the new product exclusively or predominantly." Therefore,

Petitioners could not show a sufficient benefit to adult users relative to the risk to youth users.

Lotus points to cross-sectional surveys, literature reviews, and a coalition survey, and Nude Nicotine contends that its PMTA contained abuse liability studies, a cross-sectional actual use survey, and a consumer perception studies review. But the FDA reasonably explained in the Marketing Denial Orders and TPLs that cross-sectional surveys are not sufficiently robust for flavored products because they "entail a one-time assessment of self-reported outcomes" and that "single data collection does not enable reliable evaluation of behavior change over time." Similarly, consumer perception studies, like surveys or experiments, are not sufficiently rigorous because they "are not designed to directly assess actual product use behavior." Petitioners do not contend that they offered any other forms of robust evidence that could overcome a lack of randomized controlled trials or longitudinal cohort studies.

Thus, the FDA did not act arbitrarily or capriciously in finding Petitioners' "other evidence" insufficient. *See, e.g.*, *Liquid Labs*, 52 F.4th at 539–43 (explaining that "the FDA did not newly require those specific types of [long-term] studies but instead found that Liquid Labs' other evidence was inadequate"); *Avail Vapor*, 55 F.4th at 422 (explaining that "Avail failed to include" "the type and quality of evidence" the FDA required, and "this failure, rather than the absence of certain [long-term] studies in its PMTAs, resulted in FDA issuing a marketing denial order"); *Gripum*, 47 F.4th at 558–61 (explaining that because Gripum did not (1) provide

robust, product specific evidence that "the benefits to adult users . . . outweigh[ed] the risk of fomenting youth use," or (2) offer sufficient explanations to bridge the data between long-term studies of other products and its own products, the FDA did not act arbitrarily and capriciously when it denied Gripum's application); *see also Magellan Tech., Inc.*, 2023 WL 4035722 at *5 ("Consistent with its position, the FDA considered Magellan's weak scientific evidence and found it insufficient to support an Appropriate finding."); *Prohibition Juice*, 45 F.4th at 22 (explaining that the FDA reasonably drew differing conclusions from evidence of differing strength). *But see R.J. Reynolds Vapor Company v. FDA*, 65 F.4th 182, 190 (5th Cir. 2023) (concluding that the FDA acted arbitrarily and capriciously when it previously "represented that long-term studies were likely unnecessary" and never told applicants that switching evidence would be required for menthol-flavored products).

We are not tasked with determining whether we agree with the FDA's decision, made within its area of expertise, that Petitioners' proffered evidence was insufficient. Instead, we join the Second, Third, Fourth, Seventh, and D.C. Circuits in determining that the agency consistently advised that, in the absence of long-term data, it might rely upon sufficiently robust and reliable other evidence. The agency did not act arbitrarily or capriciously by concluding that Petitioners' evidence fell short of that standard.

3

We now turn to Petitioners' contentions that the FDA's failure to consider their marketing and sales-

access-restrictions plans was arbitrary and capricious. We assume, without deciding, that the FDA erred in ignoring Petitioners' marketing plans, but we conclude that any error was harmless.

The Tobacco Control Act incorporates the APA's harmless error rule. *See* 21 U.S.C. § 387*l*(b); 5 U.S.C. § 706 ("[D]ue account shall be taken of the rule of prejudicial error."). An error is harmless if it "had no bearing on the procedure used or the substance of [the] decision reached." *Cal. Wilderness Coal. v. U.S. Dep't of Energy*, 631 F.3d 1072, 1092 (9th Cir. 2011) (alteration in original) (quoting *Paulsen v. Daniels*, 413 F.3d 999, 1006 (9th Cir. 2005)). "[T]he burden of showing an agency's deviation from the APA was not harmless rests with the petitioner." *Id.* Generally, this court "must judge the propriety of [agency] action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). But "*Chenery* does not require that [courts] convert judicial review of agency action into a ping-pong game." *N.L.R.B. v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6 (1969) (plurality opinion).

In the 2020 Guidance, the FDA identified the measures that manufacturers had proposed to restrict minors' access to ENDS products sold online and at brick-and-mortar stores. These measures included: (1) age-verification technology for online sales; (2) enhanced monitoring for retailer compliance with age-verification requirements; (3) contractual penalties for retailers selling tobacco products to minors; and (4) restrictions on the quantity of ENDS products customers can purchase within a period of time.

Despite those efforts, youth e-cigarette use continued to increase. Consequently, the 2020 Guidance reported the FDA's conclusion that "age verification alone is not sufficient" and that "focusing on how the product was sold would not be sufficient to address youth use of these products given the many sources of products available for youth access."

We are persuaded by the Second, Third, Fourth, and D.C. Circuits' analysis on this issue. In each of the cases decided by these courts, "the manufacturers were unable to identify any prejudice they suffered from the FDA's lack of individualized review of their plans to prevent youth access to their flavored e-liquids," because the proffered marketing plans contained materially identical measures to those that the FDA had already described as insufficient. *Prohibition Juice*, 45 F.4th at 24; *see also Liquid Labs*, 52 F.4th at 544 (concluding that Liquid Labs did not show that its marketing plans would have changed the result because its "age verification measures," "mystery shopper program," and "prohibition on marketing material" targeting youth were "similar, if not identical, to the kinds of approaches the FDA found did not address this serious problem," and such plans could not, in any case, have rectified the other scientific deficiencies in its applications); *Avail Vapor*, 55 F.4th at 425–26 (same); *Magellan Tech., Inc.*, 2023 WL 4035722 at *6 (same). Here, Petitioners' marketing plan arguments fail for the same reason.

Petitioners do not identify how their marketing measures are materially different from those the FDA has already said are insufficient. For example, Lotus'

marketing plan provides that its products "will continue to be strictly marketed and sold to adults in adult-only retailers and through age-verified online websites," and that the products "will not be promoted by Lotus partners, sponsors, influencers, bloggers, or brand ambassadors on non-age-gated social media, radio or television." Nude Nicotine's marketing plan similarly provides for "using and requiring age-gating and age verification for sales of all Nude Nicotine products," requiring distributors and retailers to register as licensed or authorized resellers, contractually binding its authorized retailers to use age-gating marketing procedures, and engaging in post-marketing surveillance.

At oral argument, Lotus was asked to identify how its marketing plan differed from the marketing plans in *Prohibition Juice*. Counsel identified the following differences: limiting consumer engagement to trade shows, age-gated social media, no use of social media influencers, quantity restrictions for online sales, and contractual penalties. But these measures track those that the FDA found were ineffective to counterbalance the risk of youth use, *see* 2020 Guidance at 6–8, 21–22, 44–45, and Petitioners did not otherwise argue that any of their marketing tactics were novel. *Cf. Prohibition Juice*, 45 F.4th at 16 (recognizing that some "e-cigarette companies are developing novel technologies, such as requiring age verification *assisted by facial recognition software* to unlock their products, which they assert could prevent underage use" (emphasis added)); *Bidi Vapor LLC v. FDA*, 47 F.4th 1191, 1205 (11th Cir. 2022) (finding the FDA acted arbitrarily and capriciously by not reviewing the

tobacco companies' marketing plans, which "included measures not specifically mentioned in the 2020 Guidance," such as "Trace/Verify technology" and counterfeit prevention systems); *Avail Vapor*, 55 F.4th at 418, 425–26 (explaining that "[w]hile some other ENDS manufacturers were exploring innovative 'access restriction' technology, whereby, for example, an ENDS product is tied to the thumb print of the purchaser, Avail's marketing plan included only garden variety restrictions," including non-descriptive product names and age-verification services). We therefore join the Second, Third, Fourth, and D.C. Circuits in concluding that the FDA's failure to consider Petitioners' marketing plans, if erroneous, was harmless error.

We acknowledge that in *Bidi Vapor*, the Eleventh Circuit reached a different conclusion, *see* 47 F.4th at 1205, but we do not understand our decision to conflict with that case. There, the Eleventh Circuit noted that the petitioners had submitted marketing plans containing novel restrictions designed to limit youth access. *See id.* at 1205 (discussing marketing plans that "conformed with the recommendations . . . , directly addressed the concerns of youth access . . . , and included measures not specifically mentioned in the [FDA's] 2020 Guidance"); *see also id.* at 1206 (describing "novel marketing and sales-access-restriction plans"). So, although the Eleventh Circuit concluded that the FDA's error was not harmless in *Bidi Vapor*, it did so on a materially different record.

In sum, at the time the FDA reviewed Petitioners' applications, it had already concluded that eliminating marketing aimed at youth users and monitoring

retailers' sales were ineffective in preventing youth use because children maintained a steady stream of access to the flavored products they desired through alternate means, like their friends and social networks. *See* 2020 Guidance at 44–45; *Prohibition Juice*, 45 F.4th at 24–25 ("When an agency's mistake plainly had no bearing on the substance of its decision, we do not grant a petition for review based on that mistake" and "[w]here a petitioner had ample opportunity yet failed to show that an agency error harmed it, vacatur and remand to give the agency an opportunity to fix the error is unwarranted." (internal quotation marks and citation omitted)). Therefore, even if the agency erred by failing to consider Petitioners' marketing plans, any error was harmless, and we will not remand on this basis.

IV

Finally, we address Petitioners' post-argument motions to supplement the administrative record and file supplemental briefing and seeking judicial notice of PMTA deficiency letters, FDA internal memoranda, and FDA press releases. We deny the motions to supplement the administrative record and file supplemental briefing and grant the motions for judicial notice.

First, Petitioners filed motions to supplement the administrative record with an internal FDA Memorandum, dated August 19, 2020, and for leave to file supplemental briefing.[15] The memorandum

[15] The general rule is "that courts reviewing an agency decision are limited to the administrative record." *Lands Council v. Powell*, 395

describes a "bundling and bracketing" procedure to expedite review of PMTAs. Petitioners argue that the August 2020 Memorandum demonstrates that the FDA was using a "holistic review approach" at the time Petitioners submitted their PMTAs that "made no reference whatsoever to requiring randomized controlled trials, longitudinal cohort studies, or 'other evidence' comparing flavored bottled e-liquids to tobacco-flavored bottled e-liquids in terms of their ability to promote reduction or cessation of use of combustible cigarettes." Petitioners then argue that this "holistic" approach was subsequently, and without notice, replaced by a different and more demanding evidentiary requirement. Petitioners argue from a negative—that is, because the memorandum does not state that comparative studies are required, the FDA must have been using an approach that did not require such studies and shifted the review criteria only after Petitioners submitted their PMTAs.

F.3d 1019, 1029 (9th Cir. 2005) (citing *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985)). Although "[r]eview may . . . be expanded beyond the record if necessary to explain agency decisions," we have only allowed extra-record materials in limited circumstances that do not apply here. *See Sw. Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1450 (9th Cir. 1996) (explaining that the administrative record may be supplemented "(1) if necessary to determine whether the agency has considered all relevant factors and has explained its decision, (2) when the agency has relied on documents not in the record, . . . (3) when supplementing the record is necessary to explain technical terms or complex subject matter," or (4) when "plaintiffs make a showing of agency bad faith" (internal quotation marks and citations omitted)).

The FDA responds that there is no reason to supplement the record because the memorandum prescribes procedures for a stage of review that Petitioners' PMTAs never reached and therefore is "inapplicable in these circumstances." Additionally, the FDA contends that this "wholly internal memo" could not have created reliance interests, and that it is merely "a procedural document discussing an approach for streamlining a narrow aspect of the review of certain products in further scientific review."

The agency's final argument is sufficient to demonstrate that the motion to supplement is not well taken: the August 2020 Memorandum is procedural in nature—it does not describe the *standards* that would apply to the review of the data; rather, it offers *procedural* instructions to increase the efficiency of reviewing thousands of PMTAs at the outset—and therefore it is irrelevant to the substantive issues presented here. *See Gripum*, 47 F.4th at 560–61 (finding the same memorandum "of dubious relevance"). "Bundling and bracketing," as procedural tools, say nothing about how the agency substantively reviews the applications. Even assuming that Petitioners' PMTAs were bundled and bracketed, that does not mean that their applications would have been granted. Indeed, simply using bundling and bracketing procedures cannot change the results of the review process if the PMTAs failed to include the necessary comparative studies contemplated in the Tobacco Control Act. Because a memorandum describing a procedure to streamline the review of data (either before or during scientific review) is irrelevant to the issues presented in this appeal, Petitioners' motions to

supplement and for leave to file supplemental briefs are denied.[16]

Second, Lotus filed three motions asking the court to take judicial notice of various documents. In one motion, Lotus seeks judicial notice of two PMTA deficiency letters issued by the FDA in other matters: *Logic Technology Development LLC v. FDA*, No. 22-3030, (June 26, 2020), and *R.J. Reynolds Vapor Company v. FDA*, No. 23-60037. In a second motion, Lotus seeks judicial notice of two FDA internal memoranda: *Development of the Approach to Evaluating Menthol-Flavored ENDS PMTAs* (Oct. 25, 2022); and *Process for Evaluating Menthol-Flavored ENDS PMTAs* (Oct. 25, 2022). In a third motion, Lotus seeks judicial notice of an October 26, 2022 FDA press release: *FDA Denies Marketing of Logic's Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard*, FDA (Oct. 26, 2022) ("October Press Release").

Rule 201(b) of the Federal Rules of Evidence provides that we may take judicial notice of "a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." These are published materials representing the considered views of the FDA, and the FDA does not contest their accuracy here. Therefore, we take judicial

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[16] In any event, for the reasons we have already given, supplementing the record to include this memorandum would not change the result in this case, and the parties effectively briefed the memorandum through their submissions on Petitioners' motions to supplement.

notice of the FDA's deficiency letters, internal memoranda, and press release. But, as we explain next, they do not alter our analysis.

Based on the additional PMTA deficiency letters, Lotus raises the same "surprise switcheroo" argument we rejected in Section IV.B., *supra*. Specifically, Lotus argues that the FDA indicated that scientific evidence was needed to demonstrate whether flavored ENDS products facilitate adult smokers switching from combustible cigarette use at a rate exceeding that of tobacco-flavored or menthol-flavored products *after* Lotus submitted its own PMTA. This argument fails for the reasons we have previously discussed. The FDA has consistently required sufficiently robust, product-specific evidence demonstrating that flavored ENDS products are appropriate for protection of the public health, which necessarily requires evidence of their effects on switching product use.

Lotus similarly argues that the agency's internal memoranda establish that the FDA's Office of Science preliminarily recommended that the FDA grant marketing authorization of menthol-flavored products, and that recommendation was later overruled. In Lotus's view, these memoranda demonstrate that the FDA "adopted the evidentiary standard it would ultimately apply to grant marketing authorization well after the applications were submitted." We disagree.

As an initial matter, the October 2022 memoranda address menthol-flavored ENDS products (which are not at issue here) and address the status of the review process long after Petitioners' PMTAs were denied in September 2021. Moreover, the internal memoranda

simply reflect the process by which the FDA considered the available evidence and concluded that menthol-flavored ENDS products should be treated the same as other flavored ENDS products (e.g., fruit, sweets, and mint)—that is, "the products could be found to be [appropriate for the protection of the public health] only if the evidence showed that the benefits of the menthol-flavored ENDS were greater than tobacco-flavored ENDS, which pose lower risk to youth." *See Development of the Approach to Evaluating Menthol-Flavored ENDS PMTAs* at 2–3. These memoranda do not demonstrate that the FDA engaged in a "surprise switcheroo."

Finally, Lotus argues that the FDA press release discusses the first menthol-flavored ENDS products to receive a full scientific review, and the FDA issued marketing denial orders because the applications did not demonstrate that these products are "more *effective* at promoting complete switching or significant cigarette use reduction relative to tobacco-flavored [ENDS] among adult smokers." Lotus argues that this statement is relevant to evaluating FDA's claims that its analysis of Lotus' application focused on "benefits," not "efficacy," and that it has never "required" smoking cessation studies.

But the FDA's statements in the press release simply bolster the position that it has maintained throughout this litigation: the FDA "evaluat[es] new tobacco products based on a public health standard that considers the risks and benefits of the tobacco product to the population as a whole" by assessing whether the flavored ENDS product is likely to reduce

combustible cigarette use among adults as compared to tobacco-flavored ENDs products, so as to justify the risk flavored products pose to youth. October Press Release; *see also, e.g.*, *Gripum*, 47 F.4th at 559 (explaining, in response to the argument that the FDA's approach amounted to a "product-efficacy assessment," that "all the FDA required Gripum to do [was] to show that its flavored e-cigarette products were *relatively better* at reducing rates of tobacco use than products already on the market" and concluding the FDA "properly applied the comparative standard mandated by the statute; Gripum simply failed to meet it"). Therefore, while we grant Lotus's motions seeking judicial notice, these documents do not change our analysis.

V

The FDA acted within its statutory authority under the Tobacco Control Act to require Petitioners to demonstrate that their flavored ENDS products are comparatively better at promoting smoking cessation than tobacco-flavored products. Moreover, the agency's denial of Petitioners' PMTAs was not arbitrary and capricious. The FDA did not impose a new evidentiary standard or unfairly surprise Petitioners in requiring comparative evidence and, even assuming the FDA erred in failing to assess Petitioners' marketing plans, any error was harmless.

PETITIONS FOR REVIEW DENIED.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 21-71328

[Filed September 14, 2023]

LOTUS VAPING TECHNOLOGIES, LLC, Petitioner,	)
v.	)
U.S. FOOD & DRUG ADMINISTRATION, Respondent.	)

Food & Drug Administration

ORDER

Before: RAWLINSON, BADE, and BRESS, Circuit Judges.

Judges Rawlinson, Bade, and Bress have voted to deny the petition for rehearing and rehearing en banc. The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

The combined petition for panel rehearing and for rehearing en banc, Dkt. 99, is DENIED.

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 21-71328
FDA No.

[Filed September 22, 2023]

LOTUS VAPING TECHNOLOGIES, LLC, Petitioner,	)
v.	)
U.S. FOOD & DRUG ADMINISTRATION, Respondent.	)

Food & Drug Administration

MANDATE

The judgment of this Court, entered July 07, 2023, takes effect this date.

This constitutes the formal mandate of this Court issued pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure.

FOR THE COURT:

MOLLY C. DWYER
CLERK OF COURT

APPENDIX D

FDA U.S. FOOD & DRUG ADMINISTRATION

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

[Filed September 17, 2021]

September 17, 2021

DENIAL

Lotus Vaping Technologies
Attention: Ryan Muckenthaler, Regulatory Compliance Officer
5118 N Sawyer Avenue
Boise, ID 83714

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

Dear Mr. Muckenthaler:

We are denying a marketing granted order for the products identified in Appendix A. Refer to Appendix B for a list of amendments received in support of your applications.

Based on our review of your PMTAs[1], we determined that the new products, as described in your applications and specified in Appendix A, lack sufficient evidence to demonstrate that the marketing of these products is appropriate for the protection of the public health (APPH). Therefore, you cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.

If you choose to submit new applications for these products, you must fulfill all requirements set forth in section 910(b)(1). You may provide information to fulfill some of these requirements by including an authorization for FDA to cross-reference a Tobacco Product Master File.[2] You may not cross-reference information submitted in the PMTAs subject to this Denial.

Based on review of your PMTAs, we identified the following key basis for our determination:

1. All of your PMTAs lack sufficient evidence demonstrating that your flavored ENDS will provide a benefit to adult users that would be

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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] See guidelines at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-product-master-files

> adequate to outweigh the risks to youth . In light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers. This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS. Alternatively, FDA would consider other evidence but only if it reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time. We did not find such evidence in your PMTAs. Without this information, FDA concludes that your application is insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth and, therefore, cannot find that permitting the marketing of your new tobacco products would be appropriate for the protection of the public health.

We cannot find that the marketing of your new tobacco products is APPH. The review concluded that key evidence demonstrating APPH is absent. Therefore, scientific review did not proceed to assess other aspects of the applications. FDA finds that it is not practicable to identify at this time an exhaustive list of all possible deficiencies.

Your PMTAs lack sufficient information to support a finding of APPH; therefore, we are issuing a marketing

denial order. Upon issuance of this order, your products are misbranded under section 903(a)(6) of the FD&C Act and adulterated under section 902(6)(A) of the FD&C Act. Failure to comply with the FD&C Act may result in FDA regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

We encourage you to submit all regulatory correspondence electronically via the CTP Portal[3,4] using eSubmitter.[5] 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; submissions are considered received by DCC on the day of successful upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on

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[3] For more information about CTP Portal, see https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal.

[4] FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

[5] For more information about eSubmitter, see https://www.fda.gov/industry/fda-esubmitter

or before the due date[6]; 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 Melanie Proctor, Regulatory Health Project Manager, at (301) 796-8135 or Melanie.Proctor@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman-S
Date: 2021.09.17 12:42:56 -04'00'
Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosure **(if provided electronically, the Appendix is not included in physical mail):**
Appendix A – New Tobacco Products Subject of This Letter
Appendix B – Amendments Received for These Applications

[6] https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp

Appendix A[7,8]

New Tobacco Products Subject of This Letter

Common Attributes of PMTAs	
Date of Submission:	September 8, 2020, September 9, 2020
Date of Receipt:	September 8, 2020, September 9, 2020
Applicant:	Lotus Vaping Technologies, LLC
Product Manufacturer:	Lotus Vaping Technologies, LLC
Product Category:	ENDS (VAPES)
Product Sub-Category:	ENDS Component

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

[8] Include the following as footnotes where applicable:

[*See next 5 pages for Fold-out Exhibit*]

STN	PD Number	Product Name	Category	Subcategory	Package Type	Package Quantity	Characterizing Flavor	Additional Property
PM0002365	PD2	Lotus Originals Apple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Apple	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002365	PD4	Lotus Originals Apple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Apple	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002365	PD3	Lotus Originals Apple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Apple	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002365	PD1	Lotus Originals Apple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Apple	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001579	PD1	Lotus Originals Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Banana	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001579	PD4	Lotus Originals Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Banana	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001579	PD3	Lotus Originals Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Banana	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001579	PD2	Lotus Originals Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Banana	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002468	PD2	Lotus Originals Black Walnut	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Black Walnut	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002468	PD1	Lotus Originals Black Walnut	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Black Walnut	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002468	PD4	Lotus Originals Black Walnut	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Black Walnut	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002468	PD3	Lotus Originals Black Walnut	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Black Walnut	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD25	Nomenon Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 0 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD26	Nomenon Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 3 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD38	Nomenon Ice Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 3 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD30	Nomenon Blunomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD37	Nomenon Ice Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 0 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD28	Nomenon Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 12 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD27	Nomenon Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 6 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD39	Nomenon Ice Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 6 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD29	Nomenon Blunomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD40	Nomenon Ice Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 12 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0001573	PD1	Lotus Originals Blueberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001573	PD3	Lotus Originals Blueberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001573	PD4	Lotus Originals Blueberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001573	PD2	Lotus Originals Blueberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001761	PD3	Exotics Blue Pom	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Pomegranate	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001761	PD1	Exotics Blue Pom	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Pomegranate	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001761	PD4	Exotics Blue Pom	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Pomegranate	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001761	PD2	Exotics Blue Pom	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Pomegranate	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001782	PD4	Exotics Blue Raz	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Raspberry	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001782	PD3	Exotics Blue Raz	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Raspberry	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001782	PD1	Exotics Blue Raz	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Raspberry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001782	PD2	Exotics Blue Raz	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Raspberry	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002368	PD1	Lotus Originals Caramel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Caramel	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002368	PD2	Lotus Originals Caramel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Caramel	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002368	PD3	Lotus Originals Caramel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Caramel	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002368	PD4	Lotus Originals Caramel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Caramel	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001787	PD1	Exotics Cherry Bomb	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001787	PD4	Exotics Cherry Bomb	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001787	PD2	Exotics Cherry Bomb	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001787	PD3	Exotics Cherry Bomb	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD119	Noms X2 X2 Cherry Lime Ginger	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 0 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD121	Noms X2 X2 Cherry Lime Ginger	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 6 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD120	Noms X2 X2 Cherry Lime Ginger	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 3 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD76	Noms X2 Cherry Lime Ginger Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD77	Noms X2 Cherry Lime Ginger Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0002456	PD1	Lotus Originals Cigar	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cigar	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002456	PD3	Lotus Originals Cigar	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cigar	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002456	PD2	Lotus Originals Cigar	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cigar	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002456	PD4	Lotus Originals Cigar	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cigar	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002460	PD1	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cinnamon Candy	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002460	PD3	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cinnamon Candy	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002460	PD4	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cinnamon Candy	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002460	PD2	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cinnamon Candy	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002506	PD1	Exotics Citron	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Citrus	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002506	PD2	Exotics Citron	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Citrus	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002506	PD4	Exotics Citron	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Citrus	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002506	PD3	Exotics Citron	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Citrus	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001549	PD3	Lotus Originals Coffee	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001549	PD1	Lotus Originals Coffee	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL

PM0001549	PD4	Lotus Originals Coffee	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001549	PD2	Lotus Originals Coffee	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001788	PD3	Exotics Irish Latte	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001788	PD4	Exotics Irish Latte	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001788	PD2	Exotics Irish Latte	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001788	PD1	Exotics Irish Latte	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD18	All Day Vapes Non Stop Custard Cream	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Custard	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD17	All Day Vapes Non Stop Custard Cream	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Custard	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD19	All Day Vapes Non Stop Custard Cream	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Custard	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD20	All Day Vapes Non Stop Custard Cream	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Custard	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0002372	PD1	Exotics Raging Bull	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Energy Drink	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002372	PD4	Exotics Raging Bull	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Energy Drink	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002372	PD3	Exotics Raging Bull	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Energy Drink	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002372	PD2	Exotics Raging Bull	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Energy Drink	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002534	PD1	Exotics Tropic Passion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Exotic Fruit Medley	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002534	PD4	Exotics Tropic Passion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Exotic Fruit Medley	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002534	PD2	Exotics Tropic Passion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Exotic Fruit Medley	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002534	PD3	Exotics Tropic Passion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Exotic Fruit Medley	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD61	LQiD Fins Out	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fins Out	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD59	LQiD Fins Out	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fins Out	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD60	LQiD Fins Out	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fins Out	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0002462	PD1	Exotics Fusion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fruit Punch	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002462	PD4	Exotics Fusion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fruit Punch	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002462	PD3	Exotics Fusion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fruit Punch	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002462	PD2	Exotics Fusion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fruit Punch	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002455	PD2	Lotus Originals Grape	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002455	PD1	Lotus Originals Grape	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002455	PD4	Lotus Originals Grape	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002455	PD3	Lotus Originals Grape	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD35	Nomenon Grapenomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD34	Nomenon Grapenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 12 mg/mL, PG/VG: 29/71 E-liquid Volume: 120 mL
PM0003715	PD33	Nomenon Grapenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 6 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD31	Nomenon Grapenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 0 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD32	Nomenon Grapenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 3 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD36	Nomenon Grapenomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0002516	PD3	Lotus Originals Grapefruit	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grapefruit	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002516	PD1	Lotus Originals Grapefruit	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grapefruit	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002516	PD4	Lotus Originals Grapefruit	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grapefruit	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002516	PD2	Lotus Originals Grapefruit	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grapefruit	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD122	Noms X2 X2 Kiwi Passion Fruit Nectarine	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Guava	Nicotine: 0 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD123	Noms X2 X2 Kiwi Passion Fruit Nectarine	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Guava	Nicotine: 3 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD124	Noms X2 X2 Kiwi Passion Fruit Nectarine	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Guava	Nicotine: 6 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD63	LQiD Hodad	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Hodad	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD64	LQiD Hodad	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Hodad	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD62	LQiD Hodad	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Hodad	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD116	Noms X2 X2 Cactus Jackfruit Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD117	Noms X2 X2 Cactus Jackfruit Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD118	Noms X2 X2 Cactus Jackfruit Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD74	Noms X2 Cactus Jackfruit Mandarin Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD75	Noms X2 Cactus Jackfruit Mandarin Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD66	LQiD Kahuna	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Kahuna	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD65	LQiD Kahuna	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Kahuna	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD67	LQiD Kahuna	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Kahuna	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD41	Nomenon Ice Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 0 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD44	Nomenon Ice Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 12 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD43	Nomenon Ice Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 6 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD58	Nomenon Lemonomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD54	Nomenon Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 3 mg/mL, PG/VG: 30.50/69.50, E-liquid Volume: 120 mL
PM0003715	PD53	Nomenon Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 0 mg/mL, PG/VG: 30.50/69.50, E-liquid Volume: 120 mL
PM0003715	PD56	Nomenon Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 12 mg/mL, PG/VG: 30.50/69.50, E-liquid Volume: 120 mL
PM0003715	PD42	Nomenon Ice Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 3 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD55	Nomenon Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 6 mg/mL, PG/VG: 30.50/69.50, E-liquid Volume: 120 mL

PM0003715	PD57	Nomenon Lemonomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0001930	PD1	Lotus Originals Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mandarin	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001930	PD3	Lotus Originals Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mandarin	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001930	PD2	Lotus Originals Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mandarin	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001930	PD4	Lotus Originals Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mandarin	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001789	PD3	Exotics Mango Blast	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mango	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001789	PD4	Exotics Mango Blast	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mango	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001789	PD2	Exotics Mango Blast	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mango	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001789	PD1	Exotics Mango Blast	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mango	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001929	PD3	Lotus Originals Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001929	PD1	Lotus Originals Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001929	PD2	Lotus Originals Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001929	PD4	Lotus Originals Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD10	All Day Vapes Cool Minute Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD11	All Day Vapes Cool Minute Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD12	All Day Vapes Cool Minute Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD9	All Day Vapes Cool Minute Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0001523	PD2	Lotus Originals Minty Mint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001523	PD3	Lotus Originals Minty Mint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001523	PD1	Lotus Originals Minty Mint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001523	PD4	Lotus Originals Minty Mint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD15	All Day Vapes Endless Spearmint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD14	All Day Vapes Endless Spearmint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD16	All Day Vapes Endless Spearmint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD13	All Day Vapes Endless Spearmint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD8	All Day Vapes Berries for Days	ENDS(VAPES)	ENDS Component	Plastic Bottle	2 Bottle	Mixed Berries	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD6	All Day Vapes Berries for Days	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berries	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD7	All Day Vapes Berries for Days	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berries	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD5	All Day Vapes Berries for Days	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berries	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0002383	PD3	Exotics XXX Berry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berry	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002383	PD4	Exotics XXX Berry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berry	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002383	PD2	Exotics XXX Berry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berry	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002383	PD1	Exotics XXX Berry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD79	Noms X2 Kiwi Passionfruit Nectarine Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Fruit	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD78	Noms X2 Kiwi Passionfruit Nectarine Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Fruit	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0002377	PD2	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange Cranberry Fruit Punch	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002377	PD3	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange Cranberry Fruit Punch	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002377	PD4	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange Cranberry Fruit Punch	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002377	PD1	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange Cranberry Fruit Punch	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002458	PD2	Exotics Cali-Mist	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange lemon citrus	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002458	PD1	Exotics Cali-Mist	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange lemon citrus	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002458	PD3	Exotics Cali-Mist	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange lemon citrus	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002458	PD4	Exotics Cali-Mist	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange lemon citrus	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001784	PD1	Exotics Fuzzy Navel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001784	PD4	Exotics Fuzzy Navel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001784	PD3	Exotics Fuzzy Navel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001784	PD2	Exotics Fuzzy Navel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD128	Noms X2 X2 White Peach Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD129	Noms X2 X2 White Peach Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD130	Noms X2 X2 White Peach Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0001944	PD1	Lotus Originals Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001944	PD3	Lotus Originals Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001944	PD4	Lotus Originals Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001944	PD2	Lotus Originals Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD1	All Day Vapes 24/7 Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD4	All Day Vapes 24/7 Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD3	All Day Vapes 24/7 Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD2	All Day Vapes 24/7 Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD70	LQiD Pipe Line	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pipe Line	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD69	LQiD Pipe Line	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pipe Line	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD68	LQiD Pipe Line	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pipe Line	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0001790	PD4	Exotics Pomegranate	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pomegranate	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL

PM0001790	PD2	Exotics Pomegranate	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pomegranate	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001790	PD3	Exotics Pomegranate	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pomegranate	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001790	PD1	Exotics Pomegranate	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pomegranate	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002509	PD1	Exotics Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Raspberry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002509	PD2	Exotics Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Raspberry	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002509	PD3	Exotics Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Raspberry	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002509	PD4	Exotics Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Raspberry	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD72	LQiD Rip Tide	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rip Tide	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD71	LQiD Rip Tide	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rip Tide	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD73	LQiD Rip Tide	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rip Tide	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0001948	PD4	Lotus Originals Rootbeer	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rootbeer	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001948	PD2	Lotus Originals Rootbeer	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rootbeer	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001948	PD1	Lotus Originals Rootbeer	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rootbeer	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001948	PD3	Lotus Originals Rootbeer	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rootbeer	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001497	PD2	Lotus Originals Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001497	PD3	Lotus Originals Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001497	PD1	Lotus Originals Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001497	PD4	Lotus Originals Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD109	Nomenon Stranomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD105	Nomenon Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 3 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD104	Nomenon Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 0 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD108	Nomenon Stranomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD106	Nomenon Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 6 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD107	Nomenon Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 12 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD95	Teleos Pure Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD92	Teleos Pure Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD48	Nomenon Ice Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 12 mg/mL, PG/VG: 33.50/66.50, E-liquid Volume: 120 mL
PM0003715	PD94	Teleos Pure Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD45	Nomenon Ice Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 0 mg/mL, PG/VG: 33.50/66.50, E-liquid Volume: 120 mL
PM0003715	PD46	Nomenon Ice Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 3 mg/mL, PG/VG: 33.50/66.50, E-liquid Volume: 120 mL
PM0003715	PD47	Nomenon Ice Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 6 mg/mL, PG/VG: 33.50/66.50, E-liquid Volume: 120 mL
PM0003715	PD93	Teleos Pure Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0001487	PD3	Lotus Originals Strawberry Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001487	PD1	Lotus Originals Strawberry Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001487	PD2	Lotus Originals Strawberry Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001487	PD4	Lotus Originals Strawberry Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD22	All Day Vapes Strawberry Banana Classic	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD21	All Day Vapes Strawberry Banana Classic	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD23	All Day Vapes Strawberry Banana Classic	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD24	All Day Vapes Strawberry Banana Classic	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD126	Noms X2 X2 Phenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 3 mg/mL, PG/VG: 14.75/85.25, E-liquid Volume: 120 mL
PM0003715	PD127	Noms X2 X2 Phenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 6 mg/mL, PG/VG: 14.75/85.25, E-liquid Volume: 120 mL
PM0003715	PD125	Noms X2 X2 Phenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 0 mg/mL, PG/VG: 14.75/85.25, E-liquid Volume: 120 mL
PM0003715	PD82	Nomenon Phenomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD83	Nomenon Phenomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0001410	PD4	Lotus Originals Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001410	PD1	Lotus Originals Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001410	PD3	Lotus Originals Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001410	PD2	Lotus Originals Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD103	Teleos Pure Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD102	Teleos Pure Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD101	Teleos Pure Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD100	Teleos Pure Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD90	Teleos Pure RY4	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla Caramel Tobacco	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD89	Teleos Pure RY4	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla Caramel Tobacco	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD88	Teleos Pure RY4	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla Caramel Tobacco	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD91	Teleos Pure RY4	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla Caramel Tobacco	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0002461	PD3	Exotics Sweet Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002461	PD1	Exotics Sweet Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002461	PD2	Exotics Sweet Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002461	PD4	Exotics Sweet Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD110	Nomenon Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 0 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL

PM0003715	PD115	Nomenon Watanomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD111	Nomenon Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 3 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD112	Nomenon Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 6 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD114	Nomenon Watanomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD113	Nomenon Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 12 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD52	Nomenon Ice Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 12 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD49	Nomenon Ice Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 0 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD50	Nomenon Ice Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 3 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD51	Nomenon Ice Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 6 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD81	Noms X2 White Peach Raspberry Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	White Peach Raspberry	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD80	Noms X2 White Peach Raspberry Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	White Peach Raspberry	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL

Appendix B. Amendments Received

Submission Date	**Receipt Date**	**Applications being amended**	**Reviewed**	**Brief Description**
August 23, 2021	August 23, 2021	All	Yes	Correction or clarification to the applications.
August 23, 2021	August 23, 2021	All	Yes	Correction or clarification to the applications.

APPENDIX E

FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of PMTAs

[Filed September 17, 2021]

New Products Subject of this Review[i]	
Submission tracking number (STN)	Multiple STNs, see Appendix A
Common Attributes	
Submission date	September 8, 2020, September 09, 2020
Receipt date	September 8, 2020, September 09, 2020
Applicant	Lotus Vaping Technologies LLC
Product manufacturer	Lotus Vaping Technologies LLC
Application type	Standard

[i] Product details, amendments, and dates provided in the Appendix. PMTA means premarket tobacco application. Scientific references are listed at the end of this document and referred to with Arabic numerals; general footnotes are referred to with Roman numerals.

Product category	ENDS (VAPES)
Product subcategory	ENDS Component
Cross-Referenced Submissions	
All new tobacco products	[redacted]
Recommendation	
Issue marketing denial orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

For
Digitally signed by Berran Yucesoy - S
Date: 2021.09.16 15:14:15 -04'00'

Hans Rosenfeldt, Ph.D.
Division Director
Division of Nonclinical Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
Date: 2021.09.17 12:42:18 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

[***Table of Contents Omitted
in Printing of this Appendix.***]

1. EXECUTIVE SUMMARY

These applications for flavored ENDS[ii] products lack evidence to demonstrate that permitting the marketing of these products would be appropriate for the protection of the public health (APPH). Given the known and substantial risk of flavored ENDS with respect to youth appeal, uptake, and use, applicants would need reliable and robust evidence of a potential benefit to adult smokers[iii] that could justify that risk. Accordingly, in order to show that a flavored ENDS is APPH, the applicant must show that the benefit to

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[ii] The term *flavored ENDS* in this review refers to any ENDS other than tobacco-flavored and menthol-flavored ENDS. Tobacco-flavored ENDS are discussed below. Applications for menthol-flavored ENDS will be addressed separately. When it comes to evaluating the risks and benefits of a marketing authorization, the assessment for menthol ENDS, as compared to other non-tobacco-flavored ENDS, raises unique considerations. The term *flavored ENDS* also includes unflavored "base" e-liquids that are designed to have flavors added to them . This includes e-liquids made for use with open systems as well as closed system ENDS (e.g., cartridges or disposable ENDS) containing e-liquids.

[iii] The standard described in Section 910 requires an accounting of the risks and benefits to the population as a whole, balancing the potential impacts to both current tobacco users and non-users. This review is focused on the risk to youth nonusers as well as the potential benefit to adult smokers as current users, as they are the group through which the potential benefit to public health is most substantial and could overcome the known risk to youth.

adults switching from or reducing cigarettes outweighs the risk to youth.

Based on existing scientific evidence and our experiences in conducting premarket review employing the APPH standard over the last several years, FDA has determined for these applications that, to effectively demonstrate this benefit in terms of product use behavior, only the strongest types of evidence will be sufficiently reliable and robust – most likely product specific evidence from a randomized controlled trial (RCT)[iv] or longitudinal cohort study, although other types of evidence could be adequate, and will be evaluated on a case-by-case basis.[v,vi] Moreover, tobacco-

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[iv] A randomized controlled trial is a clinical investigation or a clinical study in which human subject(s) are prospectively, and randomly assigned to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on behavioral, biomedical, or health-related outcomes. *Control or controlled* means, with respect to a clinical trial, that data collected on human subjects in the clinical trial will be compared to concurrently collected data or to non-concurrently collected data (*e.g.,* historical controls, including a human subject's own baseline data), as reflected in the pre-specified primary or secondary outcome measures.

[v] A longitudinal cohort study is an observational study in which human subjects from a defined population are examined prospectively over a period of time to assess an outcome or set of outcomes among study groups defined by a common characteristic (e.g., smoking cessation among users of flavored ENDS compared with users of tobacco-flavored ENDS).

[vi] For example, we would consider evidence from another study design if it could reliably and robustly assess behavior change (product switching or cigarette reduction) over time, comparing

flavored ENDS may offer the same type of public health benefit as flavored ENDS, i.e., increased switching and/or significant reduction in smoking, but do not pose the same degree of risk of youth uptake. Therefore, to demonstrate the potential benefit to current users, FDA has reviewed these applications for any acceptably strong evidence that the flavored products have an added benefit relative to that of tobacco-flavored ENDS in facilitating smokers completely switching away from or significantly reducing their smoking.

We have reviewed the subject applications to determine whether they contain sufficient evidence of the type described above to demonstrate APPH. Our review determined that the subject PMTAs do not contain evidence from a randomized controlled trial, longitudinal cohort study, or other evidence regarding the impact of the ENDS on switching or cigarette reduction that could potentially demonstrate the benefit of their flavored ENDS over tobacco-flavored ENDS. As a result, the applicant has failed to provide evidence to overcome the risk to youth and show a net population health benefit necessary to determine that permitting the marketing of the new tobacco product is APPH.

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users of flavored products with those of tobacco-flavored products. In our review of PMTAs for flavored ENDS so far, we have learned that, in the absence of strong evidence generated by directly observing the behavioral impacts of using a flavored product vs. a tobacco-flavored product over time, we are unable to reach a conclusion that the benefit outweighs the clear risks to youth.

2. BACKGROUND

2.1. NEW PRODUCTS

The applicant submitted information for the new products listed on the cover page and in Appendix A.

2.2. REGULATORY ACTIVITY

FDA issued an Acceptance letter to the applicant on December 1, 2020, December 8, 2020, and December 9, 2020. FDA issued a Filing letter to the applicant on September 18, 2020 for PM0000913.

Refer to Appendix B for a complete list of amendments received by FDA.

2.3. BASIS FOR REQUIRING RELIABLE, ROBUST EVIDENCE TO DEMONSTRATE BENEFIT

The rationale for FDA's decision for these flavored ENDS applications is consistent with previous decisions for other flavored ENDS and is set forth below.

The Federal Food, Drug, and Cosmetic Act (FD&C Act or Act) requires that "new tobacco products" receive marketing authorization from FDA under one of the pathways specified by the Act in order to be legally marketed in the United States. Under one pathway, the applicant submits a PMTA to FDA. Section 910 of the FD&C Act requires that, for a product to receive PMTA marketing authorization, FDA must conclude, among other things, that the marketing of the product is APPH. The statute specifies that, in assessing APPH, FDA consider the risks and benefits to the

population as a whole including both tobacco users and nonusers, taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products and the increased or decreased likelihood that those who do not use tobacco products will start using such products.[vii]

It is well recognized that ENDS, and particularly flavored ENDS, pose a significant risk to nonusers, especially youth.[1,2] After observing a dramatic increase in the prevalence of ENDS use among U.S. youth in 2018, FDA's Commissioner characterized the problem as a youth vaping epidemic. FDA has initiated a series of actions to address the risk and reduce youth use. Since August 2016, FDA has issued more than 10,000 warning letters and more than 1,400 civil money penalty complaints to retailers for the sale of ENDS products to minors. FDA has also issued a guidance

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[vii] This review focuses on risk to youth nonusers and the potential benefit to adult smokers as current tobacco product users, given that these are the subpopulations that raise the most significant public health concerns and therefore are the most relevant in evaluating the impact on the population as a whole. FDA has also considered the APPH standard with respect to the likelihood that an authorization will increase or decrease the number of tobacco users in the overall population. The availability of such products has generally led to greater tobacco use among youth overall, notwithstanding the decrease in cigarette smoking for youth, which reinforces the focus in this review on having sufficiently reliable and robust evidence to justify authorization of these PMTAs. Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students – United States, 2011-2018," Morbidity and Mortality Weekly Report, 67(45);1276-1277, 2018.

that described a policy of prioritizing enforcement of non-tobacco/non-menthol flavored ENDS, "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization" (2020 Enforcement Priorities Guidance). In this guidance, FDA described evidence that shows flavors (other than tobacco and menthol) were a key driver of the surge in ENDS use among youth and thus prioritized enforcement against certain flavored ENDS products, with the goal of protecting youth from these products.[viii]

After FDA implemented this enforcement policy prioritizing enforcement against a subset of ENDS products known to appeal to youth, there was a meaningful reduction in youth use prevalence. Youth ENDS use peaked in 2019 when these products were widely available. Although several other policy changes and interventions were occurring during this same time period,[ix] it is reasonable to infer that prioritizing enforcement against many flavored products resulting

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[viii] Due to the overwhelming amount of evidence showing a substantial increase in youth use of flavored ENDS products, as well as their demonstrated popularity among youth, in January 2020, FDA finalized a guidance prioritizing enforcement against flavored (other than tobacco or menthol) prefilled pod or cartridge-based e-cigarettes, as well as other categories of unauthorized products.

[ix] The change in ENDS product availability coincided with other events such as the enactment of legislation raising the federal minimum age for sale of tobacco products from 18 to 21 years (Tobacco 21), the outbreak of e-cigarette, or vaping, product-use associated lung injury (EVALI), and public education campaigns which also may have contributed to the decline in ENDS use.

in their removal from the market contributed to the decline in use in 2020. Despite this decline, ENDS remained the most widely used tobacco product among youth, with youth use at levels comparable to what originally led FDA to declare a youth vaping epidemic. Moreover, despite the overall reduction in ENDS youth use observed in 2020, there was simultaneously a substantial rise in youth use of disposable ENDS, products that were largely excluded from the enforcement policy described in the 2020 Enforcement Priorities Guidance because, at that time that policy was developed, those products were the least commonly used device type among high school ENDS users and therefore remained on the market as a flavored option.[3,4]

Section 910(c)(2)(A) of the FD&C Act requires that FDA deny a PMTA where it finds "there is a lack of a showing that permitting such tobacco product to be marketed would be [APPH]." Through the PMTA review process, FDA conducts a science-based evaluation to determine whether marketing of a new tobacco product is APPH. Section 910(c)(4) requires FDA, in making the APPH determination, to consider the risks and benefits to the population as a whole, including users and nonusers of tobacco, and take into account, among other things, the likelihood that those who do not use tobacco products will start using them. FDA's scientific review is not limited to considering only information in a PMTA, but also extends to any other information before the Agency, including the relevant existing scientific literature (See Section 910(c)(2)). As described in greater detail below, in reviewing PMTAs for flavored ENDS, FDA

evaluates, among other things, the potential benefit to adult smokers who may transition away from combustible cigarettes to the ENDS product, weighed against the known risks of flavored ENDS to youth.

2.3.1. The Risk to Youth of Flavored ENDS Products

As noted, the APPH determination includes an assessment of the risks and benefits to the population as a whole, and for ENDS (as well as many other tobacco products) the application of that standard requires assessing the potential impact of the marketing of a new product on youth use. As a group, youth are considered a vulnerable population for various reasons, including that the majority of tobacco use begins before adulthood[5] and thus youth are at particular risk of tobacco initiation. In fact, use of tobacco products, no matter what type, is almost always started and established during adolescence when the developing brain is most vulnerable to nicotine addiction. Indeed, almost 90 percent of adult daily smokers started smoking by the age of 18.[6] Adolescent tobacco users who initiated tobacco use at earlier ages were more likely than those initiating at older ages to report symptoms of tobacco dependence, putting them at greater risk for maintaining tobacco product use into adulthood.[7] On the other hand, youth and young adults who reach the age of 26 without ever starting to use cigarettes will most likely never become a daily smoker.[6] Because of the lifelong implications of nicotine dependence that can be established in youth, preventing tobacco use initiation in young people is a central priority for protecting population health.

2.3.1.1. Youth use of flavored ENDS

ENDS are now the most commonly used type of tobacco product among youth. In 2020, approximately 19.6% of U.S. high school students and 4.7% of middle school students were current users of ENDS, corresponding to 3.6 million youth and making ENDS the most widely used tobacco product among youth by far.[8] As noted above, this was a decline from 2019, when 27.5% of high school and 10.5% of middle school students reported ENDS use,[9] which necessitated the FDA enforcement policy described above.

The evidence shows that the availability of a broad range of flavors is one of the primary reasons for the popularity of ENDS among youth. The majority of youth who use ENDS report using a flavored ENDS product, and the use of flavored ENDS has increased over time. In the 2014 National Youth Tobacco Survey (NYTS), 65.1% of high school and 55.1% of middle school e-cigarette[x] users reported using a flavored e-cigarette.[10] By the 2020 NYTS, the proportion of e-cigarette users reporting using a flavored product[xi] increased to 84.7% of high school users and 73.9% of middle school users.[3] Among high school e-cigarette users, the most common flavors used in 2020 were fruit (73.1%); mint (55.8%); menthol (37.0%); and candy, dessert, or other sweets (36.4%).[3] Among middle school e-cigarette users, the most common flavors used in

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[x] We use "e-cigarette" here to be consistent with the survey, but we interpret it to have the same meaning as ENDS.

[xi] Flavored product use in these studies means use of flavors other than tobacco.

2020 were fruit (75.6%); candy, desserts, or other sweets (47.2%); mint (46.5%); and menthol (23.5%).[3]

Youth ENDS users are also more likely to use flavored ENDS compared to adult ENDS users. In PATH Wave 5.5 from 2020, 66.8% of youth ENDS users aged 13 to 17 reported using fruit, followed by 53.8% for mint/menthol[xii], 23.5% for candy/dessert/other sweets, and 13.3% for tobacco flavor (internal analysis). In the 2020 PATH Adult Telephone Survey, 51.5% of adult ENDS users 25 and older used fruit, 30.4% used mint/menthol, 23.8% used candy/dessert/other sweets, and 22.3% used tobacco flavor (internal analysis). Youth current ENDS users were also more likely than adult current ENDS users to use more than one flavor and to use combinations that did not include tobacco flavors.[11]

Studies show that flavors influence youth initiation of ENDS use. In particular, data show that flavors are associated with product initiation, with the majority of users reporting that their first experience with ENDS was with a flavored product. For instance, in Wave 1 of the PATH Study from 2013-2014, over 80% of youth aged 12-17, 75% of young adults 18-24, and 58% of adults 25 and older reported that the first e-cigarette that they used was flavored.[12] In another PATH study, more youth, young adults and adults who initiated e-cigarette use between Wave 1 and Wave 2 reported use of a flavored product than a non-flavored product.[13]

[xii] The PATH Study Questionnaire from Wave 5.5 did not assess mint and menthol separately. However, subsequent data collections (ATS and Wave 6) have separated the two flavors.

Finally, in PATH Wave 4 from 2016-2017, 93.2% of youth and 83.7% of young adult ever ENDS users reported that their first ENDS product was flavored compared to 52.9% among adult ever users 25 and older.[14]

In addition, nationally representative studies find that when asked to indicate their reasons for using ENDS, youth users consistently select flavors as a top reason.[15,16] In fact, among Wave 4 youth current ENDS users, 71% reported using ENDS "because they come in flavors I like."[14]

One explanation for this high prevalence and increase in frequency of use is that flavors can influence the rewarding and reinforcing effects of e-liquids, thereby facilitating ENDS use and increasing abuse liability. Research shows that flavored ENDS are rated as more satisfying than non-flavored ENDS, and participants will work harder for and take more puffs of flavored ENDS compared to non-flavored ENDS.[17] Research also shows that flavors can increase nicotine exposure by potentially influencing the rate of nicotine absorption through pH effects and by promoting the reward of ENDS use.[18] Together, this evidence suggests flavored ENDS may pose greater addiction risk relative to tobacco-flavored ENDS, which increases concerns of addiction in youth, particularly due to the vulnerability of the developing adolescent brain, which is discussed further below.

Finally, existing literature on flavored tobacco product use suggests that flavors not only facilitate initiation, but also promote established regular ENDS use. In particular, the flavoring in tobacco products (including

ENDS) make them more palatable for novice youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use. For example, regional studies have found that the use of flavored e-cigarettes was associated with a greater frequency of e-cigarettes used per day among a sample of adolescents in Connecticut in 2014[19] and continuation of e-cigarette use in a sample of adolescents in California from 2014-2017.[20] Use of non-traditional flavors (vs. tobacco, mint/menthol, flavorless) was associated with increased likelihood of continued use and taking more puffs per episode.[20] Data from a regional survey in Philadelphia, PA found initial use of a flavored (vs. unflavored or tobacco-flavored) ENDS was associated with progression to current ENDS use as well as escalation in the number of days ENDS were used across 18 months.[21] Finally, similar effects have been found in the nationally representative PATH study among young adults (18-24 years), where "ever use" of flavored e-cigarettes at Wave 1 was also associated with increased odds of current regular ENDS use a year later at Wave 2.[22] In sum, flavored ENDS facilitate both experimentation and progression to regular use, which could lead to a lifetime of nicotine dependence.

2.3.1.2. The appeal of flavors across ENDS devices

The role of flavors in increasing the appeal of tobacco products to youth – across tobacco product categories – is well-established in the literature.[23-26] The published literature is sufficient to demonstrate the substantial appeal to youth of flavored ENDS, because it is robust

and consistent. As described above, the preference for use of flavored ENDS among youth is consistently demonstrated across large, national surveys and longitudinal cohort studies.

National surveillance data suggest that, within the ENDS category, there is variability in the popularity of device types among youth, suggesting there may be differential appeal of certain product styles. Still, across these different device types, the role of flavor is consistent. As described above, the majority of youth ENDS use involves flavored products: in 2020, the majority of high school and middle school current e-cigarette users reported use of non-tobacco-flavored products (82.9%)[3] and flavored use was favored among both users of closed (87%) and open (76%) ENDS (internal analysis). In particular, across device types, including prefilled pods/cartridges, disposables, tanks, and mod systems, fruit was the most commonly used flavor type among youth, with 66.0% for prefilled pods/cartridges, 82.7% for disposables, 81.7% for tanks, and 78.9% for mod systems among youth reporting using a fruit flavor.[3]

It is also worth noting that the preference for device types and popularity of certain styles is likely fluid and affected by the marketplace, that is, the options, especially flavors, that are available for consumers to choose from. Some evidence for this was observed in the trends both leading up to, and coinciding with, the shifting marketplace following the 2020 Enforcement Priorities Guidance. In particular, the enormous rise in youth ENDS use from 2017-2019 coincided with the ascendance of JUUL (and copy-cat devices) in the

marketplace, suggesting a relationship between the availability of JUUL as an option, and the sudden popularity of pod-based devices.[xiii] Then, as noted earlier, when FDA changed its enforcement policy to prioritize pod-based flavored ENDS, which were most appealing to youth at the time, we subsequently observed a substantial rise in use of disposable flavored ENDS[xiv]--a ten-fold increase (from 2.4% to 26.5%) among high school current e-cigarette users.[4] This trend illustrates that the removal of one flavored product option prompted youth to migrate to another ENDS type that offered the desired flavor options, underscoring the fundamental role of flavor in driving appeal.

2.3.1.3. The harms of youth ENDS use: The adolescent brain and risk for addiction

In addition to the high prevalence of youth ENDS use, the data also suggest this use is leading to increases in nicotine dependence.[10] Indeed, responding to concerns related to youth ENDS dependence, at the end of 2018,

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[xiii] This is borne out by the data from 2019 NYTS, in which 59.1% of high school ENDS users reported use of this one brand. Cullen KA, Gentzke AS, Sawdey MD, et al. e-Cigarette Use Among Youth in the United States, 2019. Jama. 2019;322(21):2095-2103.

[xiv] In July 2020, FDA issued Warning letters to three companies for illegally marketing disposable e-cigarettes and for marketing unauthorized modified risk tobacco products.

FDA held a public hearing to discuss the potential role of drug therapies to support e-cigarette cessation.[xv]

In 2019, an estimated 30.4% of middle and high school student ENDS users reported frequent use (i.e., use on ≥20 of the past 30 days).[9] By school type, 34.2% (95% Cl, 31.2%-37.3%) of high school student ENDS users and 18.0% (95% Cl, 15.2%-21.2%) of middle school student ENDS users reported frequent use.[27] Among current ENDS users, 21.4% of high school users and 8.8% of middle school users reported daily ENDS use.[27] Additionally, in a study that examined changes in ENDS use in youth ages 13-18 over a 12-month period, nicotine dependence (measured using the Penn State Electronic Cigarette Dependence Index (PS-ECDI)[28,29] and salivary cotinine concentrations increased, indicating continued ENDS use and greater nicotine exposure over time.[30]

Youth and young adult brains are more vulnerable to nicotine's effects than the adult brain due to ongoing neural development.[31,32] Adolescence is a developmental period consisting of major neurobiological and psychosocial changes and is characterized by increased reward-seeking and risk-taking behaviors (e.g., experimentation with drugs), coupled with heightened sensitivity to both natural and drug rewards and an immature self-regulatory system that is less able to modulate reward-seeking impulses (e.g., diminished harm avoidance, cognitive control, self-regulation).[33-37]

[xv] On December 5, 2018, FDA hosted a public hearing on "Eliminating Youth Electronic Cigarette and Other Product Use: The Role of Drug Therapies."

Furthermore, evidence from animal studies suggests that nicotine exposure during adolescence enhances the rewarding and reinforcing effects of nicotine in adulthood[38-41]; and can induce short and long-term deficits in attention, learning, and memory.[42-45]

2.3.1.4. Risk of progression from ENDS to other tobacco products of different health risk

Among youth who use ENDS, there is a risk of progression to other tobacco products of generally greater health risk. A 2017 systematic review and meta-analysis that summarized nine prospective cohort studies found significantly higher odds of smoking initiation (OR = 3.50, 95% Cl: 2.38, 5.16) and past 30-day combusted cigarette use (OR = 4.28, 95% Cl: 2.52, 7.27) among youth who had used ENDS at compared to youth who had not used ENDS.[46] Similar associations have been observed in longitudinal studies that have been published since the Soneji et al. review.[42,47-56] The 2018 NASEM report concluded that there is substantial evidence that ENDS use increases risk of ever using combusted tobacco cigarettes among youth and young adults.[57] The transition from non-cigarette product use to combusted cigarette use has been observed for other non-cigarette products, such as cigars, as well.[58] Although it is challenging to empirically separate causality from shared risk factors among youth combusted cigarette and ENDS users, some studies have found an association between ENDS and subsequent combusted cigarette use while controlling for similar risk profiles.[54]

The precise relationship between youth ENDS use and youth smoking remains undetermined. On the one hand, the prevalence of combusted cigarette smoking in youth has continued to decline,[9,59,60] suggesting that youth use of ENDS has not significantly slowed or impeded that positive public health trajectory. On the other hand, there is a growing body of evidence showing a link between ENDS use and subsequent smoking among youth that raises significant concerns. This evidence also increases concern that over time—and particularly if youth ENDS use were to return to the rates seen in 2019 or worsen--the trend of declining cigarette smoking could slow or even reverse.

2.3.1.5. Other health risks associated with ENDS use

In addition to the risk of tobacco initiation and progression among youth, there is epidemiologic evidence from the cross-sectional[xvi] Behavioral Risk Factor Survey system (BRFSS) suggesting positive associations between ENDS use among those who never smoked and some health outcomes. Two studies found associations between ENDS use and self-reported history of asthma, chronic bronchitis, emphysema, or chronic obstructive pulmonary disease with increased ENDS use (i.e., daily use) relating to increased odds of disease.[61,62] Another found an association between ENDS use and respiratory symptoms in younger adults (ages 18-34) but not in older adults.[63] ENDS use has also resulted in acute

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[xvi] Cross-sectional surveys examine these relationships at a single point in time, and as a result, do not establish causality.

harm to individuals through battery explosion-related burns and e-liquid nicotine poisoning.[64-66] Ultimately, as this is still a relatively novel product category, much remains unknown about other potential long-term health risks.

2.3.1.6. Conclusion

The exponential growth in youth ENDS use observed from 2017 to 2019, and the enduring prevalence of youth ENDS use in the U.S. is alarming. Despite a reduction in youth use of ENDS from 2019 to 2020, there were still 3.6 million youth ENDS users in 2020 and the majority used a flavored ENDS product. Youth users are more likely to use flavored ENDS than adult ENDS users. Flavors are associated with ENDS initiation and progression among youth. The full extent of the harms of ENDS use are not yet known, but evidence to date suggests they include permanent effects of nicotine on the developing adolescent brain and the risk of nicotine addiction. Studies indicate an additive effect of e-liquid flavorings on the rewarding and reinforcing effects of nicotine containing e-liquids. Studies also demonstrate that e-liquid flavors affect nicotine exposure. Among youth who use ENDS, there is a risk of progression to other tobacco products with greater health risks including combustible cigarettes. Finally, though long-term health risks are not fully understood, studies suggest an association between never-smoking ENDS users and respiratory and cardiovascular health effects. This evidence demonstrates that flavored ENDS pose a significant risk to youth.

2.3.2. Balancing Known Risks to Youth with a Potential Benefit to Adults

Determining whether marketing a new product is APPH includes evaluating the risks and benefits to the population as a whole. This requires FDA to balance, among other things, the negative public health impact for nonusers against the potential positive public health impact for current tobacco users. Accordingly, for marketing of a new product to be found to be APPH, any risks posed by a new product to youth would need to be overcome by a sufficient benefit to adult users, and as the known risks increase, so too does the burden of demonstrating a substantial enough benefit. In the case of a new flavored ENDS product, the risk of youth initiation and use is substantial, given the clearly documented evidence described above. In order for marketing of a new flavored ENDS product to be found APPH, an applicant would have to show that the significant risk to youth could be overcome by likely benefits substantial enough such that the net impact to public health would be positive, taking into account all relevant evidence and circumstances, including whether there are effective limitations on youth access.

2.3.2.1. Potential benefit of new flavored ENDS

Current scientific literature demonstrates that ENDS are generally likely to have fewer and lower concentrations of harmful and potentially harmful constituents (HPHCs) than combustible cigarettes, and biomarker studies demonstrate significantly lower exposure to HPHCs among current exclusive ENDS users than current smokers.[57] However, whether this

is true for any particular new ENDS product, and the implications for health risks from a particular product, are considered on a case-by-case basis during the course of FDA's scientific review of a PMTA.

FDA also considers the potential that current cigarette smokers may experience a reduction in health risks if they switch completely to an ENDS, or if they use both products but substantially reduce their cigarette smoking. For a flavored ENDS product, assuming that the evaluation of the product shows the likelihood for lower HPHC exposure, then to demonstrate the likely individual and population benefit, applicants must demonstrate that current smokers are likely to start using the new ENDS product exclusively or predominantly (e.g., dual use with a significant smoking reduction).[64]

2.3.2.2. Behavioral evidence appropriate to demonstrate the potential benefit to smokers

FDA's PMTA review includes an evaluation of any potential benefits of the product for the likely users, such as a possible reduction in health risks. In general, as FDA stated in its guidance for PMTAs for ENDS,[xvii] an assessment of how a new product may be used by current smokers can be derived from a variety of sources. FDA may consider direct behavioral evidence on the specific products under review or indirect evidence derived from studies of behavioral intentions;

[xvii] Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry (p.47); October 2019 Public Meeting on Deemed Tobacco Product Applications

pharmacological studies of nicotine delivery, abuse liability, and/or use topography; and bridging from studies based on comparable products. Further, in the case of a flavored ENDS product, to demonstrate that the marketing of the new product is APPH, the magnitude of the likely benefit would have to be substantial enough to overcome the significant risk of youth uptake and use posed by the flavored ENDS product.

Section 910(c)(5) of the FD&C Act provides that determining whether marketing of a new tobacco product is APPH shall, when appropriate, be based on "well-controlled investigations, which may include one or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product." FDA believes well-controlled investigations are "appropriate" for demonstrating that permitting the marketing of specific flavored ENDS would be APPH given the significant risks to youth of flavored ENDS. One type of well-controlled investigation that could effectively demonstrate a potential benefit of a flavored ENDS product would be an RCT. In addition, as CTP has previously described,[xviii] another well-controlled investigation that could serve as an alternative to conducting an RCT to demonstrate adequate benefit is a longitudinal cohort study.

For flavored ENDS, the known and substantial risk to youth in particular is high. Therefore, to show a net

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[xviii] Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry (p.47); October 2019 Public Meeting on Deemed Tobacco Product Applications

population health benefit, FDA has determined that these applications must demonstrate potential benefits to smokers from marketing such products with robust and reliable evidence – including both robust study design and methods and the strength of the study results. In other words, because the potential benefit to adults is gained through its impact on smoking behavior, FDA is reviewing these applications to determine whether they demonstrate that a benefit of a new product is significant enough to overcome the risk to youth. In particular, FDA's review of these applications has considered the degree of benefit to a flavored ENDS product over a tobacco-flavored variety in facilitating smokers completely switching or significantly reducing their smoking, given the significant increase in risk of youth initiation associated with flavored ENDS compared to tobacco-flavored ENDS. Note that applications with this type of information may still not be APPH: applications containing this evidence would still be evaluated to determine that the totality of the evidence supports a marketing authorization. As it relates to the risk to youth, for example, this assessment includes evaluating the appropriateness of the proposed marketing plan.[xix]

[xix] Limiting youth access and exposure to marketing is a critical aspect of product regulation. It is theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal such that the risk for youth initiation would be reduced. However, to date, none of the ENDS PMTAs that FDA has evaluated have proposed advertising and promotion restrictions that would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns, and supporting evidence, discussed above regarding

We have been using the APPH standard for several years in reviewing previous PMTAs for non-ENDS products. Our substantive review of PMTAs for ENDS and our completion of numerous scientific reviews over the last 10 months have deepened our understanding of the APPH evaluation with respect to behavior. In these reviews, the expectations for scientific evidence related to potential adult benefit can vary based on demonstrated risk to youth. Although indirect evidence or bridged data from the literature may still be appropriate for many new products, including tobacco-flavored ENDS, robust and direct evidence demonstrating potential benefit has been needed when the known risks are high as with all flavored ENDS products. At the same time, we have learned from experience that, in the absence of strong direct evidence, we are unable to reach a conclusion that the benefit outweighs the clear risks to youth. For instance, applicants who do not conduct their own behavioral studies must rely on, and bridge to, the general ENDS category literature to inform an evaluation of the potential benefit to adult users. To date, that approach has not been sufficient in our evaluation of flavored ENDS PMTAs because, in contrast to the evidence related to youth initiation—which shows clear and consistent patterns of real-world use that support strong conclusions--the evidence regarding the role of

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youth use. Similarly, we are not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use ENDS. Accordingly, for the sake of efficiency, the evaluation of the marketing plans in applications will not occur at this stage of review, and we have not evaluated any marketing plans submitted with these applications.

flavors in promoting switching among adult smokers is far from conclusive.[xx] In fact, the findings are quite mixed and as a result the literature does not establish that flavors differentially promote switching amongst ENDS users in general. Aside from differences in study design/methods, the heterogeneity of the existing literature is likely due, at least in part, to differences in the products studied. Therefore, given the state of the science on flavored ENDS, and the known risks to youth, FDA has reviewed these applications for any acceptably strong product-specific evidence.

More specifically, in order to adequately assess whether such an added benefit has been demonstrated, FDA has reviewed these applications for product-specific[xxi] evidence that would enable a comparison

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[xx] This discrepancy between the literature for youth initiation and adult switching also likely reflects fundamental differences in the two outcomes being assessed—youth initiation and switching among adult smokers—and their determinants. For switching among adult smokers, the behavior change is occurring in the context of nicotine dependence. Thus, the specific product's ability to provide adequate reinforcement and continue to satisfy a smoker's cravings over time, which is a function of the design of the specific product itself, are critical factors in determining likelihood of continued use and the product's ability to promote switching. Whereas for youth initiation, experimentation among naïve or novice users is not driven by these factors.

[xxi] By product-specific, we mean the data are based on studies using the specific new products that are the subject of the application(s). If the applicant has a large number of product variants (e.g., nicotine concentration and/or flavor options), it may be justifiable to bridge data from a study including a subset of their products to one or more of their other products (not included in the study). In contrast, because of the need for product-specific

between the applications' new flavored products and an appropriate comparator tobacco-flavored product (both ENDS) in terms of their impact on tobacco use behavior among adult smokers. Consistent with section 910(c)(5), evidence generated using either an RCT design or longitudinal cohort study design is mostly likely to demonstrate such a benefit, although other types of evidence could be adequate if sufficiently reliable and robust, and will be evaluated on a case-by-case basis.[xxii]

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information, bridging from a different set of products (not the subject of the application) would not be appropriate here.

[xxii] Conversely, such longitudinal or product-specific data are not necessarily required to assess experimentation and appeal among youth. The available literature on youth initiation contains valid scientific evidence sufficient to evaluate the risk to youth of ENDS. The literature includes longitudinal cohort studies, such as the PATH study, which have been used to assess uptake of tobacco products, including flavored ENDS, among youth and young adults. These studies have evaluated the impact of flavors on the promotion of established regular use. Additionally, the literature includes large, nationally representative cross-sectional surveys, which are among the best available evidence to understand patterns of youth ENDS use and the key characteristics associated with such use These studies enable observation of youth behavior as it naturally occurs in representative samples of the U.S. population. These data available in the literature provide clear and overwhelming evidence that ENDS are the most widely used products by youth, the majority of youth users use a flavored ENDS, and that youth users are more likely to use flavored ENDS than adult ENDS users. We note that, in assessing the risks to youth from flavored ENDS, RCTs are not possible because it would be unethical to randomize youth never or naive users to try a particular ENDS to examine what impact it would have on initiation, experimentation, or progression to regular use.

CTP will consider other types of evidence if it is sufficiently robust and direct to demonstrate the impact of the new ENDS on adult switching or cigarette reduction. Uptake and transition to ENDS use is a behavioral pattern that requires assessment at more than one time point. In addition, the transition from smoking to exclusive ENDS use typically involves a period of dual use. Therefore, evaluating the behavioral outcomes needed to show any benefit of the product requires observing the actual behavior of users over time. With both RCT and cohort study designs, enrolled participants are followed over a period of time, with periodic and repeated measurement of relevant outcomes.

In contrast, cross-sectional surveys entail a one-time assessment of self-reported outcomes: although participants can be asked to recall their past behavior, the single data collection does not enable reliable evaluation of behavior change over time. Consumer perception studies (surveys or experiments) typically assess outcomes believed to be precursors to behavior, such as preferences or intentions related to the new products, but are not designed to directly assess actual product use behavior. Moreover, the general scientific literature, though informative for evaluation of some types of products, is not adequate to address this assessment because it does not provide product-specific information. This is because the effectiveness of a product in promoting switching among smokers arises from a combination of its product features—including labeled characteristics like flavor and nicotine concentration—as well as the sensory and subjective experience of use (taste, throat hit, nicotine delivery),

and can also be influenced by how the device itself looks and feels to the use.

While RCTs and cohort studies both enable direct assessment of behavioral outcomes associated with actual product use over time, there are pros and cons to each type of design. While RCTs afford greater control and internal validity; cohort studies enable stronger generalizability because conditions are closer to real-world. We are aware of these as trade-offs and generally do not favor one type over the other for addressing this question.

To be informative, a study using one of these two designs would measure the impact of use of the new or appropriate comparator product tobacco-flavored ENDS and flavored products on adult smokers' tobacco use behavior over time[xxiii]; include outcomes related to ENDS use and smoking behavior to assess switching and/or cigarette reduction; and enable comparisons of these outcomes based on flavor type. In some cases, evidence on each individual flavor option may not be feasible; bridging data from one of the applicant's flavors to other flavors of the applicant's in the same

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[xxiii] This could include studies that are long-term (i.e., six months or longer). In FDA's (2019) Guidance to Industry, "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems", FDA has previously stated that it did not expect that applicants would need to conduct long-term studies to support an application for ENDS. Because the behavior change of interest (switching or cigarette reduction) occurs over a period of time, it is possible that to observe these outcomes, investigators designing these studies may decide to follow participants over a period of six months or longer. However, it is also possible that studies with a shorter duration would be adequately reliable.

flavor category (e.g., "fruit") may be appropriate. Furthermore, consistent with previous FDA guidance, we would expect the applicant to provide justification to support this bridging.[xxiv] Likewise, if a flavor is tested with one nicotine concentration, it may be feasible for the applicant to bridge the study results to other nicotine concentrations, under certain circumstances, and with the appropriate justification for bridging.

Data from one of these studies could support a benefit to adult users if the findings showed that, compared to the new tobacco-flavored product, use of (each) new flavored product is associated with greater likelihood of either of these behavioral outcomes for adult smokers: (1) complete switching from cigarettes to exclusive new product use or (2) significant reduction in cigarettes per day (CPD).

2.3.2.3. Conclusion

Given the known and substantial risk to youth posed by flavored ENDS, FDA has reviewed these applications for the presence of particularly reliable product-specific[xxv] evidence to demonstrate a potential

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[xxiv] Bridging is discussed in FDA's 2019 Guidance to Industry cited above (fn xxiii).

[xxv] By product-specific, we mean the data are based on studies using the specific new products that are the subject of the application(s). If the applicant has a large number of product variants (e.g., nicotine concentration and/or flavor options), it may be justifiable to bridge data from a study including a subset of their products to one or more of their other products (not included in the study). In contrast, because of the need for product-specific

for benefit to adult smokers that could justify that risk. Based on our current understanding, a demonstration with sufficiently reliable and robust evidence that the flavored ENDS have an added benefit relative to tobacco-flavored ENDS in facilitating smokers completely switching or reducing their smoking could demonstrate the potential benefit to current users that would outweigh the risk to youth posed by flavored ENDS.

2.4. SCOPE OF REVIEW

The reviews evaluated whether the subject PMTAs contain evidence from a randomized controlled trial, longitudinal cohort study, and/or other evidence regarding the impact of the new products on switching or cigarette reduction that could potentially demonstrate the added benefit to adult users of their flavored ENDS over an appropriate comparator tobacco-flavored ENDS. These reviews included a search of the PMTAs to determine whether the evidence is found anywhere within the PMTAs, and if present, if certain conditions were met (e.g., was the randomized controlled trial conducted using the new products that are the subject of the PMTA). Our review also included a search for other studies that provided product-specific evidence related to the potential benefit to adult users.

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information, bridging from a different set of products (not the subject of the application) would not be appropriate here.

3. SCIENTIFIC REVIEW

Reviews were completed by Carol Christensen and Dannielle Kelley on September 16, 2021.

The reviews determined that the PMTAs did not contain evidence from a randomized controlled trial and/or longitudinal cohort study examining the benefit to adult users of their flavored ENDS over an appropriate comparator tobacco-flavored ENDS in terms of switching from or reducing cigarettes. Our review also did not identify other evidence that supports this finding.

4. ENVIRONMENTAL DECISION

Under 21 CFR 25.35(b), issuance of an order under section 910(c) of the Federal Food, Drug, and Cosmetic Act that a new product may not be introduced or delivered for introduction into interstate commerce (i.e., a marketing denial order) falls within a class of actions that are ordinarily categorically excluded from the preparation of an environmental assessment (EA) or environmental impact statement (EIS). To the best of our knowledge, no extraordinary circumstances exist that would preclude application of this categorical exclusion. FDA concludes that categorical exclusion is warranted and no EA or EIS is required.

5. CONCLUSION AND RECOMMENDATION

FDA has reviewed these applications for evidence demonstrating that the new flavored products will provide an added benefit to adult smokers relative to tobacco-flavored products. Based on our review, we determined that the PMTAs for the applicant's new

products, as described in the applications and specified in Appendix A, lack sufficient evidence to demonstrate that permitting the marketing of the new products would be APPH. Thus, a Denial letter should be issued to the applicant. The applicant cannot introduce or deliver for introduction these products into interstate commerce in the United States. Doing so is a prohibited act under section 301(a) of the FD&C Act, the violation of which could result in enforcement action by FDA.

The following deficiency should be conveyed to the applicant as the key basis for our determination that marketing of the new products is not APPH:

1. All of your PMTAs lack sufficient evidence demonstrating that your flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth. In light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the magnitude of the potential benefit to adult smokers. This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS. Alternatively, FDA would consider other evidence but only if it reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on adult smokers' switching or cigarette reduction over time. We did not find such evidence in your PMTAs. Without this information, FDA concludes that your application is insufficient to

demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth and, therefore, cannot find that permitting the marketing of your new tobacco products would be appropriate for the protection of the public health.

6. APPENDIX

Appendix A. New Products[xxvi,xxvii] (Attached)

Common Attributes	
Submission date	September 8, 2020, September 9, 2020
Receipt date	September 8, 2020, September 9, 2020
Applicant	Lotus Vaping Technologies LLC
Product manufacturer	Lotus Vaping Technologies LLC
Product category	ENDS (VAPES)
Product subcategory	ENDS Component

[xxvi] We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.

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

[*See next 5 pages for Fold-out Exhibit*]

Appendix A

STN	PD Number	Product Name	Category	Subcategory	Package Type	Package Quantity	Characterizing Flavor	Additional Property
PM0002365	PD2	Lotus Originals Apple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Apple	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002365	PD4	Lotus Originals Apple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Apple	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002365	PD3	Lotus Originals Apple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Apple	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002365	PD1	Lotus Originals Apple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Apple	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001579	PD1	Lotus Originals Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Banana	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001579	PD4	Lotus Originals Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Banana	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001579	PD3	Lotus Originals Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Banana	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001579	PD2	Lotus Originals Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Banana	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002468	PD2	Lotus Originals Black Walnut	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Black Walnut	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002468	PD1	Lotus Originals Black Walnut	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Black Walnut	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002468	PD4	Lotus Originals Black Walnut	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Black Walnut	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002468	PD3	Lotus Originals Black Walnut	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Black Walnut	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD25	Nomenon Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 0 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD26	Nomenon Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 3 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD38	Nomenon Ice Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 3 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD30	Nomenon Blunomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD37	Nomenon Ice Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 0 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD28	Nomenon Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 12 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD27	Nomenon Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 6 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD39	Nomenon Ice Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 6 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD29	Nomenon Blunomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD40	Nomenon Ice Blunomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blue Raspberry	Nicotine: 12 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0001573	PD1	Lotus Originals Blueberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001573	PD3	Lotus Originals Blueberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001573	PD4	Lotus Originals Blueberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001573	PD2	Lotus Originals Blueberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001761	PD3	Exotics Blue Pom	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Pomegranate	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001761	PD1	Exotics Blue Pom	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Pomegranate	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001761	PD4	Exotics Blue Pom	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Pomegranate	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001761	PD2	Exotics Blue Pom	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Pomegranate	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001782	PD4	Exotics Blue Raz	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Raspberry	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001782	PD3	Exotics Blue Raz	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Raspberry	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001782	PD1	Exotics Blue Raz	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Raspberry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001782	PD2	Exotics Blue Raz	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Blueberry Raspberry	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002368	PD1	Lotus Originals Caramel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Caramel	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002368	PD2	Lotus Originals Caramel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Caramel	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002368	PD3	Lotus Originals Caramel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Caramel	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002368	PD4	Lotus Originals Caramel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Caramel	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001787	PD1	Exotics Cherry Bomb	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001787	PD4	Exotics Cherry Bomb	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001787	PD2	Exotics Cherry Bomb	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001787	PD3	Exotics Cherry Bomb	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD119	Noms X2 X2 Cherry Lime Ginger	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 0 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD121	Noms X2 X2 Cherry Lime Ginger	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 6 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD120	Noms X2 X2 Cherry Lime Ginger	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 3 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD76	Noms X2 Cherry Lime Ginger Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD77	Noms X2 Cherry Lime Ginger Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cherry	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0002456	PD1	Lotus Originals Cigar	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cigar	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002456	PD3	Lotus Originals Cigar	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cigar	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002456	PD2	Lotus Originals Cigar	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cigar	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002456	PD4	Lotus Originals Cigar	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cigar	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002460	PD1	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cinnamon Candy	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002460	PD3	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cinnamon Candy	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002460	PD4	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cinnamon Candy	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002460	PD2	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Cinnamon Candy	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002506	PD1	Exotics Citron	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Citrus	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002506	PD2	Exotics Citron	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Citrus	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002506	PD4	Exotics Citron	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Citrus	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002506	PD3	Exotics Citron	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Citrus	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001549	PD3	Lotus Originals Coffee	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001549	PD1	Lotus Originals Coffee	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL

PM0001549	PD4	Lotus Originals Coffee	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001549	PD2	Lotus Originals Coffee	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001788	PD3	Exotics Irish Latte	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001788	PD4	Exotics Irish Latte	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001788	PD2	Exotics Irish Latte	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001788	PD1	Exotics Irish Latte	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Coffee	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD18	All Day Vapes Non Stop Custard Cream	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Custard	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD17	All Day Vapes Non Stop Custard Cream	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Custard	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD19	All Day Vapes Non Stop Custard Cream	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Custard	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL, 1
PM0003715	PD20	All Day Vapes Non Stop Custard Cream	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Custard	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0002372	PD1	Exotics Raging Bull	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Energy Drink	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002372	PD4	Exotics Raging Bull	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Energy Drink	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002372	PD3	Exotics Raging Bull	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Energy Drink	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002372	PD2	Exotics Raging Bull	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Energy Drink	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002534	PD1	Exotics Tropic Passion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Exotic Fruit Medley	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002534	PD4	Exotics Tropic Passion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Exotic Fruit Medley	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002534	PD2	Exotics Tropic Passion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Exotic Fruit Medley	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002534	PD3	Exotics Tropic Passion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Exotic Fruit Medley	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD61	LQiD Fins Out	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fins Out	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD59	LQiD Fins Out	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fins Out	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD60	LQiD Fins Out	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fins Out	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0002462	PD1	Exotics Fusion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fruit Punch	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002462	PD4	Exotics Fusion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fruit Punch	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002462	PD3	Exotics Fusion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fruit Punch	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002462	PD2	Exotics Fusion	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Fruit Punch	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002455	PD2	Lotus Originals Grape	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002455	PD1	Lotus Originals Grape	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002455	PD4	Lotus Originals Grape	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002455	PD3	Lotus Originals Grape	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD35	Nomenon Grapenomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD34	Nomenon Grapenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 12 mg/mL, PG/VG: 29/71 E-liquid Volume: 120 mL
PM0003715	PD33	Nomenon Grapenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 6 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD31	Nomenon Grapenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 0 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD32	Nomenon Grapenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 3 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD36	Nomenon Grapenomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grape	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0002516	PD3	Lotus Originals Grapefruit	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grapefruit	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002516	PD1	Lotus Originals Grapefruit	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grapefruit	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002516	PD4	Lotus Originals Grapefruit	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grapefruit	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002516	PD2	Lotus Originals Grapefruit	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Grapefruit	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD122	Noms X2 X2 Kiwi Passion Fruit Nectarine	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Guava	Nicotine: 0 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD123	Noms X2 X2 Kiwi Passion Fruit Nectarine	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Guava	Nicotine: 3 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD124	Noms X2 X2 Kiwi Passion Fruit Nectarine	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Guava	Nicotine: 6 mg/mL, PG/VG: 28.5/71.5, E-liquid Volume: 120 mL
PM0003715	PD63	LQiD Hodad	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Hodad	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD64	LQiD Hodad	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Hodad	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD62	LQiD Hodad	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Hodad	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD116	Noms X2 X2 Cactus Jackfruit Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD117	Noms X2 X2 Cactus Jackfruit Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD118	Noms X2 X2 Cactus Jackfruit Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD74	Noms X2 Cactus Jackfruit Mandarin Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD75	Noms X2 Cactus Jackfruit Mandarin Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Juicy Fruit	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD66	LQiD Kahuna	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Kahuna	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD65	LQiD Kahuna	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Kahuna	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD67	LQiD Kahuna	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Kahuna	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD41	Nomenon Ice Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 0 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD44	Nomenon Ice Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 12 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD43	Nomenon Ice Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 6 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD58	Nomenon Lemonomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD54	Nomenon Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 3 mg/mL, PG/VG: 30.50/69.50, E-liquid Volume: 120 mL
PM0003715	PD53	Nomenon Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 0 mg/mL, PG/VG: 30.50/69.50, E-liquid Volume: 120 mL
PM0003715	PD56	Nomenon Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 12 mg/mL, PG/VG: 30.50/69.50, E-liquid Volume: 120 mL
PM0003715	PD42	Nomenon Ice Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 3 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD55	Nomenon Lemonomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 6 mg/mL, PG/VG: 30.50/69.50, E-liquid Volume: 120 mL

PM0003715	PD57	Nomenon Lemonomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Lemon	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0001930	PD1	Lotus Originals Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mandarin	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001930	PD3	Lotus Originals Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mandarin	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001930	PD2	Lotus Originals Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mandarin	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001930	PD4	Lotus Originals Mandarin	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mandarin	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001789	PD3	Exotics Mango Blast	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mango	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001789	PD4	Exotics Mango Blast	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mango	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001789	PD2	Exotics Mango Blast	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mango	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001789	PD1	Exotics Mango Blast	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mango	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001929	PD3	Lotus Originals Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001929	PD1	Lotus Originals Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001929	PD2	Lotus Originals Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001929	PD4	Lotus Originals Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD10	All Day Vapes Cool Minute Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD11	All Day Vapes Cool Minute Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD12	All Day Vapes Cool Minute Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD9	All Day Vapes Cool Minute Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Melon	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0001523	PD2	Lotus Originals Minty Mint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001523	PD3	Lotus Originals Minty Mint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001523	PD1	Lotus Originals Minty Mint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001523	PD4	Lotus Originals Minty Mint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD15	All Day Vapes Endless Spearmint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD14	All Day Vapes Endless Spearmint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD16	All Day Vapes Endless Spearmint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD13	All Day Vapes Endless Spearmint	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mint	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD8	All Day Vapes Berries for Days	ENDS(VAPES)	ENDS Component	Plastic Bottle	2 Bottle	Mixed Berries	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD6	All Day Vapes Berries for Days	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berries	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD7	All Day Vapes Berries for Days	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berries	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD5	All Day Vapes Berries for Days	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berries	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0002383	PD3	Exotics XXX Berry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berry	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002383	PD4	Exotics XXX Berry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berry	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002383	PD2	Exotics XXX Berry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berry	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002383	PD1	Exotics XXX Berry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Berry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD79	Noms X2 Kiwi Passionfruit Nectarine Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Fruit	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD78	Noms X2 Kiwi Passionfruit Nectarine Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Mixed Fruit	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0002377	PD2	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange Cranberry Fruit Punch	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002377	PD3	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange Cranberry Fruit Punch	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002377	PD4	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange Cranberry Fruit Punch	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002377	PD1	Exotics Tropic Rush	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange Cranberry Fruit Punch	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002458	PD2	Exotics Cali-Mist	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange lemon citrus	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002458	PD1	Exotics Cali-Mist	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange lemon citrus	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002458	PD3	Exotics Cali-Mist	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange lemon citrus	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002458	PD4	Exotics Cali-Mist	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Orange lemon citrus	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001784	PD1	Exotics Fuzzy Navel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001784	PD4	Exotics Fuzzy Navel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001784	PD3	Exotics Fuzzy Navel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001784	PD2	Exotics Fuzzy Navel	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD128	Noms X2 X2 White Peach Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD129	Noms X2 X2 White Peach Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0003715	PD130	Noms X2 X2 White Peach Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Peach	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 120 mL
PM0001944	PD1	Lotus Originals Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001944	PD3	Lotus Originals Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001944	PD4	Lotus Originals Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001944	PD2	Lotus Originals Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD1	All Day Vapes 24/7 Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD4	All Day Vapes 24/7 Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD3	All Day Vapes 24/7 Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD2	All Day Vapes 24/7 Pineapple	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pineapple	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD70	LQiD Pipe Line	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pipe Line	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD69	LQiD Pipe Line	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pipe Line	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD68	LQiD Pipe Line	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pipe Line	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0001790	PD4	Exotics Pomegranate	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pomegranate	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL

PM0001790	PD2	Exotics Pomegranate	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pomegranate	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001790	PD3	Exotics Pomegranate	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pomegranate	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001790	PD1	Exotics Pomegranate	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Pomegranate	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002509	PD1	Exotics Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Raspberry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002509	PD2	Exotics Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Raspberry	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002509	PD3	Exotics Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Raspberry	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002509	PD4	Exotics Raspberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Raspberry	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD72	LQiD Rip Tide	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rip Tide	Nicotine: 3 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD71	LQiD Rip Tide	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rip Tide	Nicotine: 0 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0003715	PD73	LQiD Rip Tide	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rip Tide	Nicotine: 6 mg/mL, PG/VG: 21/79, E-liquid Volume: 30 mL, 50 mL
PM0001948	PD4	Lotus Originals Rootbeer	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rootbeer	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001948	PD2	Lotus Originals Rootbeer	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rootbeer	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001948	PD1	Lotus Originals Rootbeer	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rootbeer	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001948	PD3	Lotus Originals Rootbeer	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Rootbeer	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001497	PD2	Lotus Originals Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001497	PD3	Lotus Originals Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001497	PD1	Lotus Originals Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001497	PD4	Lotus Originals Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD109	Nomenon Stranomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD105	Nomenon Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 3 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD104	Nomenon Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 0 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD108	Nomenon Stranomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD106	Nomenon Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 6 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD107	Nomenon Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 12 mg/mL, PG/VG: 32/68, E-liquid Volume: 120 mL
PM0003715	PD95	Teleos Pure Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD92	Teleos Pure Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD48	Nomenon Ice Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 12 mg/mL, PG/VG: 33.50/66.50, E-liquid Volume: 120 mL
PM0003715	PD94	Teleos Pure Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD45	Nomenon Ice Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 0 mg/mL, PG/VG: 33.50/66.50, E-liquid Volume: 120 mL
PM0003715	PD46	Nomenon Ice Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 3 mg/mL, PG/VG: 33.50/66.50, E-liquid Volume: 120 mL
PM0003715	PD47	Nomenon Ice Stranomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 6 mg/mL, PG/VG: 33.50/66.50, E-liquid Volume: 120 mL
PM0003715	PD93	Teleos Pure Strawberry	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0001487	PD3	Lotus Originals Strawberry Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001487	PD1	Lotus Originals Strawberry Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001487	PD2	Lotus Originals Strawberry Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001487	PD4	Lotus Originals Strawberry Banana	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD22	All Day Vapes Strawberry Banana Classic	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD21	All Day Vapes Strawberry Banana Classic	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD23	All Day Vapes Strawberry Banana Classic	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,1
PM0003715	PD24	All Day Vapes Strawberry Banana Classic	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Banana	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 15 mL, 30 mL, 60 mL,
PM0003715	PD126	Noms X2 X2 Phenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 3 mg/mL, PG/VG: 14.75/85.25, E-liquid Volume: 120 mL
PM0003715	PD127	Noms X2 X2 Phenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 6 mg/mL, PG/VG: 14.75/85.25, E-liquid Volume: 120 mL
PM0003715	PD125	Noms X2 X2 Phenomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 0 mg/mL, PG/VG: 14.75/85.25, E-liquid Volume: 120 mL
PM0003715	PD82	Nomenon Phenomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD83	Nomenon Phenomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Strawberry Lemon	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0001410	PD4	Lotus Originals Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 30 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001410	PD1	Lotus Originals Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001410	PD3	Lotus Originals Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 20 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0001410	PD2	Lotus Originals Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 10 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD103	Teleos Pure Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD102	Teleos Pure Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD101	Teleos Pure Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD100	Teleos Pure Vanilla	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD90	Teleos Pure RY4	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla Caramel Tobacco	Nicotine: 6 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD89	Teleos Pure RY4	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla Caramel Tobacco	Nicotine: 3 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD88	Teleos Pure RY4	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla Caramel Tobacco	Nicotine: 0 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0003715	PD91	Teleos Pure RY4	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Vanilla Caramel Tobacco	Nicotine: 12 mg/mL, PG/VG: 30/70, E-liquid Volume: 30 mL
PM0002461	PD3	Exotics Sweet Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 18 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002461	PD1	Exotics Sweet Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 0 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002461	PD2	Exotics Sweet Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 12 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0002461	PD4	Exotics Sweet Melon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 24 mg/mL, PG/VG: 40/60, E-liquid Volume: 15 mL
PM0003715	PD110	Nomenon Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 0 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL

PM0003715	PD115	Nomenon Watanomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD111	Nomenon Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 3 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD112	Nomenon Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 6 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD114	Nomenon Watanomenon Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD113	Nomenon Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 12 mg/mL, PG/VG: 29/71, E-liquid Volume: 120 mL
PM0003715	PD52	Nomenon Ice Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 12 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD49	Nomenon Ice Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 0 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD50	Nomenon Ice Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 3 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD51	Nomenon Ice Watanomenon	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	Watermelon	Nicotine: 6 mg/mL, PG/VG: 28.50/71.50, E-liquid Volume: 120 mL
PM0003715	PD81	Noms X2 White Peach Raspberry Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	White Peach Raspberry	Nicotine: 48 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL
PM0003715	PD80	Noms X2 White Peach Raspberry Salt	ENDS(VAPES)	ENDS Component	Plastic Bottle	1 Bottle	White Peach Raspberry	Nicotine: 24 mg/mL, PG/VG: 60/40, E-liquid Volume: 30 mL

Appendix B. Amendments Received

Submission Date	**Receipt Date**	**Amendment**	**Applications being amended**	**Reviewed**	**Brief Description**
August 23, 2021	August 23, 2021	PM0004954	All[xxviii]	Yes	Correction or clarification to the applications.
August 23, 2021	August 23, 2021	PM0004955	All	Yes	Correction or clarification to the applications.

[xxviii] This amendment applies to all STN subject of this review.

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APPENDIX F

RELEVANT STATUTORY PROVISIONS

STATUTORY PROVISIONS INVOLVED

A. 5 U.S.C. § 706(2) provides in pertinent part:

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

* * *

> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

* * *

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

B. 21 U.S.C. § 387j provides in pertinent part:

(a) In general. (1) New tobacco product defined. For purposes of this section the term "new tobacco product" means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required.

(A) New products. An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 905(j) [21 USCS § 387e(j)]; and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this Act [21 USCS §§ 301 et seq.]; or

> (ii) the tobacco product is exempt from the requirements of section 905(j) [21 USCS § 387e(j)] pursuant to a regulation issued under section 905(j)(3) [21 USCS § 387(j)(3)].
>
> (B) Application to certain post-February 15, 2007, products. Subparagraph (A) shall not apply to a tobacco product—
>
> (i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act [enacted June 22, 2009]; and
>
> (ii) for which a report was submitted under section 905(j) [21 USCS § 387e(j)] within such 21-month period, except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

C. 21 U.S.C. § 387*l*(b) provides:

Standard of review. Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5, United States Code [5 USCS §§ 701 et seq.], and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in

accordance with section 706(2)(A) of title 5, United States Code.