No. 24A_____

In the Supreme Court of the United States

JOHNNY COPPER, L.L.C.,
APPLICANT

v.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.
RESPONDENTS

APPENDIX TO EMERGENCY APPLICATION FOR A STAY OF AGENCY ORDER PENDING THE DISPOSITION BY THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT OF A PETITION FOR REVIEW

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APPENDIX

In the
United States Court of Appeals
For the Eleventh Circuit

No. 24-13302

JOHNNY COPPER LLC,

Petitioner,

versus

U.S. FOOD AND DRUG ADMINISTRATION,
COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondents.

Petition for Review of a Decision of the
Food and Drug Administration
Agency No. PM0003757

Before JORDAN, LUCK, and ABUDU, Circuit Judges.

BY THE COURT:

Petitioner's motion to stay the Respondent's marketing denial order is DENIED. *See Nken v. Holder*, 556 U.S. 418 (2009).[1]

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[1] Judge Luck would grant Johnny Copper LLC's stay request. *See FDA v. Wages & White Lion*, S. Ct. Case No. 23-1038 (argued December 2, 2024).

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

September 13, 2024

DENIAL

Johnny Copper LLC
Attention: Lorelei Harper
406 Walnut Street
Green Cove Springs, FL 32043

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

Dear Lorelei Harper:

We are denying a marketing granted order for the products identified in Appendix A.

The statute places the burden on the applicant to make the required showing by providing that FDA "shall deny an application" for a product to receive a PMTA marketing authorization if, "upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product," FDA finds that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health" (APPH). 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 APPH. 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. These actions may include, but are not limited to, civil money penalties, including an enhanced civil money penalty under FD&C Act section 303(f)(9)(B)(i), seizure, and/or injunction.

If you choose to submit new applications for these products, you must fulfill all requirements set forth in section 910(b)(1) and 21 CFR Part 1114. 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. 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. There is substantial evidence that flavored ENDS, like the subject products, have significant appeal to youth and are associated with youth initiation and use. The marketing restrictions and other mitigation measures that you proposed cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. In light of the known risks to youth of marketing flavored ENDS, robust and reliable

[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

evidence is needed regarding the benefit to adults who smoke, who switch completely or significantly reduce their smoking. Whether other products give adults who smoke comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the subject ENDS arguably provide to that population. Because tobacco-flavored ENDS have not been shown to present the same risks to youth as flavored ENDS, marketing of flavored ENDS is APPH only if the evidence shows a benefit to adults who smoke as compared to tobacco-flavored ENDS.

This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit to adults who use your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS. We did not find such evidence in your PMTA. FDA would also consider other evidence that reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on complete switching or significant cigarette reduction over time among adults who use combustible cigarettes. Although your PMTA contained three cross-sectional surveys on perceptions and use of combusted cigarettes and ENDS products, this evidence is not sufficient to show a benefit of using these flavored ENDS to adults who smoke because it does not evaluate the specific products in the application; evaluate complete switching or significant cigarette reduction resulting from use of these products over time; or evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors.

Without this information, FDA cannot determine whether 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 APPH. Because you have not met your burden of "showing" that permitting the marketing of the new products would be APPH as required by Section 910(c)(2)(A), we must deny authorization for your application.

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. Because you have not met your burden of "showing" that permitting the marketing of the new products would be APPH as required by Section 910(c)(2)(A), we are issuing a marketing denial 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 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 Fatima Sow, Regulatory Health Project Manager, at (301) 796-1751 or Fatima.Sow@fda.hhs.gov.

Sincerely,

Digitally signed by Benjamin Apelberg -S
Date: 2024.09.13 10:11:54 -04'00'

Benjamin Apelberg, Ph.D.
Deputy 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

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

Appendix A

New Tobacco Products Subject of This Letter

Common Attributes[7,8,9,10,11]	
Submit date	September 6, 2020
Receipt date	September 9, 2020
Applicant	Johnny Copper LLC
Product manufacturer	Johnny Copper LLC
Product category	Electronic Nicotine Delivery Systems (ENDS) (VAPES)
Product subcategory	ENDS Component

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

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

[9] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

[10] Attributes in Appendix A may display converted values.

[11] Attributes of certain products intentionally left blank, as there were not provided by the applicant.

STN	PD#	Product Name	Package Type	Package Type, if Other	Product Quantity Numeric Value	Units (Product Quantity)	Units, if Other (Product Quantity)	Characterizing Flavor	Characterizing Flavor, If Flavored	Nicotine Source	Additional Property
PM0003757	PD1	2 BERRIEZ 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD2	2 BERRIEZ 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD3	2 BERRIEZ 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD4	APPLEMANE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD5	APPLEMANE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD6	APPLEMANE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD7	BAM 0mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 0 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD8	BAM 3mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 3 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD9	BAM 6mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 6 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD10	BANANA NUT BREAD CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 60, 120 ml, 240 ml
PM0003757	PD11	BANANA NUT BREAD CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD12	BANANA NUT BREAD CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD13	BERRY DEW 0mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD14	BERRY DEW 3mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD15	BERRY DEW 6mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD16	BERRY MONTANA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD17	BERRY MONTANA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD18	BERRY MONTANA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD19	BLUEBERRY CRUNCH GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD20	BLUEBERRY CRUNCH GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD21	BLUEBERRY CRUNCH GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD22	BUTTERSCOTCH CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD23	BUTTERSCOTCH CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD24	BUTTERSCOTCH CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD25	CARMA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD26	CARMA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD27	CARMA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD28	CnK 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD29	CnK 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD30	CnK 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD31	DOVE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD32	DOVE 12mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 12 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD33	DOVE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD34	DOVE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD35	FATHEAD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD36	FATHEAD 12mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD37	FATHEAD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD38	FATHEAD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD39	FLAKEY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD40	FLAKEY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD41	FLAKEY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD42	FLAWLESS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD43	FLAWLESS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD44	FLAWLESS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD45	FRIGID 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD46	FRIGID 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD47	FRIGID 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD48	FROZEN 0mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen	Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD49	FROZEN 3mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD50	FROZEN 6mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD51	GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD52	GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD53	GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD54	GLIDER 0mg	Other	Bottle	1	Other	Bottle	Flavored	Traditional Tobacco	Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD55	GLIDER 12mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD56	GLIDER 3mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD57	GLIDER 6mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD58	Huckleberry Cheesecake 0mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD59	Huckleberry Cheesecake 3mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD60	Huckleberry Cheesecake 6mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD61	IGNITION 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD62	IGNITION 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

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PM0003757	PD63	IGNITION 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD64	JAG 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD65	JAG 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD66	JAG 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD67	JOHNNY CANNOLI 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD68	JOHNNY CANNOLI 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD69	JOHNNY CANNOLI 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD70	KRAMPUS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD71	KRAMPUS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD72	KRAMPUS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD73	LEMON CREAM GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD74	LEMON CREAM GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD75	LEMON CREAM GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD76	LOVE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD77	LOVE 12mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD78	LOVE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD79	LOVE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD80	LOVE MENTHOL 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD81	LOVE MENTHOL 12mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD82	LOVE MENTHOL 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD83	LOVE MENTHOL 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD84	MAGOO 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD85	MAGOO 3mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD86	MAGOO 6mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD87	MARDI GRAS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD88	MARDI GRAS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD89	MARDI GRAS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD90	MAUI 0mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 0mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD91	MAUI 3mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD92	MAUI 6mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD93	NEW YORK STRAWBERRY CHEESECAKE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD94	NEW YORK STRAWBERRY CHEESECAKE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD95	NEW YORK STRAWBERRY CHEESECAKE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD96	ORIGINAL G 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD97	ORIGINAL G 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD98	ORIGINAL G 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD99	PADME 0mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD100	PADME 3mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD101	PADME 6mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD102	PARADISE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD103	PARADISE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD104	PARADISE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD105	PEACH ICE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD106	PEACH ICE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD107	PEACH ICE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD108	POLAR BLAST 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD109	POLAR BLAST 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD110	POLAR BLAST 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD111	POLAR MELON 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 0 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD112	POLAR MELON 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 3 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD113	POLAR MELON 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 6 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD114	RANGER 0mg	Other	Bottle	1	Other	Bottle	Menthol		Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD115	RANGER 12mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD116	RANGER 3mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD117	RANGER 6mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD118	RASPBERRY APPLE CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD119	RASPBERRY APPLE CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD120	RASPBERRY APPLE CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD121	RAZZ THE CHERRY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD122	RAZZ THE CHERRY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD123	RAZZ THE CHERRY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD124	SALTY GRANDMA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD125	SALTY GRANDMA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD126	SALTY GRANDMA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD127	SAMOA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD128	SAMOA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD129	SAMOA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD130	SLIM WHITTMAN 0mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD131	SLIM WHITTMAN 12mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD132	SLIM WHITTMAN 3mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD133	SLIM WHITTMAN 6mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD134	SMEXY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD135	SMEXY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD136	SMEXY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD137	STRAWBERRY GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD138	STRAWBERRY GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD139	STRAWBERRY GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD140	STRAWBERRY GRAHAM CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD141	STRAWBERRY GRAHAM CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD142	STRAWBERRY GRAHAM CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD143	THE OC 0mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD144	THE OC 3mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD145	THE OC 6mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD146	VANILLA BOURBON CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD147	VANILLA BOURBON CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD148	VANILLA BOURBON CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD149	WATERMALONE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD150	WATERMALONE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD151	WATERMALONE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD152	YUUM 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD153	YUUM 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD154	YUUM 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

U.S. FOOD & DRUG ADMINISTRATION

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

September 7, 2021

DENIAL

Johnny Copper LLC
Attention: Lorelei Harper, Business Director
406 Walnut Street
Green Cove Springs, FL 32043

FDA Submission Tracking Number (STN): PM0003757, see Appendix A

Dear Ms. Harper:

We are denying a marketing granted order for the products identified in Appendix A.

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 PMTA 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 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. Although your PMTAs contained a literature review, this evidence is not sufficient to show a benefit to adult smokers of using these flavored ENDS because it does not evaluate the specific products in the applications.

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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

> 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 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.

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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

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

If you have any questions, please contact Fatima Sow, Regulatory Health Project Manager, at (301) 796- 1751 or Fatima.Sow@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2021.09.07 14:00:07 -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

U.S. FOOD & DRUG ADMINISTRATION

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

August 02, 2024

RESCISSION OF MARKETING DENIAL

Johnny Copper LLC
Attention: Lorelei Harper, Business Director
406 Walnut Street
Green Cove Springs, FL 32043

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

Dear Lorelei Harper:

On September 7, 2021, you received a Marketing Denial Order ("MDO") stating that your new products, as described in your applications (see Appendix A), lack sufficient evidence to demonstrate that permitting the marketing of the products is appropriate for the protection of the public health (APPH). In light of the United States Court of Appeals for the Eleventh Circuit's August 23, 2022, opinion in Johnny Copper LLC v. FDA, (No. 21-13438), FDA is rescinding the September 7, 2021, MDO letter for PM0003757.

With this rescission, your tobacco products identified in Appendix A are placed back into the review process. FDA may reach out if additional steps or information is necessary. This may include but is not limited to FDA requesting to conduct manufacturing inspections or notifying you if samples are required for independent testing and verification.

If you have any questions, please contact Fatima Sow, Regulatory Health Project Manager, at (301) 796-1751 or Fatima.Sow@fda.hhs.gov.

Sincerely,

Digitally signed by Benjamin Apelberg -S
Date: 2024.08.02 10:41:26 -04'00'

Benjamin Apelberg, Ph.D.
Deputy Director
Office of Science
Center for Tobacco Products

Enclosure:

Appendix A – New Tobacco Products Subject of This Letter

Appendix A[1,2,3,4]

New Tobacco Products Subject of This Letter

Common Attributes	
Submit Date	September 6, 2020
Receipt Date	September 9, 2020
Applicant	Johnny Copper LLC
Product Manufacturer	Johnny Copper LLC
Product Category	Electronic Nicotine Delivery Systems (ENDS) (VAPES)
Product Subcategory	ENDS Component

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

[2] Product name is the brand/sub-brand or other commercial name used in commercial distribution.

[3] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

[4] Attributes in Appendix A may display converted values.

Technical Project Lead (TPL) Review of PMTAs

New Products Subject to this Review[i]	
Submission tracking numbers (STNs.PDs)	Multiple STNs.PDs, see Appendix A
Common Attributes	
Submit date	September 6, 2020
Receipt date	September 9, 2020
Applicant	Johnny Copper LLC
Product manufacturer	Johnny Copper LLC
Application type	Standard
Product category	Electronic Nicotine Delivery Systems (ENDS) (VAPES)
Product subcategory	ENDS Component
Cross-Referenced Submissions	
All STNs.PDs	MF0000068, MF0000262, MF0000397, and MF0000401
Recommendation	
Issue marketing denial orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Alexander R. Maki -S
Date: 2024.09.11 13:41:52 -04'00'

Alexander Maki, Ph.D.
Social Scientist
Division of Population Health Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

Digitally signed by Benjamin Apelberg -S
Date: 2024.09.13 09:56:11 -04'00'

Benjamin J. Apelberg, Ph.D.
Deputy Director
Office of Science

[i] Product details, amendments, and dates are provided in the Appendix. PMTA means premarket tobacco application. Scientific references are listed at the end of this document.

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1. EXECUTIVE SUMMARY

This Technical Project Lead (TPL) review relates to premarket tobacco product application(s) (PMTA(s)) submitted under Section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act), as amended by the Family Smoking Prevention and Tobacco Control Act (TCA). Based on the information provided in the application(s) and other scientific data, as described in this TPL review, I find that the applicant has not demonstrated that permitting the marketing of the new products in the PMTAs listed above ("new products" or "subject ENDS") would be appropriate for the protection of the public health (APPH). Accordingly, I recommend that marketing denial orders be issued for the new products.

1.1. APPH STANDARD

Section 910 of the FD&C Act requires that, for a product to receive a PMTA marketing authorization, FDA must conclude, among other things, that permitting the product to be marketed would be APPH. Section 910(c)(2)(A). The statute places the burden on the applicant to make the required showing by providing that FDA "shall deny an application" for a product to receive a PMTA marketing authorization if, "upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product," FDA finds that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." Section 910(c)(2)(A).

The statute further specifies that, in assessing whether the marketing of the new products would be APPH, FDA must 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. Section 910(c)(4). The APPH standard requires a showing that permitting the marketing of a new tobacco product would have a net benefit to public health based upon the risks and benefits to the population as a whole, which includes youth, young adults, and other vulnerable populations. As the statutory text makes clear, it is the applicant's burden to make a "showing"—with sufficient supporting information—that permitting the marketing of a new tobacco product would have a net benefit to public health based upon the risks and benefits to the population as a whole. In determining whether permitting the marketing of any new tobacco product would result in a net benefit to public health, FDA weighs the potential negative public health impacts (e.g., harm from initiation and use among nonusers, particularly youth) against the potential positive public health impacts (e.g., benefit from adults who smoke who completely switch to lower risk products).

In making the APPH assessment specifically for a noncombustible tobacco product such as an electronic nicotine delivery system (ENDS), FDA weighs, among other things, the negative public health impact stemming from youth initiation and use of the product against the potential positive public health impact stemming from adults who use combustible cigarettes (CC) transitioning away, i.e., completely switching, from CC to the ENDS product or significantly reducing smoking of CC. In order to show that the marketing of an ENDS is APPH, an applicant must show that the benefits, including those to adults who use CC, outweigh the risks, including

those to youth, resulting in a net benefit to the public health. As the known risks of the product increase or decrease, the burden of demonstrating a substantial enough benefit likewise increases or decreases. For flavored ENDS[ii] (i.e., ENDS with e-liquid flavors other than tobacco, such as fruit), there is a known and substantial risk of youth initiation and use; accordingly, an applicant has a higher burden to establish that the likely benefits to adults who use CC outweigh that risk.[iii] For tobacco-flavored ENDS the risk to youth is lower compared to flavored ENDS; accordingly, a lesser showing of benefit may suffice.

In making the APPH assessment for a flavored ENDS, FDA has determined that it is appropriate to compare flavored ENDS with tobacco-flavored ENDS. Tobacco-flavored ENDS may offer the same type of public health benefit as flavored ENDS, i.e., increased complete switching and/or significant reduction in smoking, but do not pose the same degree of risk of youth uptake. Whether other products, such as tobacco-flavored ENDS, give adults who use CC comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the subject ENDS may provide to that population. Therefore, in making the APPH determination for a flavored ENDS, FDA considers whether the applicant has provided acceptably strong evidence of an added benefit from the flavored ENDS relative to that of tobacco-flavored ENDS in facilitating adults who use CC in completely switching from or significantly reducing their smoking.

Before determining that permitting the marketing of a new tobacco product would be APPH, FDA also considers the potential impact of marketing restrictions and other mitigation efforts that aim to reduce the risk of youth initiation and use of tobacco products. Marketing restrictions include advertising and promotion restrictions intended to limit youth exposure to and appeal of tobacco product marketing (e.g., measures such as limiting advertising to platforms that are predominantly used by adults and using advertising content and methods that are not known to resonate with youth, or even eliminating advertising in certain media channels altogether) and sales access restrictions intended to restrict youth access to tobacco products (e.g., measures such as selling products only in face-to-face interactions, in adult-only facilities, or via websites that require robust age and identify verification). In recent years, there have been efforts to develop novel and potentially more effective types of risk mitigation measures aimed at reducing youth initiation risks, such as device access restrictions (e.g., technologies that require adult user identification by fingerprint or other biometric parameters in order to unlock and use a tobacco product). FDA evaluates these measures in the context of the overall public health evaluation of the product, weighing the known risks to youth against the benefit to adults. In the case of flavored ENDS, the risk of youth initiation and use is well documented and substantial. Thus far, FDA's experience shows that advertising and promotion restrictions and sales access restrictions cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate

[ii] The term "flavored ENDS" in this review refers to an ENDS product with any characterizing flavor other than tobacco, including menthol flavor. For the purposes of this review, it is synonymous with "non-tobacco-flavored ENDS."
[iii] Previously, FDA excluded menthol-flavored products from application decisions for other non-tobacco-flavored ENDS to allow more time to consider whether any factors unique to menthol would affect the APPH assessment. As explained in section 2.3.1, FDA has concluded that the approach to the APPH analysis for menthol-flavored ENDS is the same as for other non-tobacco-flavored ENDS, in that, to overcome the risk to youth, an applicant must provide robust evidence demonstrating their menthol-flavored ENDS products provide an added benefit for adult smokers relative to tobacco-flavored ENDS.

APPH.[iv] Rather, for flavored ENDS, only the most stringent mitigation measures have such potential; to date, the only such measures identified with the potential for that kind of impact have been device access restrictions. FDA is currently aware of no other restrictions with the potential to alter the overall net benefit assessment for flavored ENDS. In contrast to flavored ENDS, the risk of youth initiation and use with tobacco-flavored ENDS is lower. Restrictions on advertising and promotion and sales access for tobacco-flavored ENDS could mitigate that more limited risk and impact the overall net benefit assessment. In addition, restrictions on advertising and promotion and sales access are important to include in marketing granted orders (MGOs) because they can help ensure that the marketing of a new tobacco product remains APPH after authorization. FDA has included such restrictions in MGOs issued to date.

Before determining that permitting the marketing of a tobacco product would be APPH, FDA also takes into account whether the applicant has provided sufficient information regarding product design, chemistry, stability, manufacturing controls including process controls and quality assurance procedures, toxicology, abuse liability, and other factors that can impact the product's risks and benefits to individual users, including relative to those of other tobacco products on the market.

1.2. TARGETED REVIEW

We have conducted a targeted scientific review of the subject applications to determine whether they could establish a net population health benefit necessary to demonstrate that permitting the marketing of the new tobacco products is APPH. This targeted review focuses specifically on behavioral evidence and mitigation measures related to the risk to youth and benefit to adults. In general, where our targeted scientific review finds that the evidence might be capable of showing a net benefit that could meet the APPH standard, we refer the application for further scientific review because, in order to grant a marketing authorization, FDA needs to complete scientific review by all relevant disciplines (e.g., chemistry, toxicology) and ensure that nothing else precludes an APPH determination. In contrast, for applications where the evidence regarding youth risk and adult benefit is not capable of showing a net benefit that could establish APPH, that further analysis is unnecessary.

In assessing risk to youth, our starting point is the extensive published literature that establishes substantial youth risk from flavored ENDS, as detailed in section 2.3.2 below. We then consider whether the applicant has proposed any measures that could mitigate that risk for the subject products to a material degree. As discussed in detail in section 2.3.4 below, to date FDA has found that advertising and promotion restrictions and sales access restrictions cannot mitigate this substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. Rather, for flavored ENDS, only the most stringent mitigation measures have such mitigation potential; to date, the only such measures identified with the potential for that kind of impact have been device access restrictions. Nonetheless, consistent with concerns expressed by a number of federal courts, as part of targeted review,

[iv] *See* FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry* 44 (Apr. 2020) ("The reality is that youth have continued access to ENDS products in the face of legal prohibitions and even after voluntary actions by some manufacturers."); *see also id.* at 45 (noting "data that many youth obtain their ENDS products from friends or sources in their social networks").

FDA is now reviewing all applicant-proposed marketing restrictions and mitigation measures to determine whether there are novel and materially different proposed measures that might mitigate the substantial risk to youth from flavored ENDS sufficiently to decrease the magnitude of adult benefit required to show APPH.

In assessing adult benefit, where we have concluded that the risk to youth from the subject flavored ENDS products is substantial, we review the subject applications to determine whether they could show a sufficiently robust benefit to adults who use CC. Whether there are alternative products that give adults who use CC comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the subject ENDS may provide to that population. Because tobacco-flavored ENDS have not been shown to present the same risks to youth as flavored ENDS, the benefits assessment for flavored ENDS considers whether they provide a sufficiently robust benefit to adult smokers as compared to tobacco-flavored ENDS. In making this assessment, we focus primarily on the evidence contained in the application to show public health benefit in terms of product use behavior. Based on existing scientific evidence and our experiences in conducting premarket review employing the APPH standard over the last several years, FDA has determined that only the strongest types of evidence will be sufficiently reliable and robust to demonstrate this benefit in terms of product use behavior. Product specific evidence from a randomized controlled trial (RCT) or longitudinal cohort study will most likely be needed, although other types of evidence could be adequate and will be evaluated on a case-by-case basis. For example, we would consider evidence from another study design if it could reliably and robustly assess behavior change (complete product switching or significant cigarette reduction) over time, comparing 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 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 to adult smokers outweighs the clear risks to youth.

1.3. SUBJECT APPLICATION

We reviewed the subject application to determine whether it could establish a net population health benefit necessary to demonstrate that permitting the marketing of the new tobacco products is APPH. In assessing the risk to youth, we considered the extensive published literature as well as the applicant-proposed marketing restrictions and other mitigation measures. The applicant did not propose any novel or materially different measures from those that FDA has previously considered and found insufficient to overcome the substantial risk to youth from flavored ENDS and warrant further review of an application that does not include robust and reliable evidence of adult benefit. Thus, we reviewed the subject application to determine whether it contains sufficient evidence of the type described above that could demonstrate APPH. Our review determined that the subject PMTA does not contain evidence from an RCT, or longitudinal cohort study regarding the impact of the ENDS on complete switching or significant cigarette reduction that could potentially demonstrate the benefit of their flavored ENDS over tobacco-flavored ENDS. The PMTA does contain other evidence regarding the potential benefit to adult users; however, for the reasons explained below, this other evidence is not adequate. As a result the applicant has failed to provide evidence to show

a sufficiently robust benefit to adults who use CC that could outweigh the risk to youth and show a net population health benefit necessary to determine that the permitting the marketing of the new tobacco products is APPH.

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 February 24, 2021, and a Filing letter to the applicant on March 11, 2021.

FDA issued a Marketing Denial letter on September 7, 2021, for PM0003757.PD1 – PM0003757.PD47, PM0003757.PD51 – PM0003757.PD53, PM0003757.PD58 – PM0003757.PD113, and PM0003757.PD118 – PM0003757.PD154. FDA issued a Rescission of Marketing Denial letter on August 2, 2024[v], for these products by considering the Eleventh Cricut opinion and the applications were placed back into the review process.

Additionally, regulatory reviews of characterizing flavor were completed by Lambeth Allen on July 17, 2024, and Fatima Sow on August 8, 2024.

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 recent decisions for other flavored ENDS and is set forth below.

The FD&C 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 places the burden on the applicant to make the required showing by providing that FDA "shall deny an application" for a product to receive a PMTA marketing authorization if, "upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product," FDA finds that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." Section 910(c)(2)(A).

The statute specifies that, in assessing whether permitting marketing of a new product would be 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.

[v] Regulatory review was completed by Rosanna Beltre on August 2, 2024.

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]." The APPH standard in section 910(c)(2)(A) requires a showing that permitting the marketing of a new tobacco product would have a net benefit to public health based upon the risks and benefits to the population as a whole, which includes youth, young adults, and other vulnerable populations.[vi] As the statutory text makes clear, it is the applicant's burden to make a "showing"—with sufficient supporting information—that permitting the marketing of a new tobacco product would have a net benefit to public health based upon the risks and benefits to the population as a whole. 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 products, and to take into account, among other things, the likelihood that those who do not use tobacco products will start using them.

Through the PMTA review process, FDA conducts a science-based evaluation to determine whether marketing of a new tobacco product is APPH. 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)). FDA considers many factors when making its APPH determination, such as effects on tobacco use initiation, switching, and cessation, and reductions in premature mortality, or increases in life-years lived.[vii] For a noncombustible tobacco product such as ENDS, the APPH assessment also includes whether the product may help adults who currently smoke completely transition away from or significantly reduce CC use, weighed against the risks to youth.[viii]

The review of these flavored ENDS products focuses on risk to youth who do not use tobacco products and the potential benefit to adults who smoke as current tobacco product users, given that these are the subpopulations most likely to experience significant public health impacts from flavored ENDS, and therefore are the most relevant in evaluating the impact on the population as a whole. The availability of flavored ENDS has generally led to greater tobacco use among youth overall, notwithstanding the decrease in cigarette smoking for youth. (Park-Lee et al., 2021). This significant risk to youth reinforces FDA's determination to focus its review of flavored ENDS PMTAs on whether the applications have sufficiently reliable and robust evidence to justify authorization.

2.3.1. FDA'S ANALYSIS OF PMTAS FOR FLAVORED ENDS

It is well established that ENDS, and particularly flavored ENDS, pose a significant risk to youth (U.S. Food and Drug Administration, 2020; US Department of Health Human Services, 2016). 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.[ix] FDA has initiated a series of actions to address the risk and reduce youth use. As of August 2023, FDA has issued more than 20,000 warning letters and more than 3,500 civil money penalty complaints to retailers for the sale of ENDS products to minors. FDA has also issued a

[vi] Final Rule: "Premarket Tobacco Product Applications and Recordkeeping Requirements," 86 FR 55300, 55350, 55386 (Oct. 5, 2021) (PMTA Final Rule); Proposed Rule: "Premarket Tobacco Product Applications and Recordkeeping Requirements," 84 FR 50566, 50584, 50618 (Sept. 25, 2019).
[vii] PMTA Final Rule, 86 FR 55385.
[viii] PMTA Final Rule, 86 FR 55314.
[ix] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use

guidance that described a policy of prioritizing enforcement of certain 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)[x] 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.[xi]

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. 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,[xii] it is reasonable to infer that prioritizing enforcement against many flavored products resulting in their removal from the market contributed to the decline in youth use in 2020. Despite this decline, ENDS have remained the most widely used tobacco product among youth, with youth use at high levels. Moreover, despite the overall reduction in ENDS youth use observed in 2020, there was simultaneously a substantial rise in youth use of disposable ENDS (Wang et al., 2021; Wang et al., 2020).

Accordingly, FDA has determined that the review of all PMTAs for flavored ENDS must be evaluated against this backdrop of the substantial risk to youth. Because determining whether marketing a new product is APPH includes evaluating the risks and benefits to the population as a whole, FDA weighs, among other things, the negative public health impact for nonusers against the potential positive public health impact for current tobacco users, particularly adults who use CC. 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 outweighed by a sufficient benefit to adult users, supported by sufficiently robust and reliable evidence, resulting in a net benefit to public health.

As the known risks increase or decrease, the burden of demonstrating a substantial enough benefit likewise increases or decreases. For flavored ENDS, including menthol, there is a

[x] FDA has since concluded that the risk posed by flavored ENDS to youth pertains to all non-tobacco flavors, including menthol. The clear evidence of substantial use of menthol-flavored ENDS products among youth (discussed in Section 2.3.2.1) reflects evidence beyond what was available at the time that FDA issued this guidance in early 2020. The 2019 NYTS survey instrument for the data cited in the guidance grouped mint- and menthol-flavored products together, so it was not possible to differentiate youth use of mint and menthol flavors separately. Data from the 2019 Monitoring the Future Survey were available to separate out mint and menthol use at the time, but only for JUUL products specifically; these data showed greater youth use of mint, as compared to menthol-flavored JUUL products (Leventhal et al., 2019b). By contrast, the 2022 NYTS survey measured youth use of mint- and menthol-flavored ENDS separately and found the rates to be similar. As discussed below, menthol-flavored ENDS were used by 26.6% of middle- and high-school users of flavored ENDS, which is similar to the use rates for mint (29.4%) and candy/desserts/sweets (38.3%) (Cooper et al., 2022).

[xi] 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 this 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. FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data.

[xii] 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, all of which also may have contributed to the decline in ENDS use.

known and substantial risk of youth initiation and use, as shown by the documented evidence described below. Where an applicant has failed to demonstrate that this risk is sufficiently mitigated, the applicant has a high burden to establish that the likely benefits to adults who use tobacco outweigh that risk. Reliable and robust data are needed to evaluate the impact of the subject products as compared to tobacco-flavored products on complete switching or significant cigarette reduction among adults who use CC over time because tobacco-flavored products have not been shown to present the same risks to youth as tobacco products with other characterizing flavors. Whether other products give adults who use CC comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the subject ENDS may provide to that population.

Previously, FDA excluded menthol products from application decisions to allow more time to consider whether any factors unique to menthol would affect the APPH assessment. Among other things, FDA considered the potential significance of the fact that menthol-flavored combustible cigarettes currently remain on the market, unlike other non-tobacco characterizing flavors that are prohibited in combustible cigarettes. FDA conducted a thorough examination of the peer-reviewed scientific literature on this subject to determine whether it established that menthol-flavored ENDS provide a sufficient benefit for adult smokers relative to that of tobacco-flavored ENDS.

The scientific literature suggests that menthol smokers show a preference for menthol-flavored ENDS, relative to non-menthol flavored ENDS.[xiii] Based on this literature, FDA explored whether that preference for menthol-flavored ENDS among menthol smokers would be sufficient to demonstrate a benefit to adult smokers that outweighs the increased youth risks relative to tobacco-flavored ENDS, such that FDA could authorize the marketing of menthol-flavored ENDS with less robust product-specific evidence than expected for other types of flavored ENDS products. However, the existing literature does not demonstrate that menthol-flavored ENDS differentially facilitate complete switching or significant cigarette reduction, and this is the behavioral outcome measurable with available methods that most directly and most robustly determines the potential benefit to users. In addition, flavored ENDs, including menthol, pose substantial risk of youth appeal and use. Ultimately, FDA has concluded that the existing scientific literature does not demonstrate a benefit to adult smokers that outweighs the increased youth risks relative to tobacco-flavored ENDS, such that FDA could authorize the marketing of menthol-flavored ENDS with less robust product-specific evidence than expected for other types of flavored ENDS. Thus, the approach to the APPH analysis for menthol-flavored ENDS is the same as for other non-tobacco-flavored ENDS, in that, to overcome the risk to youth, an applicant must provide evidence demonstrating their

[xiii] With respect to menthol-flavored ENDS, peer-reviewed scientific literature suggests that smokers of menthol-flavored combustible cigarettes show a preference for menthol-flavored ENDS. For example, the literature supports that menthol-flavored combustible cigarette (CC) smokers indicate more enjoyment, satisfaction, and intent to use menthol-flavored ENDS compared to tobacco-flavored ENDS (DeVito et al., 2020; Goldenson et al., 2020; Rosbrook et al., 2016; Voos et al., 2020); that menthol/mint-flavored ENDS are more likely to be used by menthol-flavored CC smokers than by non-menthol-flavored CC smokers (Rostron et al., 2021), and that menthol- flavored CC smokers will most commonly substitute menthol CC with menthol-flavored ENDS (Denlinger-Apte et al., 2021; Shang et al., 2020). However, these studies were not designed to evaluate behavior change and thus do not directly address the outcomes of complete switching or cigarette reduction. Therefore, the existing literature does not demonstrate that menthol-flavored ENDS differentially facilitate switching or cigarette reduction, and this is the behavioral outcome measurable with available methods that most directly and most robustly determines the potential benefit to users.

menthol-flavored ENDS products provide an added benefit for adult smokers relative to tobacco-flavored ENDS.

FDA conducts this targeted scientific review to determine which applications to refer to further review, including, if warranted, scientific review by all relevant disciplines. FDA's multi-disciplined scientific review process for PMTAs can involve engaging ten scientific disciplines within FDA's Center for Tobacco Products (including chemistry, engineering, toxicology, environmental science, epidemiology, behavioral and clinical pharmacology, medical, microbiology, social science, and regulatory), each of which evaluates the application regarding the issues concerning that discipline. All of those reviews are then collected, reviewed, and summarized by a Technical Project Lead who then writes a summary of all of the reviews and develops a recommendation as to whether the application should be granted or denied. However, this process is labor-intensive and time-consuming and, where applications contain clear and critical deficiencies, it is ultimately unnecessary to conduct all of the discipline reviews to determine whether the product cannot be found to be APPH. Accordingly, FDA conducts a more targeted scientific review to screen applications for certain deficiencies that would make further multi-disciplined scientific review unnecessary and impracticable given the large volume of applications under review. See section 910(c)(3).

If FDA finds in its targeted review that the applicant has failed to include evidence that is capable of showing a sufficient benefit to adult smokers that could outweigh the known and substantial risk to youth from flavored ENDS (taking into account any applicant-proposed marketing restrictions or other risk mitigation measures), FDA issues a marketing denial order, because without such a showing, it will not be possible for the application to establish that the marketing of the new products will be APPH. However, if FDA determines through its targeted review that the application might be capable of showing that benefit through reliable and robust evidence, the application will be referred to further scientific review to consider whether the evidence put forth does in fact demonstrate that permitting the marketing of the new product is APPH, and whether other conditions for marketing authorization are met.

2.3.2. 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 an at risk population for various reasons, including that the majority of tobacco use begins before adulthood (U.S. Department of Health and Human Services, 2012) and thus youth are particularly susceptible to 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. Almost 90 percent of adults who smoke daily started smoking by the age of 18 (U.S. Department of Health and Human Services, 2014). Adolescents 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 (Apelberg et al., 2014). 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 daily smokers (U.S. Department of Health and Human Services, 2014). 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.

2.3.2.1. YOUTH USE OF FLAVORED ENDS

ENDS are 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 (Gentzke et al., 2020). 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 (Wang et al., 2019), which prompted the previously described FDA enforcement policy. But the prevalence of youth use remains high. In 2021, more than two million youth reported being current ENDS users, with most using a flavored ENDS product (Park-Lee et al., 2021). As of 2022, 14.1% of high school students and 3.3% of middle school students reported current ENDS use (Cooper et al., 2022).

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 (Cullen et al., 2019b). In the 2014 National Youth Tobacco Survey (NYTS), 65.1% of high school and 55.1% of middle school current (past 30 day) e-cigarette[xiv] users reported using a flavored e-cigarette (Corey et al., 2015). By the 2022 NYTS, the percentage of youth who currently use e-cigarettes reporting using a flavored product[xv] was up to 85.5% of high school users and 81.5% of middle school users (Cooper et al., 2022). In 2022, among youth who currently used flavored e-cigarettes, the most commonly used flavor type was fruit (69.1%), followed by candy, desserts, and other sweets (38.3%), mint (29.4%), and menthol (26.6%) (Cooper et al., 2022).

Although flavored ENDS use is common in both youth and adults, youth are more likely to use flavored products compared to adults. In a study of 2018 Tobacco Use Supplement to the Current Population Survey data, the percentage of current ENDS users who used flavored e-cigarettes decreased as age increased: 18-24 years (89.6%), 25-34 years (86.7%), 35-44 years (76.0%), and ≥45 years (60.4%) (Leventhal et al., 2021). In the Population Assessment of Tobacco and Health (PATH) Wave 5.5 from 2020, 67.4% of youth using ENDS aged 13 to 17 reported using fruit, followed by 53.8% for mint/menthol,[xvi] 23.4% for candy/dessert/other sweets, and 13.3% for tobacco flavor (internal analysis[xvii]). In the 2020 PATH Adult Telephone Survey, 51.5% of adults using ENDS 25 and older used fruit, 30.4% used mint/menthol, 24.1% used candy/dessert/other sweets, and 22.3% used tobacco flavor (internal analysis[xiv]). Youth who currently use ENDS were also more likely than adults who currently use ENDS to use more than one flavor (Schneller et al., 2019).

[xiv] We use "e-cigarette" here to be consistent with the survey, but we interpret it to have the same meaning as ENDS.
[xv] Flavored product use in these studies means use of flavors other than tobacco.
[xvi] 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.
[xvii] Data generated from PATH Wave 5.5 PATH-ATS Public Use Files (PUF) released in October 2022, available at https://www.icpsr.umich.edu/web/NAHDAP/studies/37786/datadocumentation#.

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 81% of youth aged 12-17, 71% of young adults 18-24, and 53% of adults 25 and older reported that the first e-cigarette that they used was flavored (Villanti et al., 2019). 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 (Rose et al., 2020). Finally, in PATH Wave 4 from 2016-2017, 93.2% of youth and 83.7% of young adults who ever used ENDS reported that their first ENDS product was flavored compared to 54.9% among adults who ever use ENDS 25 and older (Rostron et al., 2020).

In addition, nationally representative studies find that when asked to indicate their reasons for using ENDS, youth who use ENDS consistently select flavors as a top reason (Ambrose et al., 2015; Tsai et al., 2018). Among Wave 4 (2016-2017) youth who currently use ENDS, 71% reported using ENDS "because they come in flavors I like" (Rostron et al., 2020). 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 (Audrain-McGovern et al., 2016). 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 (St Helen et al., 2017). Together, this evidence suggests flavored ENDS may pose greater addiction risk relative to tobacco-flavored ENDS, which increases concerns of addiction in youth. This 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 (Morean et al., 2018). Use of non-traditional flavors (defined in the study as flavors other than tobacco, mint/menthol, or flavorless) was associated with increased likelihood of continued use and taking more puffs per episode (Leventhal et al., 2019a). 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 (Audrain-McGovern et al., 2019). 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 (Villanti et al., 2020). In sum, there is evidence that non-tobacco flavors, including menthol, may influence the rewarding and reinforcing effects of flavored ENDS in adults, including young adults, thereby facilitating ENDS use and increasing abuse liability, thus increasing concerns of addiction in youth.

2.3.2.2. 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 (Camenga et al., 2018; Carpenter et al., 2005; Harrell et al., 2017; Pepper et al., 2016). 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. Findings from 2015-2016 PATH data indicate that youth who use e-cigarettes had 21 times greater odds of using a non-tobacco flavor compared to adults who use these products after controlling for sociodemographic variables and device type (open/refillable versus closed/not refillable) (Schneller et al., 2019). As described above, the majority of youth ENDS use involves flavored products: in 2022, the majority of high school and middle school current e-cigarette users reported use of non-tobacco-flavored products (84.9%)(Cooper et al., 2022) and flavored use was favored across all types of ENDS devices (disposables: 90.5%, prefilled or refillable pods/cartridges: 85.9%, tanks or mod systems: 77.2%; internal analysis).

The evidence also indicates that the preference for device types and popularity of certain styles is likely dynamic and affected by the marketplace—that is, the options, especially flavors, that are available for consumers to choose from. Thus, as certain product types become harder to obtain, consumers, including youth, may switch to less popular products that are more readily attainable. This was observed in the trends both leading up to, and coinciding with, the shifting marketplace following the 2020 Enforcement Priorities Guidance.[xviii] In particular, the enormous rise in youth ENDS use from 2017-2019 coincided with the ascendance of JUUL (and similar devices) in the marketplace.[xix] But when FDA changed its enforcement policy to prioritize pod-based flavored ENDS, which were most appealing to youth at the time, we observed a substantial rise in use of disposable flavored ENDS[xx]--a ten-fold increase (from 2.4% in 2019 to 26.5% in 2020) among high school current e-cigarette users (Wang et al., 2021). This illustrates that the removal of one flavored product option prompted youth to migrate to another ENDS type that was available in the marketplace and offered the desired flavor options, underscoring the fundamental role of flavor in driving appeal. In addition, there is evidence that, in the intervening years since that enforcement policy was announced, youth have continued to report purchasing and using open systems (Park-Lee et al., 2021).

[xviii] We note that this guidance makes statements in the context of prioritizing the agency's limited resources to target products most popular during a youth vaping epidemic. However, that does not mean that other products are not used by youth or that they are appropriate for the protection of public health, which is the standard a product must meet to be authorized through the PMTA pathway. In other words, given the agency's limited resources, prioritizing resources for one set of products by no means implies that the FDA has reached any favorable conclusions about a different set of products.
[xix] 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 et al., 2019a).
[xx] In July 2020, FDA issued Warning letters to three companies for illegally marketing disposable e-cigarettes and for marketing unauthorized modified risk tobacco products.

2.3.2.3. 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 (Cullen et al., 2019b). In 2022, an estimated 42.3% of middle and high school students using ENDS reported frequent use (i.e., use on ≥20 of the past 30 days) (Cooper et al., 2022). By school grade, 46.0% (95% CI, 41.6%-50.4%) of high school students using ENDS and 20.8% (95% CI, 15.8%-26.8%) of middle school students using ENDS reported frequent use (Cooper et al., 2022). Among current ENDS users, 30.1% of high school users and 11.7% of middle school users reported daily ENDS use (Cooper et al., 2022). 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) (Foulds et al., 2015; Yingst et al., 2018) and salivary cotinine concentrations increased, indicating continued ENDS use and greater nicotine exposure over time (Vogel et al., 2019). Further, 23.0-38.3% of adolescents who use infrequently (<10 days out of the past 30 days) JUUL-brand ENDS reported at least one dependence symptom on the Hooked On Nicotine Checklist, with more frequent use associated with greater dependence severity (Kechter et al., 2021).

Youth and young adult brains are more vulnerable to the effects of nicotine than the adult brain due to ongoing neural development (Slotkin, 2002; Yuan et al., 2015). 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) (Bava et al., 2010; Bernheim et al., 2013; Casey et al., 2010; Doremus-Fitzwater et al., 2010; Shulman et al., 2016). Furthermore, evidence from animal studies suggests that nicotine exposure during adolescence enhances the rewarding and reinforcing effects of nicotine in adulthood (de la Peña et al., 2015; Kota et al., 2011; Natividad et al., 2013; Shram et al., 2010), and can induce short and long-term deficits in attention, learning, and memory (Conner et al., 2017; Counotte et al., 2009; Fountain et al., 2008; Holliday et al., 2017).

2.3.2.4. 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% CI: 2.38, 5.16) and past 30-day combusted cigarette use (OR = 4.28, 95% CI: 2.52, 7.27) among youth who had used ENDS as compared to youth who had not used ENDS (Soneji et al., 2017). Similar associations have been observed in longitudinal studies that have been published since the Soneji et al. review (Aleyan et al., 2018; Berry et al., 2019; Best et al., 2017; Bold et al., 2018; Conner et al., 2017; Hammond et al., 2017; Kintz et al., 2020; Loukas et al., 2018; Lozano et al., 2017; Stanton et al., 2019; Treur et al., 2018). 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 (National Academies of Sciences Engineering Medicine, 2018). The transition from non-cigarette product use to combusted cigarette use has been observed for other non-cigarette products, such as cigars, as well (Edwards et al., 2020). Although it is challenging to empirically separate causality from shared risk factors among youth who use combusted cigarette and youth who use ENDS, some studies have found an association between ENDS and subsequent combusted cigarette use while controlling for similar risk profiles (Stanton et al., 2019).

The prevalence of combusted cigarette smoking in youth has been decreasing for many years and has continued to decline (Gentzke et al., 2019; Wang et al., 2018; Wang et al., 2019), suggesting that youth use of ENDS has not significantly slowed or impeded that positive public health trajectory. However, as discussed above, there is a growing body of longitudinal 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 youth cigarette smoking could slow.

2.3.2.5. 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[xxi] Behavioral Risk Factor Surveillance System (BRFSS) suggesting positive associations between ENDS use among those who never smoked and certain adverse 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 (Osei et al., 2020; Osei et al., 2019). Another study found an association between ENDS use and respiratory symptoms in younger adults (ages 18-34) but not in older adults (Giovanni et al., 2020). ENDS use has also resulted in acute harm to individuals through battery explosion-related burns and e-liquid nicotine poisoning (Chang et al., 2020; Rossheim et al., 2019; Vyncke et al., 2020) and adverse experience reports suggest an association between ENDS use and seizure (Faulcon et al., 2020). Ultimately, as this is still a relatively novel product category, much remains unknown about other potential long-term health risks.

2.3.2.6. 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 concerning. In 2022, 2.55 million youth reported current ENDS use with 84.9% of those using a flavored ENDS product (Cooper et al., 2022). Youth who use ENDS 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 that flavors influence the rewarding and reinforcing effects of nicotine containing e-liquids, thereby facilitating ENDS use and increasing abuse liability. Studies also demonstrate that e-liquid flavors affect nicotine exposure. Among youth who use ENDS, there is evidence suggesting risk of progression to CC which pose

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

greater health risks. 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.

2.3.3. CONSIDERATION OF POTENTIAL BENEFIT TO ADULT CURRENT SMOKERS[xxii]

Because determining whether marketing a new product is APPH requires FDA to balance, among other things, the negative public health impact for nonusers against the potential positive public health impact for current adult tobacco users, we have considered the potential benefits of the new products to adult current smokers.

2.3.3.1. POTENTIAL BENEFIT OF NEW FLAVORED ENDS

Current scientific literature demonstrates that ENDS—as a general product class—are 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 (National Academies of Sciences Engineering Medicine, 2018). 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 adults who currently smoke cigarettes may experience a reduction in health risks if they switch completely to 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 adults who currently smoke are likely to start using the new ENDS product exclusively or predominantly (i.e., dual use with a significant smoking reduction) (Chang et al., 2020).

2.3.3.2. 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 to Industry, "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems" (2019) (PMTA ENDS Guidance), an assessment of how a new product may be used by adults who currently smoke can be derived from a variety of sources.[xxiii] FDA may consider direct behavioral evidence on the specific products under review or indirect evidence derived from studies of behavioral intentions; 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

[xxii] This framework applies to flavored ENDS PMTAs for which FDA has found that the applicant-proposed marketing restrictions and related measures cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. See section 2.3.4 for details.

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

benefit would have to be substantial enough to overcome the significant risk of youth uptake and use posed by the flavored ENDS product.

As the PMTA ENDS Guidance states, statutory standards govern FDA's determination of whether to authorize an ENDS product, and the guidance provides FDA's current thinking and general recommendations on a wide variety of topics that should be included in a PMTA, consistent with the statute. See PMTA ENDS Guidance, p. 1. 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 a randomized controlled trial or RCT, which is a clinical investigation or a clinical study in which human subject(s) are prospectively, and randomly, assigned to one or more interventions (or a control condition) to evaluate and compare the effect(s) of the intervention(s) on behavioral, biomedical, or health-related outcomes. There are no specific duration requirements for a randomized controlled trial; the appropriate duration of a randomized controlled trial depends on the effect being investigated. In addition, as CTP has previously described,[xxii] another well-controlled investigation that could serve as an alternative to conducting an RCT to demonstrate adequate benefit is a longitudinal cohort study, which 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). There are no specific duration requirements for a longitudinal cohort study; the appropriate duration of the study depends on the effect being investigated. See further discussion regarding study length below. Other types of studies may also suffice to meet the statutory standard, and FDA considers such evidence case by case.

For flavored ENDS, the known and substantial risk to youth in particular is high. Therefore, to show a net 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 the evidence provided is capable of demonstrating that a benefit of a new product for adults who smoke is significant enough to overcome the risk to youth. In particular, FDA's review of these applications has considered the degree of benefit of 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: before granting authorization, applications containing this evidence would still be evaluated by all disciplines, such as chemistry and toxicology, to determine whether the totality of the evidence supports a marketing authorization. As it relates to the risk to

youth, for example, this assessment includes evaluating the abuse liability and addiction potential of the product.

FDA has been using the APPH standard for several years in reviewing PMTAs for non-ENDS products. Our substantive review of PMTAs for ENDS since 2020 has deepened our experience with the APPH evaluation, including with respect to tobacco use behavior. In these reviews, the expectations for scientific evidence related to potential adult benefit can vary based on demonstrated risk to youth. Specifically, in the absence of strong, direct evidence, we are unable to reach a conclusion that the benefit of flavored ENDS outweighs the clear risks to youth. Applicants who do not conduct their own behavioral studies must rely on, and bridge to, other comparable products or 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 flavors in promoting switching among adult smokers is far from conclusive.[xxiv] Although indirect evidence or bridged data from the literature may still be appropriate for many new products, including tobacco-flavored ENDS, which do not present the same risk to youth as flavored ENDS products, robust and direct evidence demonstrating potential benefit is needed when the known risks are high. 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 to support the statutorily required showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health.

More specifically, in order to adequately assess whether such an added benefit could be demonstrated, FDA has reviewed these applications for product-specific[xxv] evidence that would enable a comparison 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. Reliable and robust data are needed to evaluate the impact of the subject products as compared to tobacco-flavored ENDS on adult smokers' switching or cigarette reduction over time because tobacco-flavored ENDS have not been shown to present the same risks to youth as flavored ENDS.[xxvi] Whether

[xxiv] 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. By contrast, for youth initiation, experimentation among naïve or novice users is not driven by these factors.

[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).

[xxvi] In general, tobacco-flavored ENDS are less appealing to youth compared to flavored ENDS, making the risk of youth initiation lower for these products. Findings from a discrete choice experiment showed that flavors were associated with more curiosity, less perceived danger, and greater perceived ease-of-use among high school students, compared to tobacco flavor (Chaffee et al., 2020). Additionally, the published literature indicates that youth report significantly higher preference for flavored ENDS compared to tobacco-flavored ENDS (Groom et al., 2020; Harrell et al., 2017; Morean et al.,

other products give adults who smoke comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the subject ENDS may provide to that population. Consistent with section 910(c)(5), evidence generated using either an RCT design or longitudinal cohort study design is most 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.[xxvii]

FDA 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 the PMTA ENDS Guidance, FDA stated that it did not expect that applicants would need to conduct long-term studies to support an application for ENDS. The guidance describes long-term studies as those studies that are conducted over six months or longer. Because the behavioral changes of interest for adults who currently use CC (i.e., switching completely to an ENDS or significantly reducing their cigarette smoking) occur over 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 sufficient to allow for evaluation of the behavioral changes of interest for adults who currently use CC. For example, actual use studies that are six-weeks in duration that demonstrate that the average number of cigarettes used per day was significantly lower during the observational period compared to baseline could help support an application. Thus, studies with a duration shorter than six months may be sufficient to evaluate reductions in cigarette smoking or the potential for switching to ENDS.

2018). Moreover, the evidence indicates that tobacco-flavored ENDS are less likely to be used by youth who initiate or regularly use ENDS compared to flavored ENDS. The findings from the 2020 Monitoring the Future (MTF) survey provide evidence that youth use of tobacco-flavored ENDS is less common compared to flavored ENDS, including mint (Miech et al., 2021). According to the 2020 MTF data, the prevalence of tobacco flavor was 2.9% among 10th and 12th graders while mint was the second most often used flavor (26.9%) after fruit (59.3%) (Miech et al., 2021).

[xxvii] 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 population-wide patterns of youth ENDS use (e.g., what percentage of youth are currently using ENDS) 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.

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 its findings are mixed, and it does not provide product-specific information.[xxviii] The heterogeneity of the literature is likely due to the fact that 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 user.

While RCTs and longitudinal 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. Although RCTs generally 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 tobacco use behavior over time among adults who use CC, as described above; 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 same applicant in the same 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.[xxix] 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, or from another similarly robust type of study, could support a benefit to adults who use tobacco products if the findings showed that,

[xxviii] This is also consistent with the PMTA ENDS Guidance, which explains that the type of evidence that is necessary to show that a product is APPH differs depending on the type of product. The guidance notes that although a literature review may be sufficient to support authorization in some circumstances, there would have to be "an established body of evidence regarding the health impact (individual or population) of your product or a similar product that can be adequately bridged" for that to be the case. As explained above, here, the general literature does not establish that flavors differentially promote switching amongst ENDS users in general. Relevantly, the guidance notes that, because "limited data may exist from scientific studies and analyses," FDA anticipates that "applicants will conduct certain investigations themselves and submit their own research findings as a part of their" application, *see* PMTA ENDS Guidance, p. 12. The guidance further explains that FDA would consider whether "information on other products (e.g., published literature, marketing information) with appropriate bridging studies" demonstrates that the marketing of a product satisfies the TCA's standard.

[xxix] Bridging is discussed in the PMTA ENDS Guidance cited above.

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 adults who use CC: (1) complete switching from cigarettes to exclusive use of the new productor (2) significant reduction in cigarettes per day.

2.3.3.3. 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[xxx] evidence to demonstrate a potential for benefit to adults who use CC 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 adult who use CC completely switching or significantly reducing their smoking is necessary to demonstrate that the potential benefit to current users would outweigh the risk to youth posed by flavored ENDS.

2.3.4. CONSIDERATION OF THE IMPACT OF MARKETING RESTRICTIONS AND OTHER MITIGATION MEASURES

2.3.4.1. TYPES OF MARKETING RESTRICTIONS AND OTHER MITIGATION MEASURES AND THEIR POTENTIAL IMPACT ON YOUTH RISK

Before determining that permitting the marketing of a new tobacco product would be APPH, FDA considers the impact of marketing restrictions and other mitigation efforts that aim to reduce the risk of youth initiation and tobacco use.[xxxi] Marketing restrictions include advertising and promotion restrictions intended to limit youth exposure to and appeal of tobacco product marketing (e.g., measures such as limiting advertising to platforms that are predominantly used by adults and using advertising content and methods that are not known to resonate with youth, or even eliminating advertising in certain media channels altogether) and sales access restrictions intended to restrict youth access to tobacco products (e.g., measures such as selling products only in face to face interactions, in adult-only facilities, or via websites that require robust age verification). In recent years, there have been efforts to develop novel and potentially more effective mitigation measures aimed at reducing youth initiation risks, such as device access restrictions (e.g., technologies that require adult user identification by fingerprint or other biometric parameters in order to unlock and use a tobacco product). FDA evaluates these measures in the context of the overall public health evaluation of the product, weighing the known risks to youth against the benefit to adults. For example, as discussed in section 2.3.2 above, in the case of flavored ENDS, the risk of youth initiation and use is

[xxx] See fn xxiv above.

[xxxi] Separately, marketing restrictions and other mitigation measures are also critical to helping ensure that any new tobacco product continues to be APPH after authorization. As a result, all new tobacco products that FDA has authorized under the PMTA pathway are subject to advertising and promotion and sales access restrictions. The fact that these restrictions are critical to ensuring that a new tobacco product remains APPH after authorization, does not mean that they are – by themselves – sufficient to establish that a product is APPH in the first place.

well documented and substantial, and thus more stringent restrictions are needed in order to meaningfully mitigate that risk.

Restrictions on advertising and promotion include measures such as: limiting advertising in various media channels like point-of-sale, print, TV, radio, digital media such as Internet websites, mobile applications, social media platforms like Facebook, Twitter, Instagram (e.g., placing advertising only in media with audience compositions of at least 85% adults 21+; limiting social media promotion to only platforms with age-gating controls; not advertising on billboards located within 500 feet of any elementary or secondary schools, youth-oriented facilities, childcare facilities, or hospitals; requiring point-of-sale advertising be placed only in areas of the facility that cannot be seen outside); limiting the timing, frequency, or overall amount of advertising (e.g., advertising on TV and radio only during certain hours; airing no more than one advertisement per half hour of programming with a minimum 20-minute separation between spots); limiting the use of certain advertising and promotional tactics (e.g., sending direct e-mail communication to only age-verified customers who have opted to receive such content; avoiding the use of direct mail advertising; avoiding use of influencers; avoiding use of product giveaways and product samples; avoiding use of sponsorships and events); developing advertising content that is intended to appeal to adults and avoid themes and images known to resonate with youth (e.g., avoiding use of cartoons; avoiding use of content depicting youth culture or lifestyle appeal; avoiding use of user-generated social media content featuring under age users; using only models who will be and appear to be ages 25+ in advertising); and utilizing product labeling and packaging designs intended to reduce youth appeal (e.g., avoiding use of confectionary or candy-like naming conventions or images, limiting use of colors and imagery, using only black and white labels). The purpose of these restrictions is to reduce youth exposure to and appeal of tobacco product images, which in turn reduces product appeal among youth, which in turn reduces the desire to buy and/or try products, which in turn reduces the likelihood of youth initiation and youth use. Because these restrictions are intended to curb youth appeal but do not directly prevent youth use, they do not in themselves provide enough assurance of a sufficient reduction in youth use to mitigate the substantial risk that flavored ENDS pose to youth—a risk that is supported by direct, robust and reliable data of behavioral outcomes (e.g., actual youth initiation rates and youth use rates). Accordingly, for flavored ENDS, these promotion and advertising restrictions do not have the potential to reduce the magnitude of adult benefit required to establish APPH and warrant further scientific review in the absence of an RCT, longitudinal cohort study, or other sufficiently robust evidence described above.

Restrictions on sales access include measures such as: complying with local, state, and federal minimum age of sale restrictions; requiring age- and identity- verification prior to selling products online; utilizing independent and reliable age- and identity-verification services; selling products only in face to face interactions; selling products only in adult-only facilities; using trace and verify QR codes linked to the purchaser's driver's license; setting limits on the number of products that can be purchased in a single transaction; requiring retailers and distributors to sign written agreements stating they will cooperate with "secret shopper" programs and audits; penalizing retailers and distributors for underage sales; conducting retailer training programs; participating in responsible retailing programs (e.g., We Card); and monitoring distribution channels for compliance.

These measures tend to be more direct than advertising and promotion restrictions in that they are intended to curtail access to products. However, FDA has found that to date these restrictions do not by themselves mitigate the high risk to youth posed by flavored ENDS to a degree material enough to justify further review in the absence of robust and reliable evidence of benefit to adults. This is because youth have been able to obtain products, including flavored ENDS, despite sales restrictions.

As FDA explained in the 2020 Enforcement Priorities Guidance, from April 2018 to August 2019, the agency sent more than 6,000 warning letters and more than 1,000 civil money penalty complaints to online and brick-and-mortar retailers for illegal sales of e-cigarettes to minors (U.S. Food and Drug Administration, 2020). FDA also asked manufacturers to propose measures they could implement to help restrict youth access to e-cigarettes (U.S. Food and Drug Administration, 2020). The proposed measures included the use of age-verification technology for online sales, enhanced monitoring of retailer compliance with age-verification requirements, and contractual penalties for retailers that failed to comply with sales restrictions (U.S. Food and Drug Administration, 2020).

Youth continue to be able to access e-cigarettes, despite legal prohibitions and voluntary actions by some manufacturers (U.S. Food and Drug Administration, 2020). This is due in substantial part to the fact that the majority of youth do not purchase e-cigarettes themselves from retail locations, but rather they obtain them from social sources, including from friends or family members, steal them, or use someone else's product (Gentzke et al., 2022; Liu et al., 2019; Meyers et al., 2017; Tanski et al., 2019). In addition, with respect to youth who do attempt to purchase e-cigarettes themselves, one study (Meyers et al., 2017) found that some e-cigarette users <18 years of age reported having last obtained e-cigarettes from adult-only locations or those that should have had age verification procedures in place: namely, at smoke shops (18.3%), and liquor stores (10.0%). Only one-quarter of youth who tried to buy tobacco products were refused sale because of their age (Liu et al., 2019).

Therefore, FDA has found to date that these sales access restrictions do not in themselves provide enough assurance of a sufficient reduction in youth use to mitigate the substantial risk flavored ENDS pose to youth. Accordingly, for flavored ENDS, these sales access restrictions do not have the independent potential to reduce the magnitude of adult benefit needed to show APPH and warrant further scientific review in the absence of an RCT, longitudinal cohort study or other sufficiently robust evidence described above.

In contrast, in recent years there have been efforts to develop novel and potentially more effective mitigation measures such as device access restrictions. These include implementation of device technologies, such as age-gating technologies that require user identification by fingerprint or other biometric parameters in order to unlock and use a tobacco product or geo-fencing technologies (e.g., technologies that make it impossible to operate a tobacco product in a particular location such as a school or playground). In contrast to advertising and promotion and sales access restrictions discussed above, FDA believes that these novel device access technologies may offer a potential to sufficiently mitigate the risk to youth if they can be shown to restrict product access in a way that cannot be disabled or defeated. The use of device access restrictions in the current marketplace is limited, and FDA continues to assess them.

2.3.4.2. CONCLUSION

In conclusion, before determining that permitting the marketing of a new tobacco product would be APPH, FDA considers the impact of marketing restrictions and other mitigation efforts that aim to reduce the risk of youth initiation and tobacco use. FDA evaluates these measures in the context of the overall public health evaluation of the product, weighing the known risks to youth against the possible benefit to adults. The assessment for flavored ENDS is different from other tobacco products because of (1) the substantial risk of youth initiation and youth use as shown by well-established data, and (2) the lack of robust evidence in the scientific literature regarding the potential of flavored ENDS to benefit adults who use CC, particularly when compared to alternatives posing less risk to youth, such as tobacco-flavored ENDS. Given those considerations, as well as the information discussed above regarding advertising, promotion and sales access restrictions, we have thus far determined that restrictions on advertising and promotion and sales access have not been adequate to mitigate the risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit needed to show APPH and warrant further review in the absence of an RCT, longitudinal cohort study, or other sufficiently robust evidence described above. In contrast, only the most stringent mitigation measures could provide sufficient assurance of youth risk mitigation and, therefore, warrant further scientific review to assess whether there would be a net benefit to public health after complete assessment of this technology together with additional consideration of the application. To date, the only such measures identified with the potential for that kind of impact have been device access restrictions.

Although we have thus far concluded that restrictions on advertising and promotion and sales access would not be adequate to mitigate the risk to youth for flavored ENDS sufficiently to warrant review of an application that does not include robust and reliable evidence of adult benefit, given the concerns expressed by certain federal courts, as part of targeted review, FDA is now reviewing all applicant-proposed marketing restrictions and mitigation measures to ensure that there are no other types of novel and materially different proposals, such as device access restrictions, that have the potential to mitigate the substantial risk to youth from flavored ENDS sufficiently to decrease the magnitude of adult benefit required to show APPH.[xxxii]

2.4. SCOPE OF REVIEW

We conducted a targeted scientific review of the subject applications, focusing on the evidence regarding risk to youth and benefit to adults, to determine whether it can establish a net population health benefit necessary to demonstrate that permitting the marketing of the new tobacco products is APPH. In assessing the risk to youth, we considered the extensive published literature and evaluated the applicant-proposed marketing restrictions and other mitigation measures. Similarly, in assessing benefit to adults, we considered the published literature and 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 complete switching or significant cigarette reduction that could potentially demonstrate the

[xxxii] See *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 24-25 (D.C. Cir. 2022); *Wages & White Lion Investments, L.L.C.,* v. FDA, 41 F.4th 427 (5th Cir. 2022), *reh'g granted en banc*, 58 F.4th 233 (Jan. 19, 2023); *Bidi Vapor LLC v. FDA*, 47 F.4th 1191 (11th Cir. 2022).

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 adults who use tobacco products.

3. SCIENTIFIC REVIEW

Reviews were completed by Nicole Pelletier and Carlos Portillo on September 11, 2024.

FDA reviewed the subject application to determine whether it could establish a net population health benefit necessary to demonstrate that permitting the marketing of the new tobacco products is APPH. In assessing the risk to youth, we considered the extensive published literature (see section 2.3.2) as well as the applicant-proposed marketing restrictions and other mitigation measures. The applicant proposed measures such as: point-of-sale identification checks, age-gating website and social media access, "Trace/Verify" product tracking, and avoiding marketing and packaging attractive to youth. The applicant did not propose any novel or materially different measures from those that FDA has previously considered and found insufficient. Consistent with the explanation in section 2.3.4 above, we find that the applicant-proposed measures do not have the potential to mitigate the substantial risk to youth from flavored ENDS sufficiently to justify further scientific review of an application that does not include robust and reliable evidence of adult benefit.

FDA also reviewed this application for evidence demonstrating that the new flavored products will provide an added benefit to adults who use CC relative to tobacco-flavored ENDS products. The reviews determined that the PMTA did not contain evidence from a randomized controlled trial and/or longitudinal cohort study examining the benefit to adults who use their flavored ENDS over an appropriate comparator tobacco-flavored ENDS in terms of completely switching from or significantly reducing cigarettes.

The PMTA contained three cross-sectional surveys on perceptions and use of CC and ENDS products, but this evidence is not sufficiently strong to support the benefit using these flavored ENDS to adults who smoke because it does not evaluate the specific products in the application; evaluate complete switching or significant cigarette reduction resulting from use of these products over time; or evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors. Accordingly, this evidence is not adequate. Given these findings, we did not refer this application for further scientific review.

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

We reviewed the subject application to determine whether it could establish a net population health benefit necessary to demonstrate that permitting the marketing of the new tobacco products is APPH. In assessing the risk to youth, we considered the extensive published literature as well as the applicant-proposed marketing restrictions and other mitigation measures. We concluded that the risk to youth from the subject flavored ENDS is substantial. Thus, FDA reviewed this application 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 PMTA for the applicant's new products, as described in the application and specified in Appendix A, lacks 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:

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. There is substantial evidence that flavored ENDS, like the subject products, have significant appeal to youth and are associated with youth initiation and use. The marketing restrictions and other mitigation measures that you proposed cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. In light of the known risks to youth of marketing flavored ENDS, robust and reliable evidence is needed regarding the benefit to adults who smoke, who switch completely or significantly reduce their smoking. Whether other products give adults who smoke comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the subject ENDS arguably provide to that population. Because tobacco-flavored ENDS have not been shown to present the same risks to youth as flavored ENDS, marketing of flavored ENDS is APPH only if the evidence shows a benefit to adults who smoke as compared to tobacco-flavored ENDS.

This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit to adults who use your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS. We did not find such evidence in your PMTA. FDA would also consider other evidence that reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on complete switching or significant cigarette reduction over time among adults who use combustible cigarettes. Although your PMTA contained three cross-sectional surveys on perceptions and use of combusted cigarettes and ENDS products, this evidence is not sufficient to show a benefit of using these flavored ENDS to adults who smoke because it does not evaluate the specific products in the application; evaluate complete switching or significant cigarette reduction resulting from use of these products over time; or evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors.

Without this information, FDA cannot determine whether 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 APPH. Because you have not met your burden of "showing" that permitting the marketing of the new products would be APPH as required by Section 910(c)(2)(A), we must deny authorization for your application.

6. APPENDIX

Appendix A

New Tobacco Products Subject of This Review

Common Attributes[xxxiii, xxxiv, xxxv, xxxvi, xxxvii]	
Submit date	September 6, 2020
Receipt date	September 9, 2020
Applicant	Johnny Copper LLC
Product manufacturer	Johnny Copper LLC
Product category	Electronic Nicotine Delivery Systems (ENDS) (VAPES)
Product subcategory	ENDS Component

[xxxiii] We interpret package type to mean container closure system and package quantity to mean product quantity within the container closure system, unless otherwise identified.
[xxxiv] Product name is brand/sub-brand or other commercial name used in commercial distribution.
[xxxv] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.
[xxxvi] Attributes in Appendix A may display converted values.
[xxxvii] Attributes of certain products intentionally left blank, as there were not provided by the applicant.

STN	PD#	Product Name	Package Type	Package Type, if Other	Product Quantity Numeric Value	Units (Product Quantity)	Units, if Other (Product Quantity)	Characterizing Flavor	Characterizing Flavor, If Flavored	Nicotine Source	Additional Property
PM0003757	PD1	2 BERRIEZ 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD2	2 BERRIEZ 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD3	2 BERRIEZ 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD4	APPLEMANE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD5	APPLEMANE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD6	APPLEMANE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD7	BAM 0mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 0 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD8	BAM 3mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 3 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD9	BAM 6mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 6 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD10	BANANA NUT BREAD CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 60, 120 ml, 240 ml
PM0003757	PD11	BANANA NUT BREAD CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD12	BANANA NUT BREAD CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD13	BERRY DEW 0mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD14	BERRY DEW 3mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD15	BERRY DEW 6mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD16	BERRY MONTANA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD17	BERRY MONTANA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD18	BERRY MONTANA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD19	BLUEBERRY CRUNCH GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD20	BLUEBERRY CRUNCH GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD21	BLUEBERRY CRUNCH GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD22	BUTTERSCOTCH CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD23	BUTTERSCOTCH CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD24	BUTTERSCOTCH CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD25	CARMA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD26	CARMA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD27	CARMA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD28	CnK 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD29	CnK 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD30	CnK 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD31	DOVE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD32	DOVE 12mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 12 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD33	DOVE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD34	DOVE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD35	FATHEAD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD36	FATHEAD 12mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD37	FATHEAD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD38	FATHEAD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD39	FLAKEY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD40	FLAKEY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD41	FLAKEY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD42	FLAWLESS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD43	FLAWLESS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD44	FLAWLESS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD45	FRIGID 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD46	FRIGID 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD47	FRIGID 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD48	FROZEN 0mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen	Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD49	FROZEN 3mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD50	FROZEN 6mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD51	GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD52	GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD53	GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD54	GLIDER 0mg	Other	Bottle	1	Other	Bottle	Flavored	Traditional Tobacco	Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD55	GLIDER 12mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD56	GLIDER 3mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD57	GLIDER 6mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD58	Huckleberry Cheesecake 0mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD59	Huckleberry Cheesecake 3mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD60	Huckleberry Cheesecake 6mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD61	IGNITION 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD62	IGNITION 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD63	IGNITION 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD64	JAG 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD65	JAG 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD66	JAG 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD67	JOHNNY CANNOLI 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD68	JOHNNY CANNOLI 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD69	JOHNNY CANNOLI 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD70	KRAMPUS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD71	KRAMPUS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD72	KRAMPUS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD73	LEMON CREAM GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD74	LEMON CREAM GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD75	LEMON CREAM GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD76	LOVE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD77	LOVE 12mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD78	LOVE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD79	LOVE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD80	LOVE MENTHOL 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD81	LOVE MENTHOL 12mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD82	LOVE MENTHOL 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD83	LOVE MENTHOL 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD84	MAGOO 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD85	MAGOO 3mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD86	MAGOO 6mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD87	MARDI GRAS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD88	MARDI GRAS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD89	MARDI GRAS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD90	MAUI 0mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 0mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD91	MAUI 3mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD92	MAUI 6mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD93	NEW YORK STRAWBERRY CHEESECAKE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD94	NEW YORK STRAWBERRY CHEESECAKE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD95	NEW YORK STRAWBERRY CHEESECAKE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD96	ORIGINAL G 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD97	ORIGINAL G 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD98	ORIGINAL G 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD99	PADME 0mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD100	PADME 3mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD101	PADME 6mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD102	PARADISE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD103	PARADISE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD104	PARADISE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD105	PEACH ICE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD106	PEACH ICE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD107	PEACH ICE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD108	POLAR BLAST 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD109	POLAR BLAST 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD110	POLAR BLAST 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD111	POLAR MELON 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 0 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD112	POLAR MELON 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 3 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD113	POLAR MELON 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 6 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD114	RANGER 0mg	Other	Bottle	1	Other	Bottle	Menthol		Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD115	RANGER 12mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD116	RANGER 3mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD117	RANGER 6mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD118	RASPBERRY APPLE CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD119	RASPBERRY APPLE CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD120	RASPBERRY APPLE CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD121	RAZZ THE CHERRY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD122	RAZZ THE CHERRY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD123	RAZZ THE CHERRY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD124	SALTY GRANDMA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD125	SALTY GRANDMA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD126	SALTY GRANDMA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD127	SAMOA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD128	SAMOA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD129	SAMOA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD130	SLIM WHITTMAN 0mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD131	SLIM WHITTMAN 12mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD132	SLIM WHITTMAN 3mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD133	SLIM WHITTMAN 6mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD134	SMEXY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD135	SMEXY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD136	SMEXY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD137	STRAWBERRY GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD138	STRAWBERRY GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD139	STRAWBERRY GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD140	STRAWBERRY GRAHAM CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD141	STRAWBERRY GRAHAM CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD142	STRAWBERRY GRAHAM CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD143	THE OC 0mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD144	THE OC 3mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD145	THE OC 6mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD146	VANILLA BOURBON CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD147	VANILLA BOURBON CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD148	VANILLA BOURBON CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD149	WATERMALONE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD150	WATERMALONE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD151	WATERMALONE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD152	YUUM 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD153	YUUM 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD154	YUUM 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

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Case No.: _____

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Johnny Copper LLC,

Petitioner,

v.

U.S. Food and Drug Administration; Robert M. Califf, M.D., Commissioner; U.S. Department of Health and Human Services; Xavier Becerra, Secretary,

Respondents.

ON PETITION FOR REVIEW OF A FINAL MARKETING DENIAL ORDER BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION
AGENCY DOCKET NO. PM0003757

PETITION FOR REVIEW

/s/ J. Gregory Troutman
J. GREGORY TROUTMAN
TROUTMAN LAW OFFICE, PLLC
4205 Springhurst Blvd., Suite 201
Louisville, KY 40241
(502) 412-9179
jgtatty@yahoo.com

Counsel for Petitioner

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, Petitioner hereby certifies that the following have an interest in the outcome of this petition for review:

1. Samuel R. Bagenstos (HHS General Counsel)
2. Xavier Becerra (Respondent; HHS Secretary)
3. Robert M. Califf (Respondent; FDA Commissioner)
4. Merrick B. Garland (Attorney General of the United States)
5. Troutman Law Office, PLLC (counsel for Petitioner)
6. Dr. Brian King (Director, FDA Center for Tobacco Products)
7. J. Gregory Troutman (counsel for Petitioner)
8. Johnny Copper LLC (Petitioner)
9. United States Department of Health & Human Services (Respondent)
10. United States Department of Justice
11. United States Food & Drug Administration (Respondent)
12. Wendy S. Vicente (FDA Deputy Chief Counsel for Litigation)

FED. R. APP. P. 26.1 Disclosure Statement: No parent corporation or publicly held corporation owns 10% or more of any stock in either Respondent.

11th Cir. R. 26.1-3 Certification: No publicly traded company or corporation has an interest in the outcome of this appeal.

11th Cir. R. 26.1-2 Certification: The undersigned certifies that this CIP is complete at the time of filing.

Dated: October 12, 2024.

/s/ J. Gregory Troutman

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TROUTMAN LAW OFFICE, PLLC
4205 Springhurst Blvd., Suite 201
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Counsel for Petitioner

PETITION FOR REVIEW

Petitioner Johnny Copper LLC (Johnny Copper), pursuant to Section 912 of the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Family Smoking Prevention and Tobacco Control Act (TCA), 21 U.S.C. § 387*l*, as well as FED. R. APP. P. 15(a) and 11th CIR. R. 15-2, respectfully submits this petition for review of a Marketing Denial Order (MDO) issued by Respondent U.S. Food and Drug Administration (FDA) under 21 U.S.C. § 387j(c) for various Johnny Copper vaping products (STN PM0003757). A copy of the MDO is attached as Ex. 1. The MDO is dated September 13, 2024, and this petition is timely pursuant to 21 U.S.C. § 387*l*(a).

Venue is proper in this Circuit because Johnny Copper has its principal place of business located at 406 Walnut Street, Green Cove Springs, Florida 32043, within this Circuit. Johnny Copper is also a "person adversely affected by" the MDO, as required by 21 U.S.C. § 387*l*(a)(1)(B), as it manufactured and sold the vaping products subject to the MDO and will not be able to do so if the MDO remains in place.

Johnny Copper seeks review of the MDO under Section 19 of the TCA, 21 U.S.C. § 387*l*(b), and the Administrative Procedure Act (APA), 5

U.S.C. § 701, *et seq.*, on the grounds that the MDO: (i) is arbitrary, capricious, an abuse of discretion, and not in accordance with the law; (ii) violates the Constitution, including the Due Process Clause of the Fifth Amendment, and the TCA; (iii) is in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (iv) was issued without observance of procedure required by law; and (v) is not otherwise supported by substantial evidence.

Accordingly, Johnny Copper respectfully requests that this Court grant the following relief: (i) adjudge the constitutionality of FDA's regulatory authority over vaping products; (ii) hold that the MDO is unlawful; (iii) vacate the MDO and remand to FDA for further proceedings; (iv) stay the MDO pending the outcome of this petition for review; and (v) provide such other relief as this Court deems appropriate.

Dated: October 12, 2024

/s/ J. Gregory Troutman

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TROUTMAN LAW OFFICE, PLLC
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Louisville, KY 40241
(502) 412-9179
jgattty@yahoo.com

Counsel for Petitioner

CERTIFICATE OF SERVICE

I hereby certify that on October 12, 2024, I filed the foregoing Petition for Review via the Court's ECF filing system. I further certify that I will cause a copy to be served on the following by Certified Mail/Return Receipt Requested and by electronic mail where indicated:

Hon. Merrick B. Garland
Attorney General of the United States
United States Department of Justice
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Washington, D.C. 20530-0001

Attorney General for Administration
Justice Management Division
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/s/ J. Gregory Troutman
J. GREGORY TROUTMAN

EXHIBIT 1

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

September 13, 2024

DENIAL

Johnny Copper LLC
Attention: Lorelei Harper
406 Walnut Street
Green Cove Springs, FL 32043

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

Dear Lorelei Harper:

We are denying a marketing granted order for the products identified in Appendix A.

The statute places the burden on the applicant to make the required showing by providing that FDA "shall deny an application" for a product to receive a PMTA marketing authorization if, "upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product," FDA finds that "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health" (APPH). 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 APPH. 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. These actions may include, but are not limited to, civil money penalties, including an enhanced civil money penalty under FD&C Act section 303(f)(9)(B)(i), seizure, and/or injunction.

If you choose to submit new applications for these products, you must fulfill all requirements set forth in section 910(b)(1) and 21 CFR Part 1114. 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. 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. There is substantial evidence that flavored ENDS, like the subject products, have significant appeal to youth and are associated with youth initiation and use. The marketing restrictions and other mitigation measures that you proposed cannot mitigate the substantial risk to youth from flavored ENDS sufficiently to reduce the magnitude of adult benefit required to demonstrate APPH. In light of the known risks to youth of marketing flavored ENDS, robust and reliable

[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

evidence is needed regarding the benefit to adults who smoke, who switch completely or significantly reduce their smoking. Whether other products give adults who smoke comparable options for complete switching or significant cigarette reduction bears on the extent of the public health benefit that the subject ENDS arguably provide to that population. Because tobacco-flavored ENDS have not been shown to present the same risks to youth as flavored ENDS, marketing of flavored ENDS is APPH only if the evidence shows a benefit to adults who smoke as compared to tobacco-flavored ENDS.

This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit to adults who use your flavored ENDS products over an appropriate comparator tobacco-flavored ENDS. We did not find such evidence in your PMTA. FDA would also consider other evidence that reliably and robustly evaluated the impact of the new flavored vs. tobacco-flavored products on complete switching or significant cigarette reduction over time among adults who use combustible cigarettes. Although your PMTA contained three cross-sectional surveys on perceptions and use of combusted cigarettes and ENDS products, this evidence is not sufficient to show a benefit of using these flavored ENDS to adults who smoke because it does not evaluate the specific products in the application; evaluate complete switching or significant cigarette reduction resulting from use of these products over time; or evaluate these outcomes based on flavor type to enable comparisons between tobacco and other flavors.

Without this information, FDA cannot determine whether 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 APPH. Because you have not met your burden of "showing" that permitting the marketing of the new products would be APPH as required by Section 910(c)(2)(A), we must deny authorization for your application.

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. Because you have not met your burden of "showing" that permitting the marketing of the new products would be APPH as required by Section 910(c)(2)(A), we are issuing a marketing denial 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 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 Fatima Sow, Regulatory Health Project Manager, at (301) 796-1751 or Fatima.Sow@fda.hhs.gov.

Sincerely,

Digitally signed by Benjamin Apelberg -S
Date: 2024.09.13 10:11:54 -04'00'

Benjamin Apelberg, Ph.D.
Deputy 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

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

Appendix A

New Tobacco Products Subject of This Letter

Common Attributes[7,8,9,10,11]	
Submit date	September 6, 2020
Receipt date	September 9, 2020
Applicant	Johnny Copper LLC
Product manufacturer	Johnny Copper LLC
Product category	Electronic Nicotine Delivery Systems (ENDS) (VAPES)
Product subcategory	ENDS Component

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

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

[9] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. Therefore, nicotine source should be included in future submissions.

[10] Attributes in Appendix A may display converted values.

[11] Attributes of certain products intentionally left blank, as there were not provided by the applicant.

STN	PD#	Product Name	Package Type	Package Type, if Other	Product Quantity Numeric Value	Units (Product Quantity)	Units, if Other (Product Quantity)	Characterizing Flavor	Characterizing Flavor, If Flavored	Nicotine Source	Additional Property
PM0003757	PD1	2 BERRIEZ 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD2	2 BERRIEZ 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD3	2 BERRIEZ 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Blueberry		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD4	APPLEMANE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD5	APPLEMANE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD6	APPLEMANE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Apple		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD7	BAM 0mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 0 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD8	BAM 3mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 3 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD9	BAM 6mg	Other	Bottle	1	Other	Bottle	Flavored	Fruity Cereal		Nicotine Concentration: 6 mg, PG/VG: 26/74, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD10	BANANA NUT BREAD CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 60, 120 ml, 240 ml
PM0003757	PD11	BANANA NUT BREAD CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD12	BANANA NUT BREAD CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Nut Bread Custard		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD13	BERRY DEW 0mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD14	BERRY DEW 3mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD15	BERRY DEW 6mg	Other	Bottle	1	Other	Bottle	Flavored	Honeydew, Honeysuckle, Pear & Strawberry		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD16	BERRY MONTANA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD17	BERRY MONTANA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD18	BERRY MONTANA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Blackberry		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD19	BLUEBERRY CRUNCH GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD20	BLUEBERRY CRUNCH GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD21	BLUEBERRY CRUNCH GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Blueberry Crunch Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD22	BUTTERSCOTCH CUSTAFD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD23	BUTTERSCOTCH CUSTAFD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD24	BUTTERSCOTCH CUSTAFD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Butterscotch Custard		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD25	CARMA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD26	CARMA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD27	CARMA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Macchiato		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD28	CnK 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD29	CnK 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD30	CnK 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cookies & Cream		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD31	DOVE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD32	DOVE 12mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 12 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD33	DOVE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD34	DOVE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Cuban Cigar		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD35	FATHEAD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD36	FATHEAD 12mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD37	FATHEAD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD38	FATHEAD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Caramel Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD39	FLAKEY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD40	FLAKEY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD41	FLAKEY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Frosted Dessert		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD42	FLAWLESS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD43	FLAWLESS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD44	FLAWLESS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Apple Apricot & Berries		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD45	FRIGID 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD46	FRIGID 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD47	FRIGID 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD48	FROZEN 0mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen	Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD49	FROZEN 3mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD50	FROZEN 6mg	Other	Bottle	1	Other	Bottle	Flavored	Frozen		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD51	GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD52	GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD53	GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD54	GLIDER 0mg	Other	Bottle	1	Other	Bottle	Flavored	Traditional Tobacco	Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD55	GLIDER 12mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD56	GLIDER 3mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD57	GLIDER 6mg	Other	Bottle	1	Other	Bottle	Flavored	Glider		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD58	Huckleberry Cheesecake 0mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD59	Huckleberry Cheesecake 3mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD60	Huckleberry Cheesecake 6mg	Other	Bottle	1	Other	Bottle	Flavored	Huckleberry Cheesecake		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD61	IGNITION 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD62	IGNITION 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD63	IGNITION 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sweet Citrus Blend		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD64	JAG 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD65	JAG 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD66	JAG 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Strawberry		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD67	JOHNNY CANNOLI 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD68	JOHNNY CANNOLI 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD69	JOHNNY CANNOLI 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cannoli		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD70	KRAMPUS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD71	KRAMPUS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD72	KRAMPUS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peppermint Candy		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD73	LEMON CREAM GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD74	LEMON CREAM GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD75	LEMON CREAM GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Lemon Cream Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD76	LOVE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD77	LOVE 12mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD78	LOVE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD79	LOVE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Clove Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD80	LOVE MENTHOL 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD81	LOVE MENTHOL 12mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD82	LOVE MENTHOL 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD83	LOVE MENTHOL 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Clove Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD84	MAGOO 0mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD85	MAGOO 3mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD86	MAGOO 6mg	Other	Bottle	1	Other	Bottle	Flavored	Banana Dragonfruit Strawberry		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD87	MARDI GRAS 0mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD88	MARDI GRAS 3mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD89	MARDI GRAS 6mg	Other	Bottle	1	Other	Bottle	Flavored	Rainbow Candy		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD90	MAUI 0mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 0mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD91	MAUI 3mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD92	MAUI 6mg	Other	Bottle	1	Other	Bottle	Flavored	Pineapple Peach		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD93	NEW YORK STRAWBERRY CHEESECAKE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD94	NEW YORK STRAWBERRY CHEESECAKE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD95	NEW YORK STRAWBERRY CHEESECAKE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Cheesecake		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD96	ORIGINAL G 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD97	ORIGINAL G 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD98	ORIGINAL G 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Grape		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD99	PADME 0mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD100	PADME 3mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD101	PADME 6mg	Other	Bottle	1	Other	Bottle	Flavored	Butter Cake		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD102	PARADISE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD103	PARADISE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD104	PARADISE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Pina Colada		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD105	PEACH ICE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD106	PEACH ICE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD107	PEACH ICE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Peach & Menthol		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 60 ml, 120 ml, 240 ml
PM0003757	PD108	POLAR BLAST 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD109	POLAR BLAST 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD110	POLAR BLAST 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Citrus Blend		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD111	POLAR MELON 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 0 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD112	POLAR MELON 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 3 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD113	POLAR MELON 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon		Nicotine Concentration: 6 mg, PG/VG: 22/78, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD114	RANGER 0mg	Other	Bottle	1	Other	Bottle	Menthol		Tobacco	Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD115	RANGER 12mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD116	RANGER 3mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD117	RANGER 6mg	Other	Bottle	1	Other	Bottle	Menthol			Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD118	RASPBERRY APPLE CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD119	RASPBERRY APPLE CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD120	RASPBERRY APPLE CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Raspberry Custard		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD121	RAZZ THE CHERRY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD122	RAZZ THE CHERRY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD123	RAZZ THE CHERRY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Raspberry & Black Cherry		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD124	SALTY GRANDMA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD125	SALTY GRANDMA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD126	SALTY GRANDMA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Salted Pretzel		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

PM0003757	PD127	SAMOA 0mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD128	SAMOA 3mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD129	SAMOA 6mg	Other	Bottle	1	Other	Bottle	Flavored	Chocolate Coconut		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD130	SLIM WHITTMAN 0mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 0 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD131	SLIM WHITTMAN 12mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 12 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD132	SLIM WHITTMAN 3mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 3 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD133	SLIM WHITTMAN 6mg	Other	Bottle	1	Other	Bottle	Flavored	Honey Tobacco		Nicotine Concentration: 6 mg, PG/VG: 40/60, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD134	SMEXY 0mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD135	SMEXY 3mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD136	SMEXY 6mg	Other	Bottle	1	Other	Bottle	Flavored	Creamy Exotic Fruit		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD137	STRAWBERRY GLAZED DONUT 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD138	STRAWBERRY GLAZED DONUT 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD139	STRAWBERRY GLAZED DONUT 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Infused Glazed Donut		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD140	STRAWBERRY GRAHAM CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 0 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD141	STRAWBERRY GRAHAM CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 3 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD142	STRAWBERRY GRAHAM CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Strawberry Vanilla Graham Custard		Nicotine Concentration: 6 mg, PG/VG: 25/75, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD143	THE OC 0mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD144	THE OC 3mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD145	THE OC 6mg	Other	Bottle	1	Other	Bottle	Flavored	Orange Creamsickle		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD146	VANILLA BOURBON CUSTARD 0mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 0 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD147	VANILLA BOURBON CUSTARD 3mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 3 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD148	VANILLA BOURBON CUSTARD 6mg	Other	Bottle	1	Other	Bottle	Flavored	Vanilla Bourbon Custard		Nicotine Concentration: 6 mg, PG/VG: 15/85, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD149	WATERMALONE 0mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 0 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD150	WATERMALONE 3mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 3 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD151	WATERMALONE 6mg	Other	Bottle	1	Other	Bottle	Flavored	Sour Watermelon		Nicotine Concentration: 6 mg, PG/VG: 20/80, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD152	YUUM 0mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 0 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD153	YUUM 3mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 3 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml
PM0003757	PD154	YUUM 6mg	Other	Bottle	1	Other	Bottle	Flavored	Cool Watermelon Grape		Nicotine Concentration: 6 mg, PG/VG: 30/70, E-liquid volume: 30 ml, 60 ml, 120 ml, 240 ml

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

Johnny Copper L.L.C.,	)	
	)	
Petitioner,	)	
	)	
v.	)	CASE NO. 24-13302
	)	
U.S. Food and Drug Administration, *et al.*	)	
	)	
	)	
Respondents.	)	

DECLARATION OF DAN MARLIN

I, Dan Marlin, declare and state as follows:

1. I am the operations manager for Johnny Copper L.L.C. (Johnny Copper), and my son, Justin Marlin, is the company's sole owner. Johnny Copper has been in business since 2015, but my experience in the vaping products industry began in 2011. In 2021, Johnny Copper owned and operated 3 brick-and-mortar locations and had 12 employees. The factors discussed herein have forced Johnny Copper to reduce its footprint to own and operate 2 retail stores and have 3 employees.

2. In my role as operations manager, I was primarily responsible for the management of Johnny Copper's efforts to prepare and submit a premarket tobacco application (PMTA) for its e-liquid vaping products.

3. I am also tasked with ensuring Johnny Copper's compliance with applicable regulations and regulatory requirements and with monitoring the company's financial performance and, in conjunction with the company's owners, making appropriate adjustments to staffing levels based on demand for our open-system flavored e-liquid products.

4. The vaping products industry is segmented into the distinct "open-system" and "closed-system." This segmentation tracks the character of the manufacturers, the products' physical characteristics, and the retail channels which sell them.

5. Open-system products are typically larger and rely on: (1) high powered, rechargeable batteries (replaceable or self-contained within the device); (2) computer circuitry which allows the independent regulation of the device's temperature and wattage; and (3) interchangeable and refillable e-liquid tanks (referred to as atomizers). Open-system products are typically sold only in age-restricted specialty retail stores (*i.e.* vape shops) dedicated to such products. The technology used in open-system products allows adult consumers virtually unlimited freedom to customize their experience.

6. Closed-system products use a smaller device with either a disposable pre-filled cartridge or a fully disposable device/cartridge combination which offers e-liquids in a limited variety of flavors. Closed-system products are typically sold by general retailers like convenience stores which are not age-restricted. Since 2021 when FDA began issuing marketing denials to open-system products, many age-restricted specialty retailers began selling disposable products out of financial necessity. Closed-system products allow consumers few customization options but are simple to operate.

7. The small device size of closed-system products, their easy of use, and easy of purchase at non- age-restricted stores led to them becoming the overwhelming choice of youths, as evidenced by the 2023 National Youth Tobacco Survey (NYTS). The data from the NYTS evidenced that closed-system disposable vaping products are the vastly predominant choice of youths.[1]

8. Johnny Copper manufactures flavored open-system e-liquid brands, which it sells in company-owned stores (*i.e.* vape shops), directly

[1] Birdsey, J., *et al. Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023.* MMWR Morb. Mortal Wkly. Rep. 2023;72:1173–1182 at Table 3.

through vape shops owned by other industry stakeholders, or to vape shops through distributors. In total, Johnny Copper's revenues in recent years based on both sales of its own branded flavored e-liquids and the e-liquids that it manufactures for third parties have typically been about $4.3 million.

9. Although Johnny Copper exclusively sells its vaping products in age-restricted retail stores, it nevertheless attempted to avoid using child-attractive or child-enticing branding and labeling. Specimens of Johnny Copper's branding is included as Attachment 1 and incorporated by this reference.

10. When it became clear that Johnny Copper would be required to prepare and submit a PMTA to FDA for all of its e-liquid products in order to keep selling them in the United States, the company embarked on extensive efforts to prepare an appropriate PMTA that would provide the information FDA had indicated was necessary in both its final PMTA guidance document and its proposed PMTA rule.

11. While initially fearing that Johnny Copper's lack of resources would make preparing a PMTA cost prohibitive, I soon found various trade groups that assisted in preparing a PMTA. I am a board member

of the Florida Smoke Free Association (FSFA) and Johnny Copper is a FSFA member. Johnny Copper is also a member of the Smoke Free Alternatives Trade Association (SFATA), the United States Vaping Association (USVA), and the American Vapor Manufacturers Association (AVM). Johnny Copper was also a member of the Vapor Technology Association at the time of its PMTA and adopted its standard operating procedures regarding the prevention of youth vaping. *See* Attachment 2 which is incorporated by this reference. Joining these various organizations was Johnny Copper's only way to attempt to comply as, despite its attempts at a constant dialogue, no one at FDA could ever provide is concrete answers or guidance beyond that made publicly available.

12. In order to ensure that Johnny Copper complied with FDA's published requirements, it relied upon the guidance and peer-to-peer resources which AVM offered its vaping product industry members. This membership has cost Johnny Copper $5,000 per year.

13. Overall, Johnny Copper spent several thousand labor hours preparing its PMTA. Johnny Copper also conducted additional testing which brought its total cost of submitting and compiling a PMTA to over

$150,000. Johnny Copper's PMTA consisted of 330,000 pages which comprised 66 gigabytes of data. Due to FDA's constantly shifting guidance concerning the contents of the PMTA and other compliance issues, Johnny Copper separately spent more than $100,000 on compliance-related issues.

14. Based on Johnny Copper's reviews of the materials published by FDA, it understood the completion of long-term clinical studies would not be required. I understood from FDA's materials that a long-term clinical study was a longitudinal study lasting six months or more which FDA specifically stated in its final PMTA guidance, proposed PMTA rule and final PMTA rule that it did not expect would be required.

15. All of the e-liquids subject to Johnny Copper's PMTA are used in "open-system" vaping devices, which have only ever been sold in retail stores which require age verification to enter or through online retail portals which I ensured would only sell to customers who were legally permitted to make purchases. Johnny Copper's PMTA emphasized age restrictions for physical and online sales as part of the description of its marketing plan and emphasized that the FDA's concern with youth initiation did not pertain to e-liquids designed for open-system devices.

See Attachment 3 which is incorporated herein by reference. None of Johnny Copper's e-liquids have ever been sold in convenience stores or other non- age-restricted general retail outlets. Further, Johnny Copper's review of FDA's online compliance database reveals that none of its products have been the subject of illicit purchases.

16. Johnny Copper also did not understand from any of FDA's pre-PMTA materials that it had any requirement to conduct a comparative efficacy study whereby it would have to compare the effectiveness of its non- tobacco-flavored e-liquids in helping existing smokers to stop smoking versus the effectiveness of its tobacco-flavored e-liquids. Frankly, this idea never crossed my mind because Johnny Cooper has never been able to market its e-liquids as smoking cessation products because the Tobacco Control Act (TCA) and FDA's regulations specifically prohibit such comparisons. In fact, the TCA requires that a manufacturer first obtain a modified risk tobacco product order from FDA before explicitly comparing vaping products to combustible cigarettes.

17. Johnny Copper's PMTA, however, included the results of a survey given to its customers. *See* Attachment 4 which is incorporated by reference. In total, Johnny Copper received over 195 customer responses.

The survey responses revealed that:

- 66.2 percent of the customers were over the age of 34;
- 97.9 percent were former smokers;
- Only 7.7 percent of the customers stated they used both vaping devices and combustible tobacco;
- 52.3 percent of the customers who smoked combustibles in the past were able to stop immediately after using vaping products;
- Only 5.1 percent of the customers reported that they were still using combustibles;
- Of those customers who still smoked, almost all of them reported their goal was to stop;
- 74.9 percent of the customers reported their goal was to stop using all tobacco products;
- 91.8 percent of the customers stated that vaping products helped them avoid smoking combustibles;
- 96.4 percent of the customers use non-tobacco-flavored vaping products;
- 73.8 percent of the customers had used other means of cessation in the past, such as Chantix;
- 98.1 percent of the customers stated that they either only used "open-system" vaping devices or used both open and closed systems.

18. Johnny Copper's survey also allowed customers to share their personal stories about how vaping products had changed their lives by allowing them to avoid combustible tobacco products. Their responses

were stories I have repeatedly heard many times since 2011—articulating how vaping products had helped them stop smoking, in some cases after many years, or how vaping "saved their life."

19. The e-liquids that were subject to Johnny Copper's PMTA have only ever been sold in age-restricted vape and tobacco-specialty shops or through vetted age-restricted online retail portals. This means that customers must prove they are at least 21 years old, the minimum purchase age under federal law, in order to have access to, or purchase, Johnny Copper's e-liquid products

20. In conjunction with submission of Johnny Copper's PMTA and included as a part of the required marketing plan, the company determined not to engage in any marketing for its vaping products outside of the vape and tobacco-specialty shop, online store context, or its business pages on Instagram and Facebook. As such, Johnny Copper has never run radio advertisements, magazine advertisements, television spots, or social media posts to attempt to promote our products. Rather, Johnny Copper's products are only marketed at the actual point of purchase. Part of the reason that Johnny Copper restricts its marketing in this manner to ensure its completion of long-term clinical studies are

carefully targeted towards its customer base — adult consumers who are cigarette smokers or consumers of vaping products—and not individuals who are non-users of tobacco products.

21. Johnny Copper timely submitted its PMTA to FDA on September 9, 2020, and included over 53 scientific studies. *See* Attachment 5 which is incorporated herein by reference.[2]

22. Johnny Copper did not learn about FDA's August 26, 2021 press release which first stated its requirement for a product-specific comparative efficacy study until received such information from the aforementioned industry organizations. Johnny Copper attempted to communicate with FDA to get more information and clarification shortly before the 2021 MDO but received no response.

23. Because Johnny Copper's initial MDO came after many manufacturers had received an MDO, I was not surprised when FDA issued its MDO. I was, however, very surprised that the MDO also applied to some of Johnny Copper's menthol-flavored products because FDA's pre-PMTA guidance, proposed PMTA rule and final PMTA rule

[2] As republishing the studies here would be voluminous, Johnny Copper has attached only the "Index of Studies," which contains links for each study and was part of its PMTA. This index was an excel spreadsheet which Johnny Copper has reformatted for readability as a PDF file.

stated an intention to treat menthol-flavored products the same as tobacco-flavored products.

24. The Technical Project Lead (TPL) report which accompanied the 2021 MDO explained that FDA reviews Johnny Copper's PMTA and did not look beyond whether it contained a long-term comparative efficacy study. When FDA conducted its re-review of Johnny Copper's PMTA after the *Bidi* ruling, it appears to have merely conducted a "targeted" review, nearly 2 years later. It also appears that FDA again refused to conduct a full and individualized review of Johnny Copper's PMTA which the TCA requires.

25. The vaping products that were subject to Johnny Copper's PMTA and MDO represent 99.5 percent of its revenues in 2020 (the last full year before the initial MDO), approximately $1.2 million dollars. As of today, Johnny Copper's revenues have been reduced to between $500,000.00 and $600,000.00.

26. Since the initial MDO, disposable vaping products have now dominated the vaping products market although none of them have been granted market authorization by FDA. *See* Attachment 6 which is incorporated by this reference. It has been my experience as a vape

industry retailer that unauthorized disposable vaping products are now the predominant choice of consumers and that fact has reduced the revenues of the brick-and-mortar retail sector and explains Johnny Copper's reduced revenues.

27. In addition, several states have adopted laws since 2022 which created a "registry" of vaping products either authorized by FDA, still under a PMTA review, or subject to a federal court stay. Johnny Copper has been able to continue selling its vaping products in those states because of the stay issued as a result of the *Bidi* case and the subsequent re-review status following remand. Johnny Copper, however, will be forced to immediately remove its vaping products from those states absent a stay of the second MDO.

28. If Johnny Copper does not receive a stay of the second MDO, it will lose much its current revenues and will potentially be forced to lay off employees shut down our operations within approximately the 60 days if it does not receive a stay from the Court.

29. Pursuant to 28 U.S.C. § 1746, I verify under penalty of perjury that the factual statements in this declaration concerning myself, my activities, and my intentions are true and current.

Dated: October 22, 2024.

DAN MARLIN

Executed in Clay County, Florida.

ATTACHMENT 1


120ml
TOBACCO
0,3,6,12mg
DOVE
SWEET CUBAN CIGAR
FATHEAD
SWEET TOBACCO
GLIDER
TRADITIONAL TOBACCO
LOVE
TOBACCO
LOVE MENTHOL
MENTHOL TOBACCO
RANGER
MENTHOL TOBACCO
SLIM WHITTMAN
BLACK HONEY TOBACCO
COPPER
E-LIQUID
- DOVE : Sweet Cuban Cigar
- FATHEAD : Sweet Tobacco
- GLIDER : Traditional Tobacco
- LOVE : Clove Tobacco
- LOVE MENTHOL : Clove Menthol Tobacco
- RANGER : Menthol Tobacco
- SLIM WHITTMAN : Black Honey Tobacco


120ml
CUSTARDS
0,3,6mg
JOHNNY COPPER
E-LIQUID
est. 2015
BANANA NUT BREAD CUSTARD
BUTTER SCOTCH CUSTARD
MAPLE CARAMEL VANILLA BOURBON CUSTARD
RASPBERRY APPLE CUSTARD
STRAWBERRY GRAHAM CUSTARD
VANILLA BOURBON CUSTARD
- BANANA NUT BREAD CUSTARD
- BUTTERSCOTCH CUSTARD
- MAPLE CARAMEL VANILLA BOURBON CUSTARD
- RASPBERRY APPLE CUSTARD
- STRAWBERRY GRAHAM CUSTARD
- VANILLA BOURBON CUSTARD


120ml
CHEESECAKE
0,3,6mg
JOHNNY COPPER
E-LIQUID
HUCKLEBERRY CHEESECAKE
NEW YORK STRAWBERRY CHEESECAKE
- HUCKLEBERRY CHEESECAKE
- NY SRAWBERRY CHEESECAKE

WARNING: This product contains nicotine. Nicotine is an addictive chemical.

WARNING: This product contains nicotine. Nicotine is an addictive chemical.

ATTACHMENT 2

Youth Access Prevention Plan for Johnny Copper LL

With the ever-increasing use of ENDS products by adult smokers looking for an alternative to combustible tobacco, Johnny Copper is committed to doing our part in preventing underage use of ENDS products in our community. As this Youth Action Prevention Plan will show, we have implemented thorough methods of preventing youth access to Johnny Copper open-system e-liquid products.

- **Point of Sale ID Checks, Training, and Certification**

  At the point of sale, IDs are examined and scanned for each purchase no matter the age of the purchaser. Each employee must complete WeCard training. Our locations have been implementing age restrictions before it was law on these products due to their nature. All our locations have exceptionally large readable signage that indicates to be prepared with ID, as well as prominent signage on retail locations stating, "No one under 21 permitted". Our state jurisdictions conduct many underage sting operations. We have received congratulatory letters state authorities on passing these sting operations by refusing to sell to a minor. Our retail locations have an exemplary record and have never been cited for sales to minors. We will continue to strive to achieve this excellence as we have for many years. We discourage sales to anyone who is not a current smoker. This stems from our belief of not encouraging any unnecessary behaviors. Our mission is to step the customer down over time in nicotine strengths until the customer is eventually at 0% nicotine.

- **Vapor Sales Policy and Procedure**

  Johnny Copper has spent a significant amount of time and resources to ensure that the company is doing everything it can to prevent youth access to our products. Johnny Copper prohibits entry of minors into all our retail locations. We require ID verification for all purchases. Our register system requires an ID swipe for every transaction processed, and ID's are examined by retail employees to verify that the photograph on the ID matches the purchaser; then the ID is scanned to verify that the purchaser is over 21 and that the ID is valid. All retail employees undergo thorough training on our age verification procedures.

  Each employee has a moral, ethical and legal responsibility to refuse to sell vapor products to anyone under the age of 21. Vapor products must not be sold to anyone under the age of 21. This is the law. We require all employees to check for proof of age for any customer who is attempting to purchase vapor products.

  - **Verify the customer's age before selling vapor products.**

    The customer must have an acceptable and valid Driver's License, Non Driver ID, or Commercial Driver's License to purchase tobacco products.

  - **Verify the identity of the customer.**

The person attempting to make the purchase must be the person shown on the card. The card cannot be expired. If the card is expired, the sale must be refused. When reviewing an ID card, always do the following: verify that the photo is of the customer presenting the ID, the ID is not expired, verify that the issuing agency of the ID is acceptable, and verify that the ID has not been altered and is not fake.

Always verify that the photo is of the customer presenting the ID. If a customer is unable to produce a valid photo ID, you must refuse the sale. They cannot purchase the product and then bring the ID back at a later time.

- **Conducting a sale.**

  Card each customer BEFORE reaching for the vapor product requested by the customer. First ask for a form of identification. Review the card (photo, dob, expiration date, description, agency issuing card). Be sure the person giving you the ID is the person standing in front of you. If you have placed the tobacco product on counter before carding and you determine the person is under 21 or does not have a valid ID, immediately remove product from the counter and customer's reach and state, "I'm sorry, it's against the law for me to sell this product to you, and I would lose my job". Always be polite, but be firm, and refuse the sale.

- **Other points**

  It is illegal for a minor to purchase vapor products for anyone for any reason. A minor may not purchase these products for a parent. It is illegal for an adult to purchase these products for a minor. Never sell vapor products to anyone if you have reason to believe they are going to give them to someone under the age of 21. Remember, no one under 21 may possess vapor products of any kind.

- **Training**

  Upon beginning employment, all employees will receive training to ensure that they understand all state laws and company policies regarding the prohibition against selling tobacco products to minors. In particular, the training will consist of the following:

  - Review of Policy and Procedures for Vapor Sales. Each employee will read policy and manager will review the policy with them.

  - Review of ID Brochures from relevant state agencies. Employees will be shown the markings indicating underage and how to determine the customer’s age

- Review of WeCard Training Materials. Employees will receive explanation of all WeCard materials including the calendar

- Employee will sign the Age-Verification/Youth Prevention Training Form indicating that they agree not to sell vapor products to anyone underage and will fully comply with all Johnny Copper Age-Verification Procedures.

- **Additional Aides**

  We make use of several aides to help our employees identify underage customers. Some of these aides include:

  - Every register is equipped with an ID scanner. Registers require ID scans before a sale can be processed.

  - WeCard calendars at all registers.

  - Current Birth Year of Age 21 posters and stickers visible from register.

  - Ongoing training and refresher materials provided to all employees.

- **Online E-Commerce Age-Restrictions**

  Online sales are restricted to adults following age verification through independent, third-party agencies using public records databases. Johnny Copper' e-commerce platform (www.JohnnyCopper.org) utilizes third-party age verification technology through AgeChecker.net.

  - Age Restriction. Company product sales must comply with all county, city, and state age restriction laws for e-vapor product purchase.

  - Age Verification. Online company product sales are restricted to adults age verified by independent third-party companies using public records databases. For all sales made to individuals under the age of 27 years old, age verify by means of government issued photographic identification containing the bearer's date of birth.

  - Compliance with California's Stop Tobacco Access to Kids Enforcement Act ("STAKE Act") for sales in California. California law prohibits the sale of tobacco products to anyone under the age of 21 (Cal. Bus. & Prof. Code § 22958(a)) and the STAKE Act imposes mandatory steps that online distributors and sellers of tobacco products are required to follow to verify that a purchaser of these items is 21 years of age or older. The steps required under the STAKE ACT are:

- Attempt to match the name, address and date of birth provided by the customer to information contained in records in a database of individuals whose age has been verified to be 21 years or older by reference to an appropriate database of government records kept by the distributor, a direct marketing firm, or any other entity.

- Verify that the billing address on the check or credit card offered for payment by the purchaser matches the address listed in the database.

- If unable to verify that the purchaser is 21 years of age through the above, require the customer or recipient to submit an age-verification kit consisting of an attestation signed by the customer that he or she is 21 years of age or older and a copy of a valid form of government identification.

- Verify that the billing address on the check or credit card provided by the consumer matches the address listed in the form of government identification.

- For credit card transactions, submit information to each credit card company so that the words "tobacco product" may be printed in the purchaser's credit card statement.

- Regardless of the form of payment, prior to shipping the tobacco product to a California customer, make a telephone call after 5 p.m. to the purchaser or recipient confirming the order. The call may be a recorded message left on voicemail.

- Deliver only to the purchaser or recipient's verified billing address on the check or credit card used for payment. Delivery to a post office box address is prohibited.

- **Child Resistant Packaging**

  Johnny Copper open-system e-liquid products will use child resistant packaging in compliance with the Child Nicotine Poisoning Prevention Act of 2015.

- **Appropriate Marketing and Packaging**

  - As a member of the Vapor Technology Association, we adhere to their strict marketing guidelines. VTA Marketing Standards for Membership are based on the following core principles:

    - VTA is committed to educating and informing its members on the best ways to comply with applicable laws and regulations governing electronic cigarettes, vaporizers and related electronic nicotine delivery systems ("Vapor Products"),

which laws include, but are not limited to, the Federal Food Drug & Cosmetic Act (21 USC Ch. 9 et seq.) as modified by the Family Smoking Prevention and Tobacco Control Act and 21 CFR Parts 1100, 1140 and 1143 (Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, May 10, 2016) (the "Tobacco Control Act")and the Child Nicotine Poisoning Prevention Act of 2015, 15 U.S.C. §§ 1471, et seq.

- Vapor Products are for adults only and should not be intentionally marketed to, sold to or used by those who have not attained the age of 21 years (or the appropriate age restriction within the subject territory) ("Minors").

- VTA Members' marketing activities must refrain from knowingly marketing Vapor Products to Minors, which is strictly prohibited.

- Our social media accounts are age restricted to 21+, meaning that no one under the age of 21 can view them.

- Our website utilizes an age gate which requires users to confirm they are of legal vaping age (21+) before viewing the site.

- Our packaging is never labeled in a way that is misleading or resembles copyright protected or kid-friendly food products.

- Our vapor products do not include content which is directed towards Minors.

- Our marketing of vapor products is not directed at Minors and no channel of marketing is employed if more than 15% of its audience is Minors. This restriction includes, but is not necessarily limited to, TV, print and radio advertising, as well as event marketing or sponsorships. Our advertising is limited to radio stations whose target market is age 25 and up. *(Note: Johnny Copper does not utilize TV, print, or radio advertising.)*

- Our vapor products do not use in commerce names, imagery or designs that intentionally mimic, play upon, invoke or otherwise infringe upon existing trademarks, trade names or trade dress, particularly if they are associated with products that are or were primarily marketed to Minors.

- Our vapor products are not portrayed as any sort of smoking cessation device or as a product which may be used to help quit smoking.

- Our vapor products are not marketed as providing a therapeutic value, as being safe or healthy for consumers, or as products which do not produce secondhand health effects.

- Our vapor products are not be marketed or sold using modified risk descriptors or claims (e.g., "light," "low," and/or "mild"). Our vapor products are not marketed as

(a) having no ash or smoke, (b) having no tar, (c) being less harmful, (d) posing lower risk of disease or (e) as containing reduced or zero levels of harmful ingredients.

- We accurately represent the ingredients contained in our Vapor Products and, in particular, the ingredients contained in any e-liquid. We do not deceive the consumer regarding the contents of our vapor products.

- We ensure that all product sampling is restricted to adults and follow all applicable laws.

- We do not use health professionals to market or otherwise endorse our vapor products, directly or indirectly.

- Our marketing is directed towards those who are current users of tobacco products and are never designed to encourage non-tobacco users to start using Vapor Products.

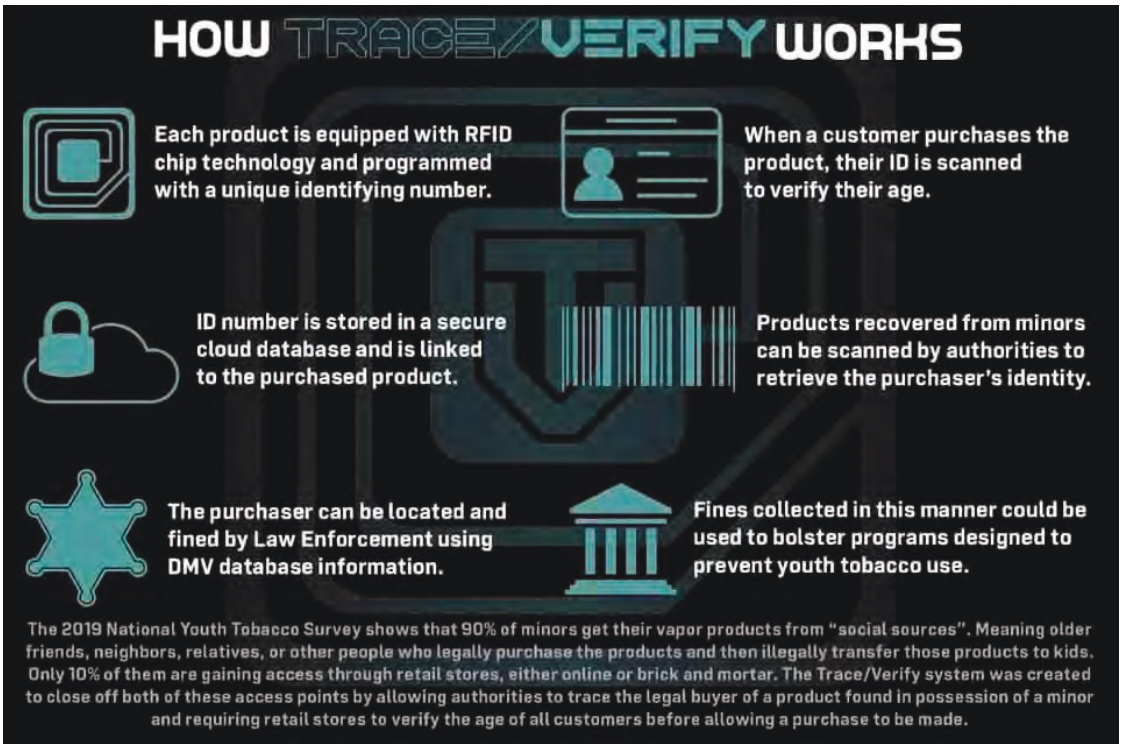
- Contracted spokespeople and individuals endorsing Vapor Products on our behalf must be and appear to be at least 35 years of age.

- Billboard advertisements used for the purpose of promoting or marketing vapor products are not physically located within 500 feet of any elementary or secondary school, youth-oriented facility, or childcare facility. *(Note: Johnny Copper does not utilize billboard advertising.)*

- **Trace/Verify**

Johnny Copper is also implementing Trace/Verify technology on all the bottles of e-liquid we produce to assist retailers and law enforcement in efforts to prevent minor use of vapor products. Trace/Verify utilizes QR codes placed on each vapor product sold. The QR code stores the driver's license number used to purchase the product, as well as the date and location of the transaction. This information can later be retrieved if that product is found to be in possession of a minor, in order to identify how the minor came to be in possession of the product. Johnny Copper is continually looking at new and innovative ways to prevent youth access to vapor products.

The goal of Trace/Verify is to provide accountability for tobacco manufacturers and retailers as well as a method for law enforcement and regulatory authorities to ensure that significantly fewer ENDS products end up in the hands of youth. In addition, authorities can confiscate those products that do and levy enforcement action against the parties who are responsible, whether they are manufacturers, retailers, or straw buyers such as family members or friends.



- **Conclusion**

Johnny Copper' goal in its efforts is to provide adult consumers who would otherwise be smoking combustible cigarettes with an alternative source of nicotine, while preventing minors for accessing vapor products. To that end, Johnny Copper has implemented robust youth prevention methods for its retail operations including preventing entry of minors into retail locations, mandatory ID scanning for all purchases in retail locations, third party age-verification technology, as well as Trace/Verify QR tracking on Johnny Copper open systems e-liquid products.

Johnny Copper consumer survey data demonstrates that the company's safeguards and stringent age-verification protocols have made the company successful in its mission of providing quality products to an older adult consumer base of former combustible tobacco smokers. Furthermore, Johnny Copper consumer demographic and age data shows that this Youth Prevention Plan is successful in its effort to prevent underage use of Johnny Copper products.

Accordingly, as detailed in this application, based on a robust Youth Prevention Plan, evidence of adult-only sales and a restricted, adult-oriented marketing plan, as well as a comprehensive review of the scientific literature, we demonstrate that the marketing of Johnny Copper open system e-liquid products as an alternative source of nicotine for current adult combustible tobacco users is APPH.

MARKETING STANDARDS FOR MEMBERSHIP

The Vapor Technology Association (VTA) is a leading national trade association in the electronic cigarette and vapor product industry. VTA represents the manufacturers, wholesalers, distributors, vape shop owners, small business owners and entrepreneurs who have developed innovative and quality vapor products, providing adult consumers with a safer alternative to traditional combustible products. VTA and its members are leaders in the vapor community, promoting small businesses and job growth, responsible public policies and regulations, and a high standard of safety within the industry.

To continue to promote high standards, VTA's Board of Directors has developed and adopted these *Marketing Standards for Membership*.

Released January 2018

VTA SALES AND MARKETING PRINCIPLES

VTA Marketing Standards for Membership are based on the following core principles:

1. VTA is committed to educating and informing its members on the best ways to comply with applicable laws and regulations governing electronic cigarettes, vaporizers and related electronic nicotine delivery systems ("Vapor Products"), which laws include, but are not limited to, the Federal Food Drug & Cosmetic Act (21 USC Ch. 9 et seq.) as modified by the Family Smoking Prevention and Tobacco Control Act and 21 CFR Parts 1100, 1140 and 1143 (Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, May 10, 2016) (the "Tobacco Control Act") and the Child Nicotine Poisoning Prevention Act of 2015, 15 U.S.C. §§ 1471, et seq.

2. Vapor Products are for adults only and should not be intentionally marketed to, sold to or used by those who have not attained the age of 18 years (or the appropriate age restriction within the subject territory) ("Minors").

3. VTA Members' marketing activities must refrain from knowingly marketing Vapor Products to Minors, which is strictly prohibited.

As described in more detail below, VTA strongly supports efforts to prevent Minors' access to Vapor Products and VTA embraces marketing restrictions that will reduce Minors' exposure to marketing of and promotions for Vapor Products.

At the same time, VTA is committed to ensuring that adult smokers have equal access to truthful and factual information about Vapor Products, as well as a wide array of Vapor Products. Hence, VTA will continue to advocate for new regulations that properly recognize the game changing role that safe and innovative Vapor Products will continue to play in reducing, if not eliminating altogether, adult smokers' dependence on combustible cigarettes.

VTA encourages and expects that its members, if they haven't already, will take the appropriate steps to ensure that their marketing standards reflect the core principles and prescriptions contained in these Marketing Standards for Membership within six months.

PREVENTING MINOR ACCESS TO VAPOR PRODUCTS

Vapor Products should only be sold to and used by adults, 18 and older (or the appropriate age of majority for any given market). To ensure continued limited access of Vapor Products, VTA adopts the following policies and practices:

1. VTA fully supports compliance with the age restrictions embodied in the Tobacco Control Act and other legislation.

2. VTA fully supports compliance with the child resistant packaging requirements of the Child Nicotine Poisoning Prevention Act.

3. VTA fully supports state laws, and local ordinances, that impose penalties on retailers or others who sell or provide vapor products to Minors, and Minors who are found in possession of vapor products.

4. All vape shops and other retailers of Vapor Products should implement strict underage policies requiring that their employees card anyone who appears fewer than 27 years of age.

5. Vape shops shall ask Minors who are unaccompanied by an adult to leave their shop immediately.

6. Vape shops should display signage indicating that (a) "Unaccompanied Minors Are Not Allowed on Premises" and (b) "Products are Not for Sale to Minors" or (c) "Underage Sale Prohibited."

7. All Vapor Products should be displayed behind the counter or in some other enclosed display which is not accessible without the assistance of a sales representative in convenience stores or other retail establishments where Minors may be present.

8. All online sales of Vapor Products should be restricted to adults through either direct verification of government issued photo ID upon delivery of product or through the use of age verification technologies provided by independent third party agencies using public records databases.

9. VTA Members' packaging and marketing materials for Vapor Products must contain a warning which indicates that such products are "Not For Sale to Minors" or "Underage Sale Prohibited" or comparable language whether or not required by law.

10. VTA Members' packaging and marketing materials for Vapor Products must contain a statement which warns "Keep Out of Reach of Children" or comparable language whether or not required by law.

11. All manufacturers, distributors and retailers should forbid the sale of their Vapor Products through any vending machine or unattended kiosk.

VTA MARKETING STANDARDS

1. No Appeal to Minors. Marketing of Vapor Products should not include content which is directed towards Minors. In establishing their marketing, VTA Members should consider that content which may appeal or be directed to Minors could include, without limitation, the following: (a) product names, (b) cartoons, (c) other imagery; and (d) promotional items.

2. Intended Audience for Marketing. Marketing for Vapor Products should not be directed at Minors and no channel of marketing should be employed if more than 15% of its audience is Minors. This restriction includes, but is not necessarily limited to, TV, print and radio advertising, as well as event marketing or sponsorships. For regional (local, city or state) advertising, content must be directed to persons who meet or exceed the specific region's age of majority.

3. No Improper Use of Trademarks or Trade Dress. VTA Members should have a zero tolerance policy for Vapor Products that use in commerce names, imagery or designs that intentionally mimic, play upon, invoke or otherwise infringe upon existing trademarks, trade names or trade dress, particularly if they are associated with products that are or were primarily marketed to Minors.

4. No Smoking Cessation Claims. Vapor Products should not be portrayed as any sort of smoking cessation device or as a product which may be used to help quit smoking.

5. No Claims Regarding Health or Safety.** Vapor Products should not be marketed as providing a therapeutic value, as being safe or healthy for consumers, or as products which do not produce secondhand health effects.

6. No Modified Risk Descriptors or Claims.** Vapor Products should not be marketed or sold using modified risk descriptors or claims (e.g., "light," "low," and/ or "mild"). By way of example only, Vapor Products should not be marketed as (a) having no ash or smoke, (b) having no tar, (c) being less harmful, (d) posing lower risk of disease or (e) as containing reduced or zero levels of harmful ingredients.

7. Ingredients. VTA Members should accurately represent the ingredients contained in their Vapor Products and, in particular, the ingredients contained in any e-liquid. Deceiving any consumer regarding the contents of the Vapor Products is strictly prohibited.

*** Litigation challenging the law upon which this standard is based is currently pending. VTA reserves the right to revisit and/or amend this standard in the event that any pending legal challenge is successful.*

8. Product Sampling. VTA Members shall ensure that all product sampling is restricted to adults and follows all applicable laws.

9. No Health Professionals. VTA Members should not use health professionals to market or otherwise endorse their Vapor Products, directly or indirectly.

10. No Marketing to Non-Tobacco Users. Vapor Product marketing should be intentionally directed towards those who are current users of tobacco products and should not be designed to encourage non-tobacco users to start using Vapor Products.

11. Spokespeople. VTA Members shall ensure contracted spokespeople and individuals endorsing Vapor Products on the company's behalf must be and appear to be at least 25 years of age.

12. Billboards. Billboard advertisements used for the purpose of promoting or marketing Vapor Products shall not be physically located within 500 feet of any elementary or secondary school, youth oriented facility, or childcare facility.

Code of Responsible Conduct

Vapor Product Advertising, Marketing, Packaging, Sales, Distribution, Transportation, and Disposal

Version 2 - Adopted by Board of Directors on April 25, 2019

OUR MISSION

Founded in 2012, the Smoke-Free Alternatives Trade Association (SFATA) is the leading and the largest trade association in the vapor products industry. Our mission and Code of Responsible Conduct is intended to responsibly and appropriately maintain safer access to nicotine in the form of vapor products for adult smokers and nicotine consumers of legal age.

SFATA members commit to The Code of Responsible Conduct ("Code") by promoting responsible Advertising, Marketing, Packaging, Sales, Distribution, Transportation, and Disposal according to the guidelines presented in this Code and agree to hold themselves to a higher standard than required. The Association provides guidance on compliance with the Code to all members involved in the promotion of their respective brands.

Scope

The Code of Responsible Conduct applies to all activities required to advertise, market, package, sell, distribute, transport, and dispose of vapor products, including product advertising, consumer communications, promotional events, packaging, labels, sales collateral, distribution, transportation, and disposal.

The Code applies to:

· All print and electronic media, including the Internet and any other online communications, including social media, used to advertise or market vapor products.
· Every type of promotional or marketing activity or event, including all product placements (e.g., movies, television programs, music videos, video games), and sponsorships.
· Sponsorships are commercial, contractual agreements between a vapor company (the sponsor) and a sponsored party or sponsorship property to support an event, activity, person, or organization financially or through the provision of products and/or services. A sponsor is the individual or group that provides the support, similar to a benefactor.

SFATA members understand it is not possible to address every eventuality and, therefore, agree to observe the spirit, as well as the letter, of the Code of Responsible Conduct.

Questions about the interpretation of the Code, member companies' compliance with the Code, and the application of its provisions should be directed to SFATA's Board of Directors.

Advertising

· No Health, Safety, or Cessation Claims - While vapor products have the potential to positively impact the public health hazards caused by combustible tobacco cigarettes, SFATA members do not make implicit or explicit health, safety, therapeutic, curative, or cessation claims about the products they sell. They further do not publish customer testimonials claiming benefits achieved through vaping on their websites or on any other marketing media, whether in digital, print, or aural form. Such claims would grant FDA jurisdiction over the product as a pharmaceutical product.
· Members must list any nicotine or other package warnings required by local, state, and federal law.

· Follow Federal CAN-SPAM, endorsement, and telemarketing laws. https://www.ftc.gov/tips-advice/business-center/guidance/can-spam-act-compliance-guide-business

Marketing

Under the law, claims in advertisements must be truthful, cannot be deceptive or unfair, and must be evidence-based, with the exception of cessation or health claims as per FDA guidelines as noted above.

SFATA MEMBERS DO NOT MARKET TO MINORS.

· Prohibit the use of "child-friendly" or "childish" marketing images, names, practices, or ads such as superheroes, food, media characters, cartoon characters, babies, animals, toys, candy, or otherwise, that might appeal to under-age persons.
· Prohibit the use of others' intellectual property.
· Products will not be marketed as a "coming of age" product or ritual.
· Branded/logoed apparel will be limited to adult sizes.
· Ensure business name, address, and contact information are on all products or inserts and website.
· Prohibit the sponsorship of events for youth specifically or where an event would be a mix of those under the lawful legal age to vape and over.
· Follow Federal CAN-SPAM, endorsement, and telemarketing laws. https://www.ftc.gov/tips-advice/business-center/guidance/can-spam-act-compliance-guide-business

Deceptive or Derogatory Marketing

SFATA members agree to maintain reasonable standards in their marketing and to not engage in marketing or advertising that would be considered deceptive or defamatory, or create a negative impression of the vapor industry.

Packaging

· Commitment to not advertise, label, market, sell, or manufacture products which do not meet federal packaging regulations and child resistant packaging requirements.
· Members agree to adhere to guidelines based on the Poison Prevention Packaging Act of 1970 (PPPA) administered by the Consumer Protection Safety Commission or meet ISO 8317:2003 requirements and test methods for re-closable packages designated as resistant to opening by children (Generic Certificate of Compliance).
· List all ingredients on product packaging/product insert(s) as required by law.
· Ensure business name, address, and contact information are on all products or inserts and website.
· Follow federal packaging requirements as required by the FDA as authorized by Section 906(d) of the FD&C Act, 21 U.S.C. 387f(d) (https://www.gpo.gov/fdsys/pkg/USCODE-2017-title21/html/USCODE-2017-title21-chap9-subchapIX-sec387.htm)

Sales

· Age Verification Policy for online and face-to-face purchases.

· SFATA members do not sell to purchasers under the legal age within or outside of their state.
· For online sales, age verification at checkout executed by a 3rd party and in compliance with any applicable local, state, or federal laws or regulations.
· Age verification before completion of face-to-face transactions as required by local, state, and federal law.
· Members are strongly encouraged to participate in the Intellicheck Age ID Program in partnership with SFATA.
· Members are strongly encouraged to participate in the WeCard Program in partnership with SFATA.

Distribution and Transportation

· Compliance with US Dept. of Transportation and IATA (International Air Transport Association) rules regarding the packaging of devices containing lithium batteries and/or other hazardous materials.

Disposal

· Proper disposal and/or recycling of lithium ion batteries.
· Follow Environmental Protection Agency (EPA) guidelines and any other state and local laws for the disposal of hazardous waste (Nicotine, Vegetable Glycerin, Propylene Glycol).

Code Review Process

The SFATA Board will consider complaints lodged by SFATA members or other interested parties, including members of the public.

ATTACHMENT 3

Youth Access Prevention Plan for Johnny Copper LLC

With the ever-increasing use of ENDS products by adult smokers looking for an alternative to combustible tobacco, Johnny Copper is committed to doing our part in preventing underage use of ENDS products in our community. As this Youth Action Prevention Plan will show, we have implemented thorough methods of preventing youth access to Johnny Copper open-system e-liquid products.

- **Point of Sale ID Checks, Training, and Certification**

  At the point of sale, IDs are examined and scanned for each purchase no matter the age of the purchaser. Each employee must complete WeCard training. Our locations have been implementing age restrictions before it was law on these products due to their nature. All our locations have exceptionally large readable signage that indicates to be prepared with ID, as well as prominent signage on retail locations stating, "No one under 21 permitted". Our state jurisdictions conduct many underage sting operations. We have received congratulatory letters state authorities on passing these sting operations by refusing to sell to a minor. Our retail locations have an exemplary record and have never been cited for sales to minors. We will continue to strive to achieve this excellence as we have for many years. We discourage sales to anyone who is not a current smoker. This stems from our belief of not encouraging any unnecessary behaviors. Our mission is to step the customer down over time in nicotine strengths until the customer is eventually at 0% nicotine.

- **Vapor Sales Policy and Procedure**

  Johnny Copper has spent a significant amount of time and resources to ensure that the company is doing everything it can to prevent youth access to our products. Johnny Copper prohibits entry of minors into all our retail locations. We require ID verification for all purchases. Our register system requires an ID swipe for every transaction processed, and ID's are examined by retail employees to verify that the photograph on the ID matches the purchaser; then the ID is scanned to verify that the purchaser is over 21 and that the ID is valid. All retail employees undergo thorough training on our age verification procedures.

  Each employee has a moral, ethical and legal responsibility to refuse to sell vapor products to anyone under the age of 21. Vapor products must not be sold to anyone under the age of 21. This is the law. We require all employees to check for proof of age for any customer who is attempting to purchase vapor products.

  - **Verify the customer's age before selling vapor products.**

    The customer must have an acceptable and valid Driver's License, Non Driver ID, or Commercial Driver's License to purchase tobacco products.

  - **Verify the identity of the customer.**

The person attempting to make the purchase must be the person shown on the card. The card cannot be expired. If the card is expired, the sale must be refused. When reviewing an ID card, always do the following: verify that the photo is of the customer presenting the ID, the ID is not expired, verify that the issuing agency of the ID is acceptable, and verify that the ID has not been altered and is not fake.

Always verify that the photo is of the customer presenting the ID. If a customer is unable to produce a valid photo ID, you must refuse the sale. They cannot purchase the product and then bring the ID back at a later time.

- **Conducting a sale.**

  Card each customer BEFORE reaching for the vapor product requested by the customer. First ask for a form of identification. Review the card (photo, dob, expiration date, description, agency issuing card). Be sure the person giving you the ID is the person standing in front of you. If you have placed the tobacco product on counter before carding and you determine the person is under 21 or does not have a valid ID, immediately remove product from the counter and customer's reach and state, "I'm sorry, it's against the law for me to sell this product to you, and I would lose my job". Always be polite, but be firm, and refuse the sale.

- **Other points**

  It is illegal for a minor to purchase vapor products for anyone for any reason. A minor may not purchase these products for a parent. It is illegal for an adult to purchase these products for a minor. Never sell vapor products to anyone if you have reason to believe they are going to give them to someone under the age of 21. Remember, no one under 21 may possess vapor products of any kind.

- **Training**

  Upon beginning employment, all employees will receive training to ensure that they understand all state laws and company policies regarding the prohibition against selling tobacco products to minors. In particular, the training will consist of the following:

  - Review of Policy and Procedures for Vapor Sales. Each employee will read policy and manager will review the policy with them.

  - Review of ID Brochures from relevant state agencies. Employees will be shown the markings indicating underage and how to determine the customer’s age

- Review of WeCard Training Materials. Employees will receive explanation of all WeCard materials including the calendar

- Employee will sign the Age-Verification/Youth Prevention Training Form indicating that they agree not to sell vapor products to anyone underage and will fully comply with all Johnny Copper Age-Verification Procedures.

- **Additional Aides**

  We make use of several aides to help our employees identify underage customers. Some of these aides include:

  - Every register is equipped with an ID scanner. Registers require ID scans before a sale can be processed.

  - WeCard calendars at all registers.

  - Current Birth Year of Age 21 posters and stickers visible from register.

  - Ongoing training and refresher materials provided to all employees.

- **Online E-Commerce Age-Restrictions**

  Online sales are restricted to adults following age verification through independent, third-party agencies using public records databases. Johnny Copper' e-commerce platform (www.JohnnyCopper.org) utilizes third-party age verification technology through AgeChecker.net.

  - Age Restriction. Company product sales must comply with all county, city, and state age restriction laws for e-vapor product purchase.

  - Age Verification. Online company product sales are restricted to adults age verified by independent third-party companies using public records databases. For all sales made to individuals under the age of 27 years old, age verify by means of government issued photographic identification containing the bearer's date of birth.

  - Compliance with California's Stop Tobacco Access to Kids Enforcement Act ("STAKE Act") for sales in California. California law prohibits the sale of tobacco products to anyone under the age of 21 (Cal. Bus. & Prof. Code § 22958(a)) and the STAKE Act imposes mandatory steps that online distributors and sellers of tobacco products are required to follow to verify that a purchaser of these items is 21 years of age or older. The steps required under the STAKE ACT are:

- Attempt to match the name, address and date of birth provided by the customer to information contained in records in a database of individuals whose age has been verified to be 21 years or older by reference to an appropriate database of government records kept by the distributor, a direct marketing firm, or any other entity.

- Verify that the billing address on the check or credit card offered for payment by the purchaser matches the address listed in the database.

- If unable to verify that the purchaser is 21 years of age through the above, require the customer or recipient to submit an age-verification kit consisting of an attestation signed by the customer that he or she is 21 years of age or older and a copy of a valid form of government identification.

- Verify that the billing address on the check or credit card provided by the consumer matches the address listed in the form of government identification.

- For credit card transactions, submit information to each credit card company so that the words "tobacco product" may be printed in the purchaser's credit card statement.

- Regardless of the form of payment, prior to shipping the tobacco product to a California customer, make a telephone call after 5 p.m. to the purchaser or recipient confirming the order. The call may be a recorded message left on voicemail.

- Deliver only to the purchaser or recipient's verified billing address on the check or credit card used for payment. Delivery to a post office box address is prohibited.

- **Child Resistant Packaging**

  Johnny Copper open-system e-liquid products will use child resistant packaging in compliance with the Child Nicotine Poisoning Prevention Act of 2015.

- **Appropriate Marketing and Packaging**

  - As a member of the Vapor Technology Association, we adhere to their strict marketing guidelines. VTA Marketing Standards for Membership are based on the following core principles:

    - VTA is committed to educating and informing its members on the best ways to comply with applicable laws and regulations governing electronic cigarettes, vaporizers and related electronic nicotine delivery systems ("Vapor Products"),

which laws include, but are not limited to, the Federal Food Drug & Cosmetic Act (21 USC Ch. 9 et seq.) as modified by the Family Smoking Prevention and Tobacco Control Act and 21 CFR Parts 1100, 1140 and 1143 (Deeming Tobacco Products To Be Subject to the Federal Food, Drug and Cosmetic Act, May 10, 2016) (the "Tobacco Control Act")and the Child Nicotine Poisoning Prevention Act of 2015, 15 U.S.C. §§ 1471, et seq.

- Vapor Products are for adults only and should not be intentionally marketed to, sold to or used by those who have not attained the age of 21 years (or the appropriate age restriction within the subject territory) ("Minors").

- VTA Members' marketing activities must refrain from knowingly marketing Vapor Products to Minors, which is strictly prohibited.

- Our social media accounts are age restricted to 21+, meaning that no one under the age of 21 can view them.

- Our website utilizes an age gate which requires users to confirm they are of legal vaping age (21+) before viewing the site.

- Our packaging is never labeled in a way that is misleading or resembles copyright protected or kid-friendly food products.

- Our vapor products do not include content which is directed towards Minors.

- Our marketing of vapor products is not directed at Minors and no channel of marketing is employed if more than 15% of its audience is Minors. This restriction includes, but is not necessarily limited to, TV, print and radio advertising, as well as event marketing or sponsorships. Our advertising is limited to radio stations whose target market is age 25 and up. *(Note: Johnny Copper does not utilize TV, print, or radio advertising.)*

- Our vapor products do not use in commerce names, imagery or designs that intentionally mimic, play upon, invoke or otherwise infringe upon existing trademarks, trade names or trade dress, particularly if they are associated with products that are or were primarily marketed to Minors.

- Our vapor products are not portrayed as any sort of smoking cessation device or as a product which may be used to help quit smoking.

- Our vapor products are not marketed as providing a therapeutic value, as being safe or healthy for consumers, or as products which do not produce secondhand health effects.

- Our vapor products are not be marketed or sold using modified risk descriptors or claims (e.g., "light," "low," and/or "mild"). Our vapor products are not marketed as

(a) having no ash or smoke, (b) having no tar, (c) being less harmful, (d) posing lower risk of disease or (e) as containing reduced or zero levels of harmful ingredients.

- We accurately represent the ingredients contained in our Vapor Products and, in particular, the ingredients contained in any e-liquid. We do not deceive the consumer regarding the contents of our vapor products.

- We ensure that all product sampling is restricted to adults and follow all applicable laws.

- We do not use health professionals to market or otherwise endorse our vapor products, directly or indirectly.

- Our marketing is directed towards those who are current users of tobacco products and are never designed to encourage non-tobacco users to start using Vapor Products.

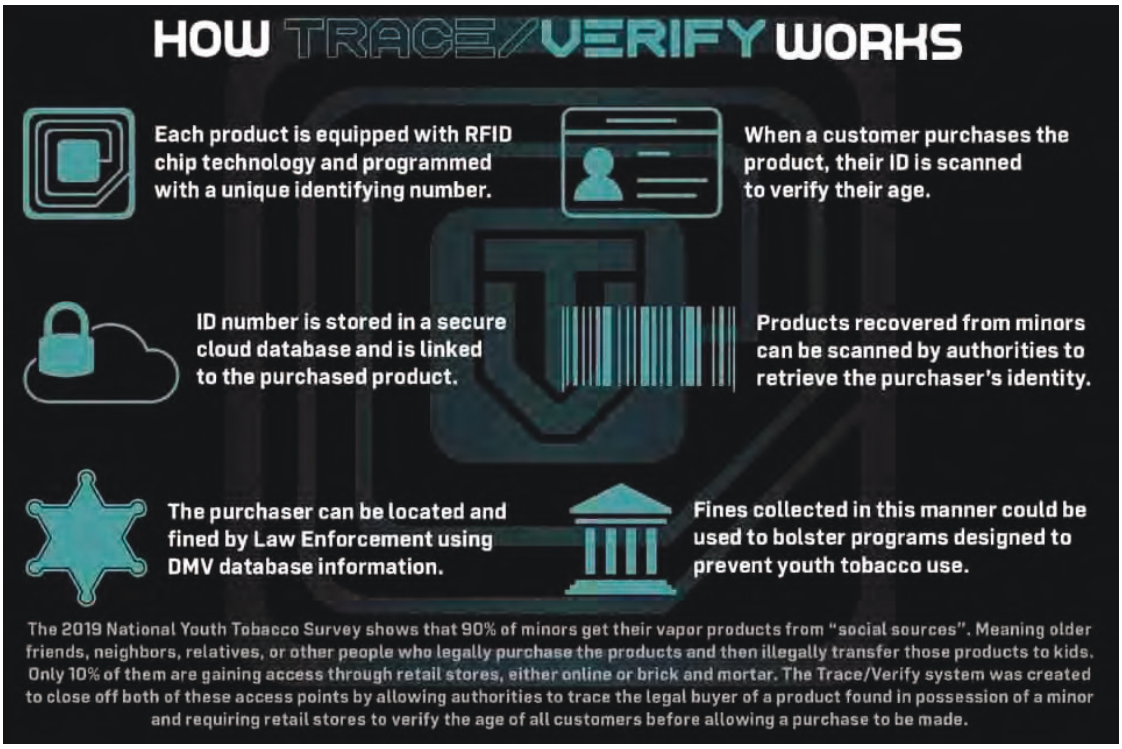
- Contracted spokespeople and individuals endorsing Vapor Products on our behalf must be and appear to be at least 35 years of age.

- Billboard advertisements used for the purpose of promoting or marketing vapor products are not physically located within 500 feet of any elementary or secondary school, youth-oriented facility, or childcare facility. *(Note: Johnny Copper does not utilize billboard advertising.)*

- **Trace/Verify**

Johnny Copper is also implementing Trace/Verify technology on all the bottles of e-liquid we produce to assist retailers and law enforcement in efforts to prevent minor use of vapor products. Trace/Verify utilizes QR codes placed on each vapor product sold. The QR code stores the driver's license number used to purchase the product, as well as the date and location of the transaction. This information can later be retrieved if that product is found to be in possession of a minor, in order to identify how the minor came to be in possession of the product. Johnny Copper is continually looking at new and innovative ways to prevent youth access to vapor products.

The goal of Trace/Verify is to provide accountability for tobacco manufacturers and retailers as well as a method for law enforcement and regulatory authorities to ensure that significantly fewer ENDS products end up in the hands of youth. In addition, authorities can confiscate those products that do and levy enforcement action against the parties who are responsible, whether they are manufacturers, retailers, or straw buyers such as family members or friends.



- **Conclusion**

Johnny Copper' goal in its efforts is to provide adult consumers who would otherwise be smoking combustible cigarettes with an alternative source of nicotine, while preventing minors for accessing vapor products. To that end, Johnny Copper has implemented robust youth prevention methods for its retail operations including preventing entry of minors into retail locations, mandatory ID scanning for all purchases in retail locations, third party age-verification technology, as well as Trace/Verify QR tracking on Johnny Copper open systems e-liquid products.

Johnny Copper consumer survey data demonstrates that the company's safeguards and stringent age-verification protocols have made the company successful in its mission of providing quality products to an older adult consumer base of former combustible tobacco smokers. Furthermore, Johnny Copper consumer demographic and age data shows that this Youth Prevention Plan is successful in its effort to prevent underage use of Johnny Copper products.

Accordingly, as detailed in this application, based on a robust Youth Prevention Plan, evidence of adult-only sales and a restricted, adult-oriented marketing plan, as well as a comprehensive review of the scientific literature, we demonstrate that the marketing of Johnny Copper open system e-liquid products as an alternative source of nicotine for current adult combustible tobacco users is APPH.

ATTACHMENT 4

JOHNNY COPPER VAPING SURVEY

195 responses

Publish analytics

First Name (Initials preferred)

195 responses

C

J

A

D

M

S

L

B

T

Last Name (Initials Preferred)

195 responses

B

H

S

C

M

F

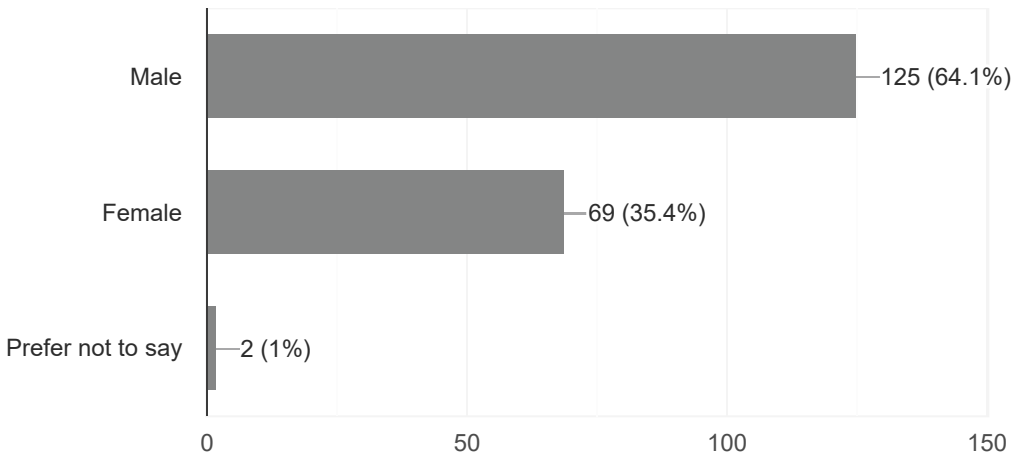
D

W

R

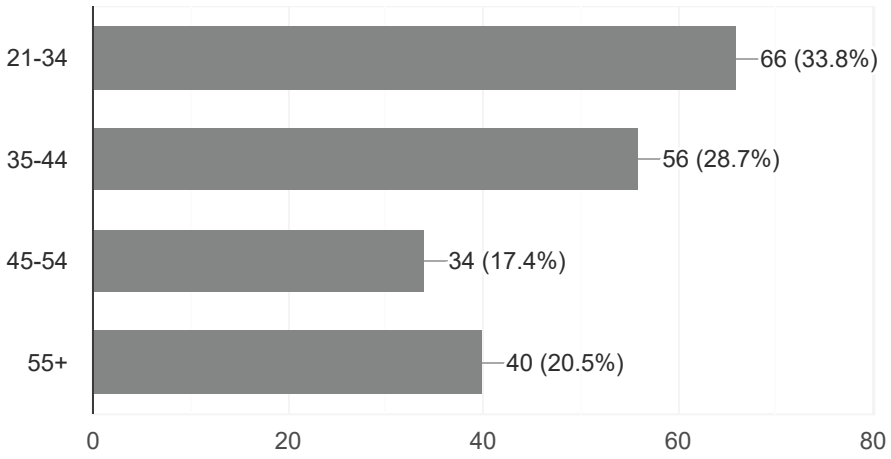
Are you

195 responses



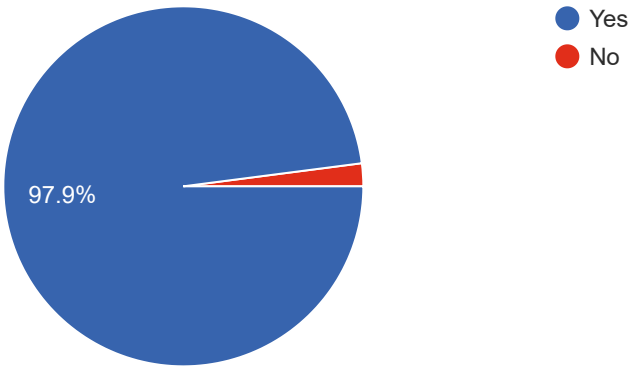
Age

195 responses



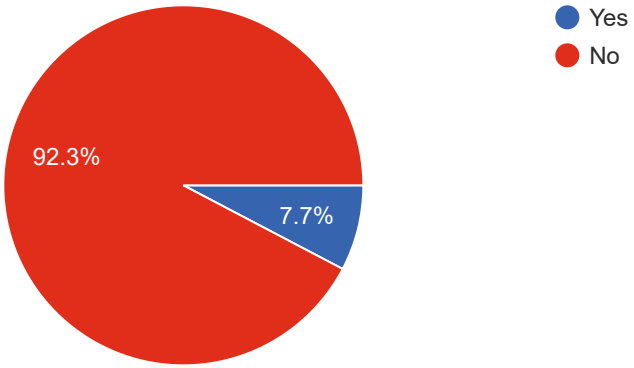
Have You Ever Smoked Cigarettes

195 responses



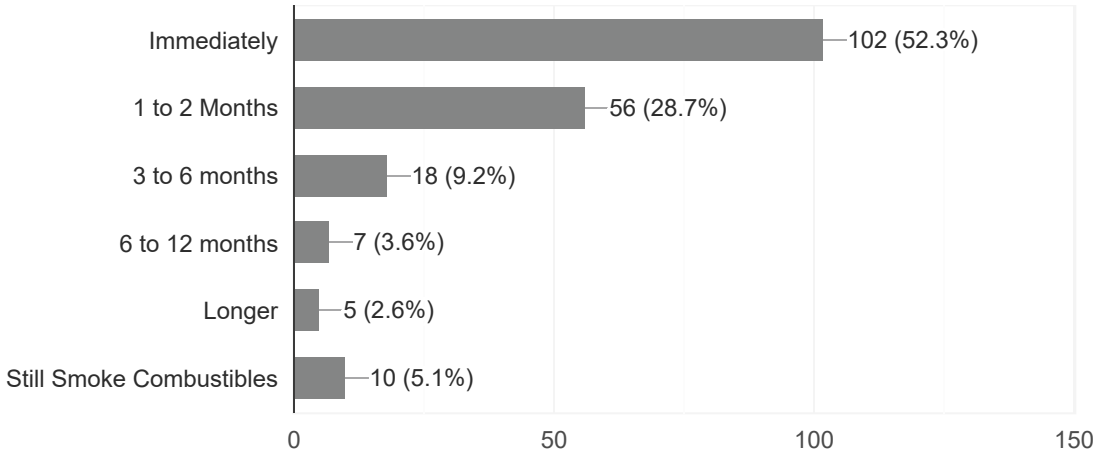
Do you Smoke and Vape (Dual Use)

195 responses



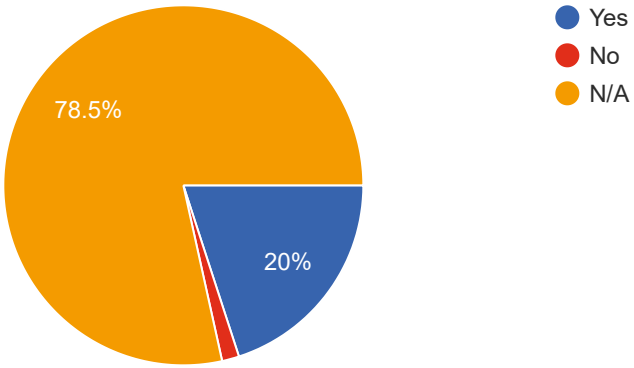
If you quit smoking with vaping how long did it take?

195 responses



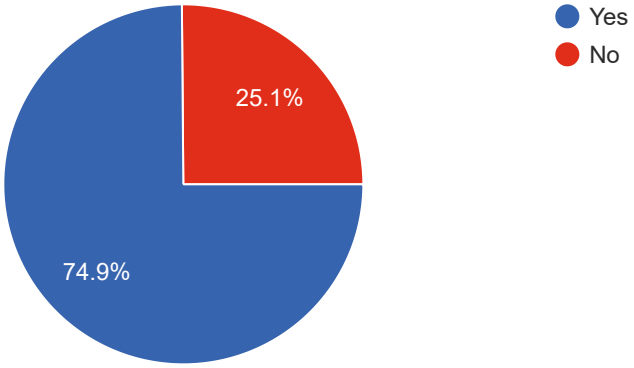
If you vape and smoke is your goal to quit smoking?

195 responses



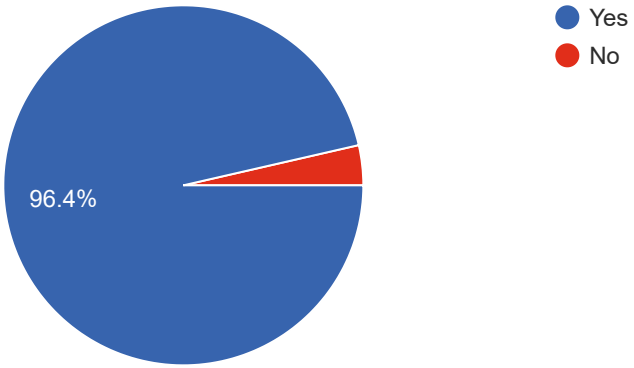
Is your goal to stop using all tobacco products?

195 responses



Do you use a flavor other than tobacco?

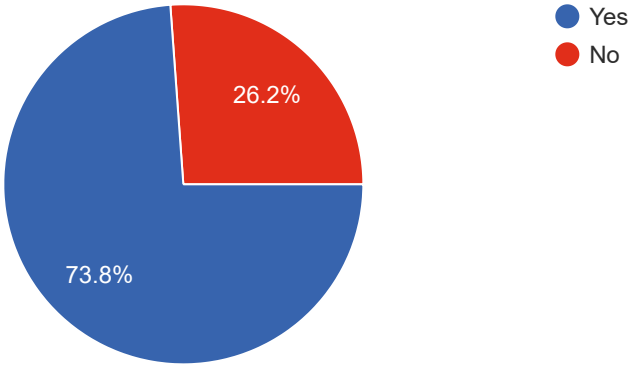
195 responses



125a

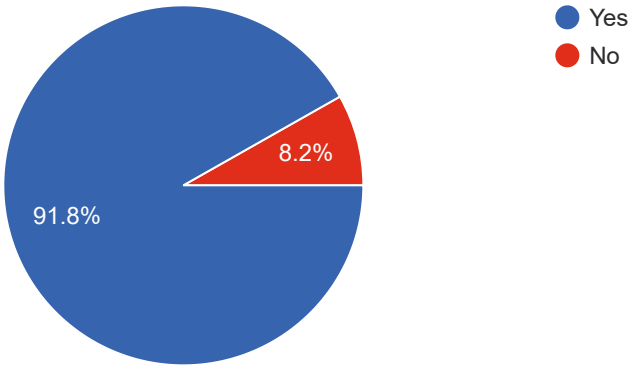
Have you tried other FDA approved cessation products. Example Chantix, Gum

195 responses



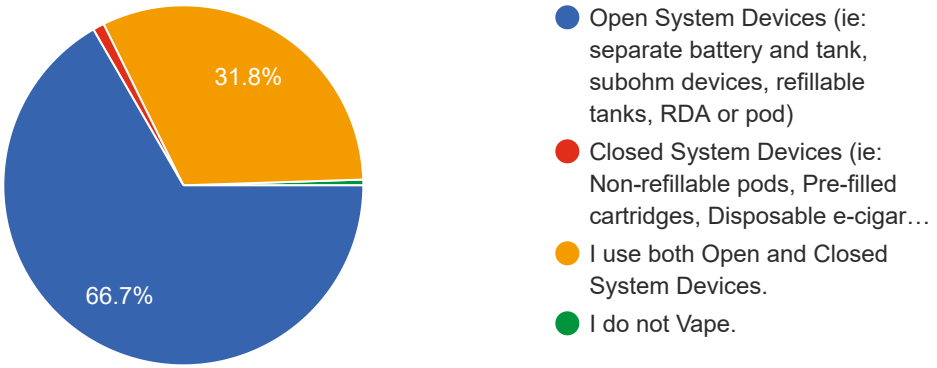
Is the use of this ENDS product helpful in keeping you from combustible tobacco?

195 responses



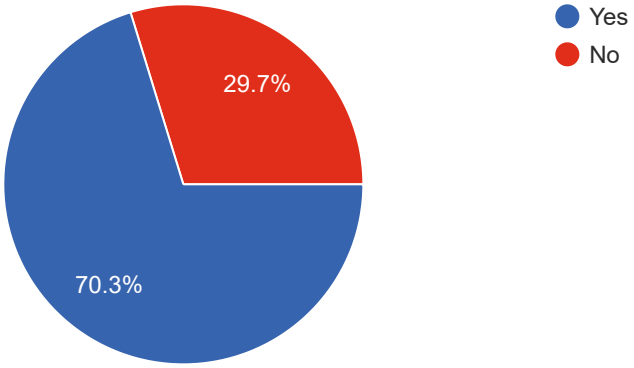
What type of e-cigarette (ENDS) product(as) do you prefer?

195 responses



Without vaping would you return to smoking combustible cigarettes?

195 responses



What's your story? Please feel free to provide a brief testimonial about your electronic nicotine product use or tell us if you do not use any electronic nicotine products.

124 responses

I was smoking cigarettes about 2 packs a day. With my vap I smoke maybe 5 cigarettes a day. I don't smoke at home or in my car... I vape. I love all my flavors and trying new ones

Smoked cigs for 30yrs, picked up a vape to try & quit, never looked back & never smoked a cig again. 12+ years smoke free.

Vapeing saved my life

I was smoking 2 packs a day for about 5 of the 12 years I smoked. I was starting to smoke more and I knew it wasn't good for me. A friend turned me on to vaping, said she had been vaping for awhile with successfully quitting smoking. Some of us still enjoy vaping and still enjoy our flavors years after quitting smoking. It's what helps us stay always from harmful combustible tobacco. It's been a better alternative for me for the last 7 years and millions of others. I work in the industry now for about 6 years..about a month ago I had sold a 25 year smoker a small device with a fruit flavored ejuice. He came in 3 weeks later and said he hadn't touched a cigarette. That's a life saved from harmful tobacco. I've helped so many people quit smoking using vaping. Friends, family and so many strangers. The gums don't work, chaotic

ATTACHMENT 5

Study or Article Title	Author and Notes	Author and Notes		Link if available
Electronic cigarettes as part of a comprehensive plan to reduce the cancer burden in the European Union		Konstantinos Farsalinos	2020	https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan/F507413
E-cigarette use high among recent quitters but rare among those who gave up longer ago			2020	https://medicalxpress.com/news/2020-02-e-cigarette-high-quitters-rare-gave.html
Most Young People Do Not Vape, and Even Fewer Vape Regularly			2020	https://www.nyu.edu/about/news-publications/news/2020/january/youth-vaping.html
Electronic Cigarette Use and Myocardial Infarction Among Adults in the US Population Assessment of Tobacco and Health	RETRACTED	Stanton Glantz, PhD, Dharma N. Batta, PhD	2019	https://www.ahajournals.org/doi/pdf/10.1161/JAHA.119.012317
Retraction to: Electronic Cigarette Use and Myocardial Infarction Among Adults in the US Population Assessment of Tobacco and Health			2020	https://www.ahajournals.org/doi/10.1161/JAHA.119.014519
Vaping in England: 2020 evidence update summary		Public Health England	2020	https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary
Does the gateway theory justify a ban on nicotine vaping in Australia?			2020	https://athra.org.au/wp-content/uploads/2020/03/Mendelsohn-CP-Hall-W.-Does-the-gateway-theory-justify-a-ban-on-nicotine-vaping-in-Australia.-International-Journal-of-Drug-Policy-2020.pdf
Are E-Cigarette Regulations Jeopardizing the Public Health? A Review of the Evidence and Policy Missteps			2020	https://www.theamericanconsumer.org/wp-content/uploads/2020/03/E-Cigarette-Report.pdf
The emotional and irrational hysteria in the US about the "vaping-related" (or cannabis-related?) lung disease that goes far beyond confirmation bias		Konstantinos Farsalinos	2019	http://ecigarette-research.org/research/index.php/whats-new/2019/274-us-lungs
Current advances in research in treatment and recovery: Nicotine addiction			2019	https://advances.sciencemag.org/content/5/10/eaay9763
Use of e-cigarettes among young people in Great Britain		Action on Smoking and Health, UK	2019	https://ash.org.uk/wp-content/uploads/2019/06/ASH-Factsheet-Youth-E-cigarette-Use-2019.pdf
Effects of Electronic Cigarette Constituents on the Human Lung: A Pilot Clinical Trial			2019	https://cancerpreventionresearch.aacrjournals.org/content/early/2019/10/11/1940-6207.CAPR-19-0400
Toxicity classification of e-cigarette flavouring compounds based on European Union regulation: analysis of findings from a recent study		Konstantinos Farsalinos	2019	https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-019-0318-2
Exposure to e-cigarette vapor fails to induce pneumonia in mouse models			2019	https://medicalxpress.com/news/2019-12-exposure-e-cigarette-vapor-pneumonia-mouse.html
A critique that does not even address its target			2019	https://pubpeer.com/publications/DA0D9A784751D3528E21E2F0469127
RCP advice on vaping following reported cases of deaths and lung disease in the US			2019	https://www.rcplondon.ac.uk/projects/outputs/rcp-advice-vaping-following-reported-cases-deaths-and-lung-disease-us
A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy			2019	https://www.nejm.org/doi/full/10.1056/NEJMoa1808779
Changes in Flavor Preference in a Cohort of Long-term Electronic Cigarette Users			2019	https://www.atsjournals.org/doi/abs/10.1513/AnnalsATS.201906-472OC
Investigating gateway effects using the PATH study			2019	https://ncbi.nlm.nih.gov/pmc/articles/PMC6950312/pdf/f1000research-8-23710.pdf
	Lisa Miyashita, et al	European Respiratory Journal	2018	http://erj.ersjournals.com/content/51/2/1701592
Public Health Consequences of E-Cigarettes			2018	http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx
Safety Profile of Closed System, Cigalike Product over 2 years - No Clinically Significant Adverse Health Impacts	Tanvir Walele et al	Regulatory Toxicology and Pharmacology	2018	http://www.fontemscience.com/wp-content/uploads/2018/01/2-year-vaping-study-full-report.pdf
Behavioral Econ Survery: E-cigs/VLN must be priced lower than Cigs to have more switch	Bryan W Heckman, et al	Nicotine & Tobacco Research	2018	https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/nty042/4934144
Secong hand vapor - Characterization of the Spatial and Temporal Dispersion Differences Between Exhaled E-Cigarette Mist and Cigarette Smoke	Dainius Martuzevicius, PhD, et a;	Nicotive & Tobacco Research	2018	https://academic.oup.com/ntr/advance-article/doi/10.1093/ntr/nty121/5040053

Metal Concentrations in e-Cigarette Liquid and Aerosol Samples: The Contribution of Metallic Coils	Pablo Olmedo, et al	Emvironmental Health Perspectives	2018	https://ehp.niehs.nih.gov/ehp2175/#c1
Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA	Christopher Russell, et al	Harm Reduction Journal	2018	https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-018-0238-6
Amer. Cancer Society: Public Health Statement on Eliminating Combustible Tobacco Use in US		Americn Cancer Society	2018	https://onlinelibrary.wiley.com/doi/pdf/10.3322/caac.21455?utm_source=VAPEnews.com&utm_campaign=e1081cdce7-ACS_DOUBLE_DOWN_06_12_18&utm_medium=email&utm_term=0_3044bba587-e1081cdce7-191495793
Nic/0nic heart impact - Sympathomimetic Effects of Acute E?Cigarette Use: Role of Nicotine and Non?Nicotine Constituents	Roya S. Moheimani, et al	Journal of the American Heart Association	2018	https://www.ahajournals.org/doi/10.1161/JAHA.117.006579
Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives		Abrams et Al.	2018	https://www.annualreviews.org/doi/full/10.1146/annurev-publhealth-040617-013849
E-cigarettes and heated tobacco products: evidence review			2018	https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review
Health effects in COPD smokers who switch to electronic cigarettes: a retrospective-prospective 3-year follow-up			2018	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6113943/
Role of testing standards in smoke-free product assessments	M.Belushkin, etal	Regulatory Toxicology and Pharmacology	2018	https://www.sciencedirect.com/science/article/pii/S0273230018301776
Do flavouring compounds contribute to aldehyde emissions in e-cigarettes?	Farsilinos & Voudris	Food and Chemical Toxicology	2018	https://www.sciencedirect.com/science/article/pii/S0278691518301339
Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study	Shahab etal	Ann Intern Med.	2017	http://annals.org/aim/article/2599869/nicotine-carcinogen-toxin-exposure-long-term-e-cigarette-nicotine-replacement
Toxicity of PG, VG & PG/VG vapor inhalation in Rats - Almost None	Phillips, et al	Food and Chemical Toxicology	2017	http://europepmc.org/abstract/med/29046158
Nicotine delivery to users from cigarettes and from different types of e-cigarettes	Hajek P. et al	Psychopharmacology	2017	http://link.springer.com/article/10.1007%2Fs00213-016-4512-6
Comparative tumor promotion assessment of e-cigarette and cigarettes (Vapor<Cigs)	D. Breheny, et al	Envir. &Mol. Mutagensis	2017	http://onlinelibrary.wiley.com/doi/10.1002/em.22091/full
Aldehyde Detection in Electronic Cigarette Aerosols	Ogunwale etal	ACS Omega	2017	http://pubs.acs.org/doi/pdf/10.1021/acsomega.6b00489
Comparing the cancer potencies of vapor vs tobacco smoke	Stephens	BMJ Journal	2017	http://tobaccocontrol.bmj.com/content/27/1/10.long
Harm Minimization and Tobacco Control:- long survey study on Harm Reduction	David B. Abrams	Annual Rev - Public Health	2017	http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-040617-013849
A comparison of nicotine dependence among exclusive E-cigarette and cigarette users in the PATH study	Liu etal	Preventive Medicine	2017	http://www.sciencedirect.com/science/article/pii/S0091743517301226
E-cigarettes emit very high formaldehyde levels only in conditions that are aversive to users: A replication study under verified realistic use conditions	Farsalinos etal.	Food and Chemical Toxicology	2017	http://www.sciencedirect.com/science/article/pii/S0278691517305033
Vapor does NOT degrade lung surfactant ability to reduce surface tension, Clg Smoke does a lot	Rebecca J. Przybyla etal	BMC Respiratory Research	2017	https://respiratory-research.biomedcentral.com/articles/10.1186/s12931-017-0676-9
Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke			2017	https://tobaccocontrol.bmj.com/content/tobaccocontrol/27/1/10.full.pdf
E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys			2017	https://www.bmj.com/content/358/bmj.j3262
Adolescents and e-cigarettes: Objects of concern may appear larger than they are			2017	https://www.buffalo.edu/content/dam/www/news/documents/Study%20PDFs/Kozlowski-Warner-DAD-2017-inpress.pdf
What the CDC Found When They Tested Vape Shop Air		CDC	2017	https://www.cdc.gov/niosh/hhe/reports/pdfs/2015-0107-3279.pdf

Health effects in COPD smokers who switch to electronic cigarettes: a retrospective-prospective 3-year follow-up			2017	https://www.dovepress.com/health-effects-in-copd-smokers-who-switch-to-electronic-cigarettes-a-r-peer-reviewed-article-COPD
Health impact of E-cigarettes: a prospective 3.5-year study of regular daily users who have never smoked			2017	https://www.nature.com/articles/s41598-017-14043-2
Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices	O'Leary etal		2017	https://www.uvic.ca/research/centres/cisur/assets/docs/report-clearing-the-air-review-exec-summary.pdf
Propylene glycol in e cigarettes might keep us healthy, says researchers			2009	https://www.news-medical.net/news/20091104/Propylene-glycol-in-e-cigarettes-might-keep-us-healthy-says-researchers.aspx
THE BACTERICIDAL ACTION OF PROPYLENE GLYCOL VAPOR ON MICROORGANISMS SUSPENDED IN AIR. I			1942	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2135271/

ATTACHMENT 6

Current Challenges in Vaping Markets

July 26, 2024 • 7 min read

By: **Adam Hoffer**, **Jacob Macumber-Rosin**

The US vaping market is a disaster. As much as 98 percent of vaping products sold in the US are illicit. Most states levy an excise tax on vaping products, but these tax systems vary substantially. The result is a messy tax system covering largely illicit products, and no one knows whether taxes are being collected and remitted on most products sold nationwide.

How Did the Vaping Market Become Such a Mess?

Unlike the standard process for selling products in a market economy—where entrepreneurs and innovators can immediately sell their products to consumers—nicotine or tobacco companies must receive written permission (a marketing order) from the Food and Drug Administration (FDA) to legally market a new nicotine or tobacco product in the United States. Any tobacco or nicotine product lacking a marketing authorization order from the FDA cannot legally be sold in the United States.

The FDA has been extraordinarily slow and stringent when it comes to authorizing products for sale. From October 2019 to March 2024, the FDA received approximately 26.6 million premarket tobacco product applications (PMTAs). Of those 26.6 million applications, the FDA agreed to review roughly 1.2 million (rejecting the rest). Of the 1.2 million files reviewed, the FDA granted marketing granted orders (MGOs) for 30 products—just 0.001 percent of new product applications.

It took the FDA until June 2024 to issue the first MGO for a flavored product—four versions of NJOY Menthol. The vaping market, however, has demonstrated strong demand for a variety of flavors, not just menthol. Without legally authorized products available for sale, illicit products quickly filled the void to meet consumer demand.

Illicit vapes were perfectly situated to take over the vaping market. They provided sizable markups for retailers and may have also had a pricing advantage over legal vapes, as some

retailers didn't charge and remit taxes on products that weren't legally available for sale. And there continues to be exceptionally weak enforcement of product prohibitions.

The primary tool in the FDA enforcement arsenal is a warning letter. As of June 2024, the FDA has issued more than 1,100 warning letters to manufacturers, importers, distributors, and retailers. In February 2023, the FDA filed the agency's first civil money penalty complaints against four e-cigarette manufacturers.

In May 2023, the FDA attempted to block Chinese imports of market leader, Elf Bar, by ordering customs officials to seize incoming shipments. Elf Bar products didn't have an FDA MGO, but their products were available nationwide, including flavors like strawberry melon and bubble gum. In response, Elf Bar changed its product names (e.g., EBCreate) to those not on the seizure list and products continued to flow from China into the US.

Are Illicit Vaping Products Taxed?

Determining whether illicit products are being appropriately taxed is a difficult endeavor. Data on illicit markets and products are scarce. Vaping tax data is also not granularly reported across taxing jurisdictions. In an attempt to answer this question, we instead use the variation in US state vaping tax rates, combined with data on market prices, to look for irregularities. Our data illustrate that the pricing of small-market and Chinese vaping products—those without an MGO—does not mimic pricing patterns we observe in products granted an MGO for which we know taxes are being applied.

Unlike cigarettes—which have a nearly universal standard for size, are sold in packs of 20, and are single-use—vaping products vary substantially. Perhaps the most notable divide in vaping products is between single-use products, often called closed systems, and open-system vaping devices that are reused by consumers refilling the device with e-liquid or vaping pods.

Closed-system or disposable vaping devices are designed to be thrown away after use. Once the vaping liquid is depleted or the battery loses its charge, the entire device is discarded. Unlike rechargeable and open-system vaping devices, closed-system vaping products do not require any maintenance or refilling.

require any maintenance or refilling. 135a

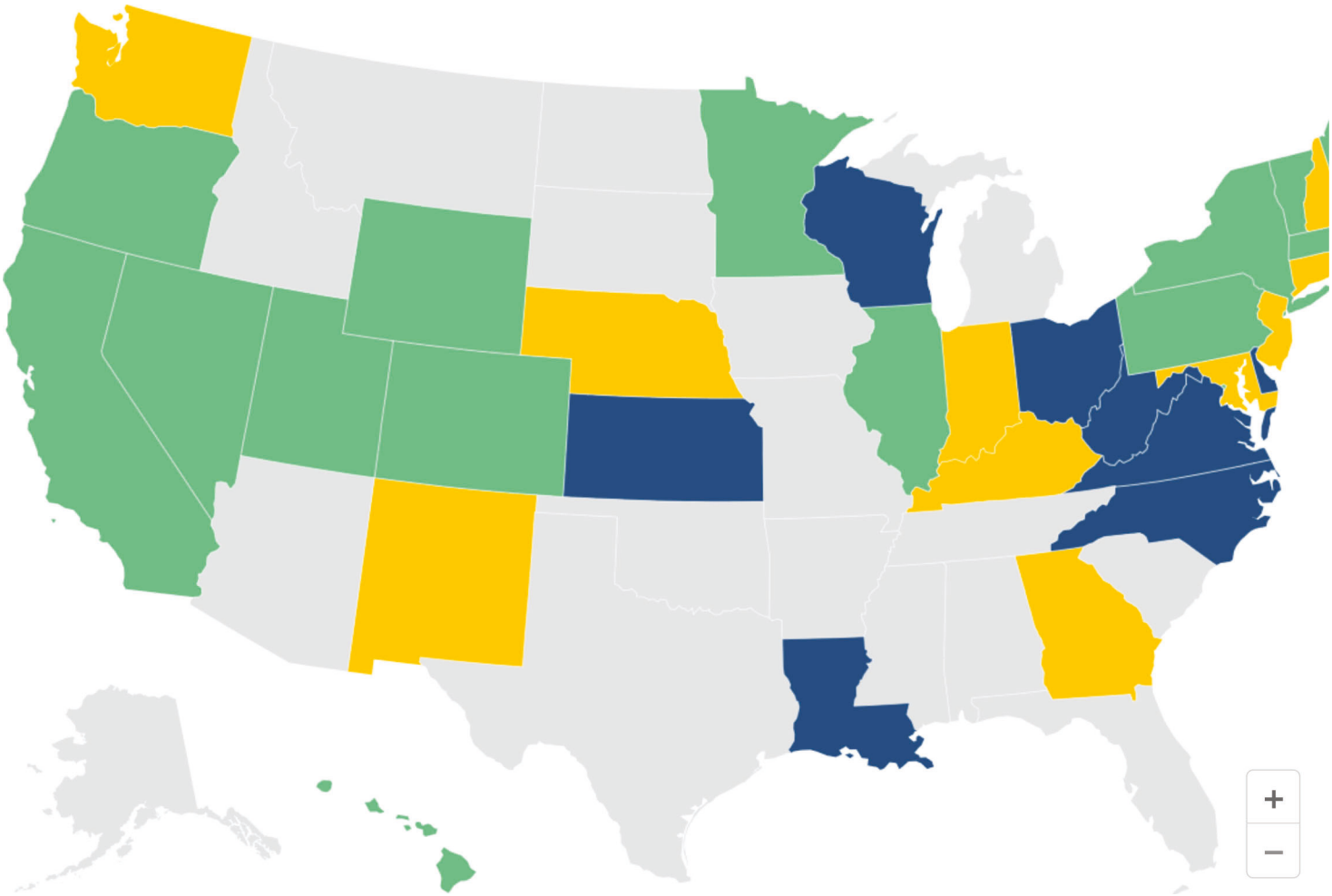
In part because of their ease of use and portability, disposable vaping product popularity grew, eventually taking over prefilled cartridge products as the market leader by 2022, even though most products with MGOs were prefilled cartridges.

States use a variety of designs to tax vaping products. Some states tax based on manufacturer, wholesale, or retail price; other states tax based on product, volume, or number of cartridges; while other states apply a bifurcated system with different rates for open- and closed-tank systems.

How Do Vaping Taxes in Your State Compare?

State Vaping Tax Rates and Design, June 2024

Ad Valorem Bifurcated Specific per mL No Tax



Source: State statutes; Bloomberg Tax.

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To test whether illicit vaping products are being taxed, we collected data on average retail prices of several vaping products for all 50 states and Washington, DC (from Management Science Associates Inc., corroborated by hand data collection across multiple states). We then calculated the tax that would be charged to each product in each state and analyzed the correlation between tax and price, hypothesizing that the excise taxes applied to vaping products would affect market prices for the taxed products, a well-documented phenomenon across various products.

We find that legal products—those for which the FDA has granted marketing orders, or products that have pending litigation regarding their PMTA—had prices that were strongly correlated to the tax charged on their products. The average correlation for MGO products was roughly 80 percent.

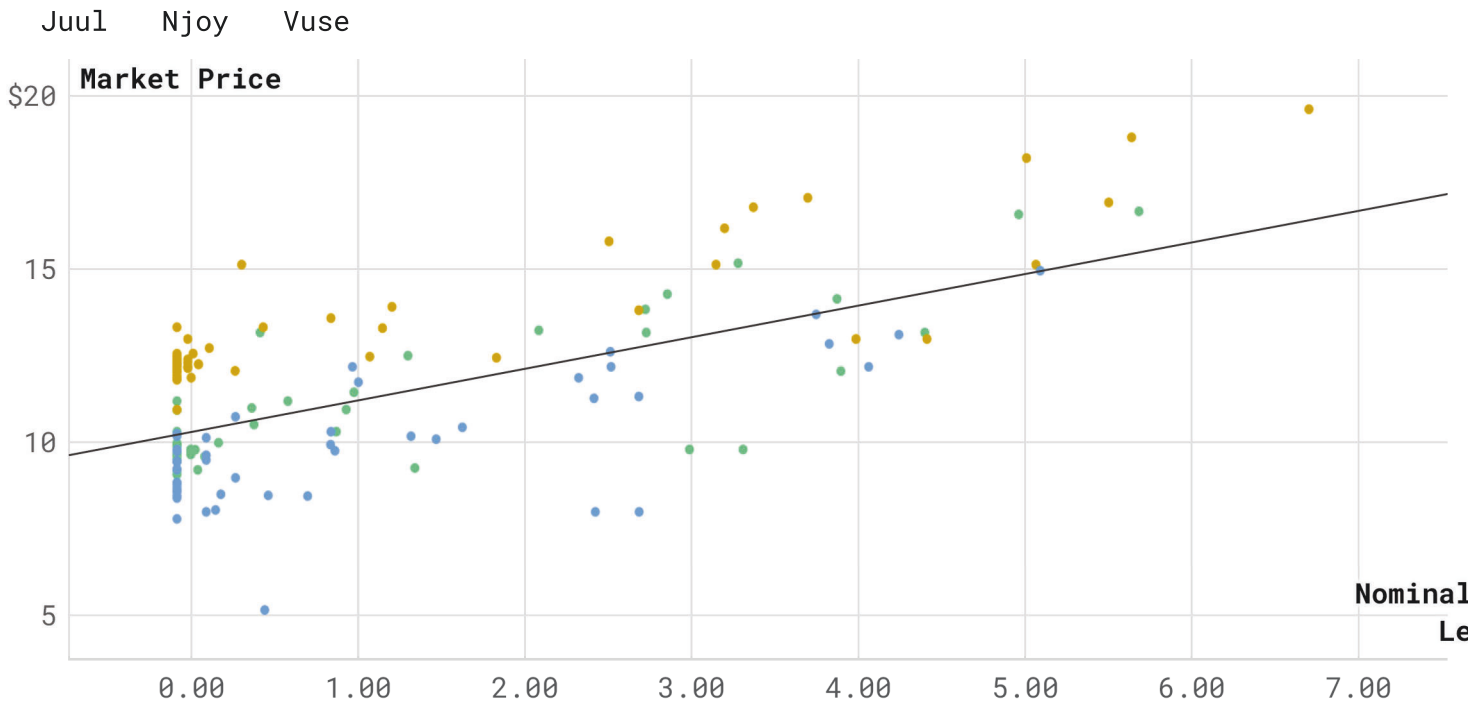
Chinese imports and other products without an MGO, on the other hand, are a different story entirely. The average correlation between price and tax was only 33 percent. Some products displayed no relationship between price and tax, and a few products even displayed a negative relationship.

Figure 2 displays the market prices (vertical axis) and tax estimates (horizontal axis) for select vaping products. Column 1 displays products with an MGO or a legally disputed PMTA application—Juul, NJOY, and Vuse. Column 2 displays small-market or Chinese products for which the FDA hasn't granted an MGO—Lost Mary, Raz, and Mr. Fog.

The products in the first column look as we would expect—a line of best fit with a close to unitary positive slope. The products in the second column don't look the way we would expect if the state taxes were being incorporated into the price. In other words, these data suggest sellers of illicit products may not be applying state tax rates to vaping products.

Sellers of Illicit Vaping Products May Not Be Applying State Taxes: MGO Products

Correlation Between Pricing and Estimated Taxes for MGO vs Non-MGO Vaping Products



Source: State statutes; Management Science Associates; Author's calculations.

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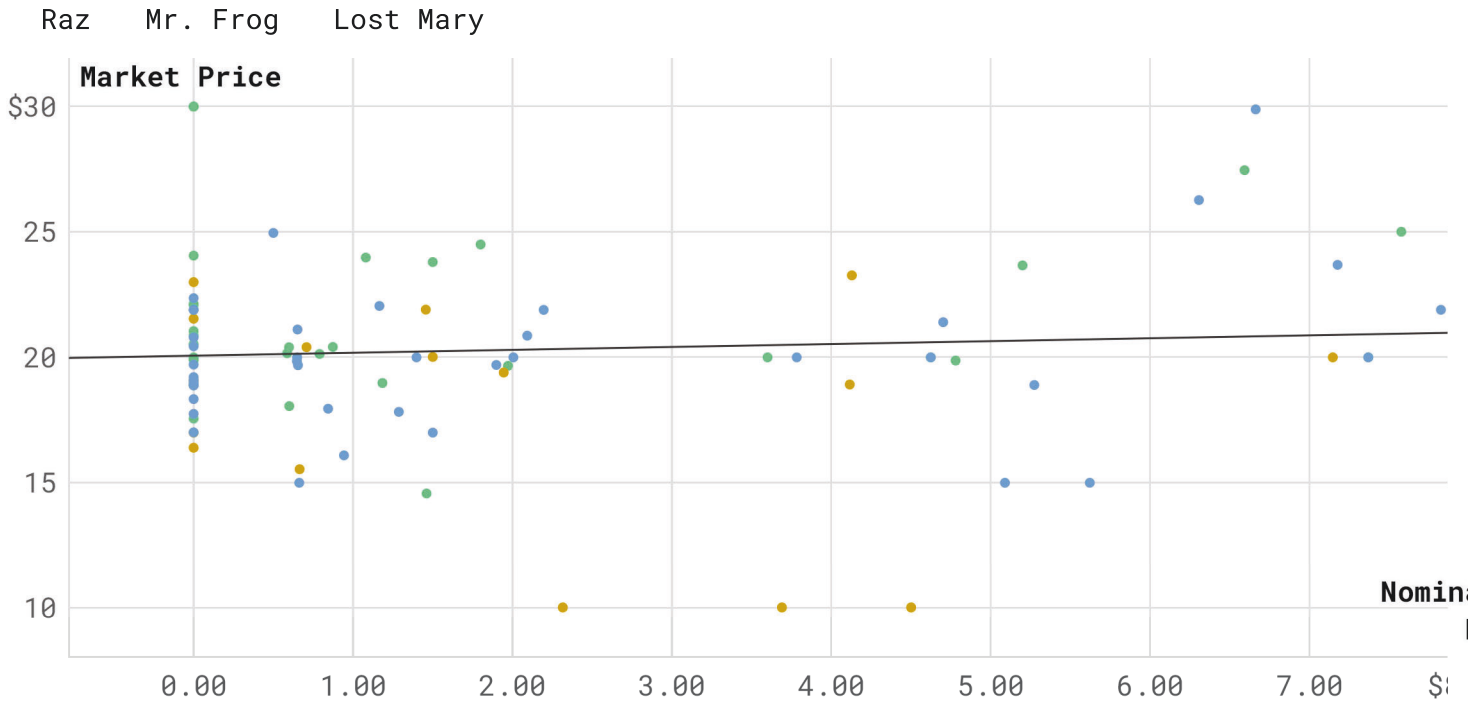
Sellers of Illicit Vaping Products May Not Be Applying State Taxes: Non-MGO Products

Correlation Between Pricing and Estimated Taxes for MGO vs Non-MGO Vaping Products



Source: State statutes; Management Science Associates; Author's calculations.

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What Can Be Done?

Legal vaping products are harm reduction tools for many existing smokers. Vapor products deliver nicotine to users without the combustion and inhalation of tar inherent to traditional cigarettes. While more research into the long-term harm-reduction potential of vapor products is needed, the present consensus is that vapor products are significantly less harmful than traditional combustible tobacco products. The English Ministry for Health concluded that vaping is 95 percent less harmful than smoking cigarettes.

This is why the FDA-induced disaster that has become the vaping market is such a tragedy. Instead of having a thriving, well-regulated, and taxed vaping industry, the FDA has handed control of the vaping market to illicit Chinese operators.

The good news is that the fix is easy. A two-pronged approach of better enforcement and quicker, broader FDA product approvals can quickly correct the US vaping market.

The FDA has increased enforcement on illicit products being sold in the United States, but there is still more work to do to enforce current regulations. Further, the government cannot rely solely on enforcement of prohibitions. Harm-reducing vapor products must face lower regulatory barriers to enable their competition with illicit vaping products and with legal combustible cigarettes to maximize their potential to improve public health.

One potential ally on the enforcement front could come from state departments of revenue and tax enforcement agencies. Our evidence on tax evasion of illicit products, largely Chinese imports, is only suggestive. State revenue departments could collect better microdata on vaping sales to determine if taxes are being properly charged, collected, and remitted. State agencies may have more enforcement options at their discretion and better tools to identify illicit operations.

Finally, the market approval process is too cumbersome, lengthy, and lacks transparency. The FDA Center for Tobacco Products acknowledged these faults and has started improving the

PMTA process. The approval of the first flavored tobacco vaping products is a major step in the right direction. However, the process still lacks clarity and the timeline for an FDA decision is unacceptably long.

Given the FDA's demonstrated inability to efficiently operate a premarket approval process, policymakers should consider reversing the order for approving marketing nicotine products for sale in the US. Under this system, products could be marketed and sold by default and only prohibited if the FDA provided scientific evidence, with a well-defined criterion approved by Congress.

It is also possible that the Supreme Court will weigh in. A vaping case, *Wages and White Lion (Triton) v. FDA*, is set to be considered next term. Previously, courts have relied partially on Chevron deference to rule against vaping businesses, but with the Court recently overturning this doctrine in favor of a lower standard of deference, there is potential for judicially mandated modifications to the regulatory process. Policy change is necessary to fix the US vaping market, but if not possible through legislative changes, the court system may mandate important corrections.