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**Programmatic Environmental Assessment for  
Marketing Orders for  
New Electronic Nicotine Delivery System Products  
Marketed by Juul Labs, Inc.**

**Prepared by Center for Tobacco Products  
U.S. Food and Drug Administration**

July 10, 2025

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**CONFIDENTIAL APPENDIX 1: First- and Fifth-Year Market Volume Projections for the New Products 166**

## 1. Introduction

### 1.1 Background

On July 29, 2020, Juul Labs Inc. submitted premarket tobacco product applications (PMTAs) for five electronic nicotine delivery system (ENDS) products. In the PMTAs, Juul Labs Inc. requests the U.S. Food & Drug Administration issue marketing orders under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Public Law 111-31).

This document reviews the potential environmental effects from marketing the new products in the United States, and from the no-action alternative of the Agency not issuing marketing orders for the new products.

### 1.2 Applicant and Manufacturer Information

<b>Applicant Name:</b>	Juul Labs, Inc.
<b>Applicant Address:</b>	560 20th St. San Francisco, CA 94107 U.S.
<b>Manufacturers Name:</b>	Asteelflash Suzhou Co., Ltd. (Asteelflash Suzhou or AFG) (PM0000878.PD1)  Pegatron Corporation (Pegatron) (PM0000878.PD1)  Phillips-Medisize, LLC New Richmond facility (PMC-New Richmond) (PM0000864.PD1 - PM0000876.PD1)  Phillips-Medisize, LLC Saint Croix Meadows facility (PMC-Hudson) (PM0000864.PD1 - PM0000876.PD1)
<b>Product Manufacturing Locations:</b>	Asteelflash Suzhou Wujiang Economic Development Zone, 8 Gu Tang Road, Wujiang City, Jiangsu, China  Pegatron No. 233 Jinfeng Rd, SND, Suzhou City, Jiangsu Province, PR. China  PMC-New Richmond 705 Wisconsin Drive, New Richmond, WI 54017, U.S.  PMC-Hudson 2202 Carmichael Road, Hudson, WI 54016, U.S.

### 1.3 Product Information

#### New Product Names and Submission Tracking Numbers (STNs)

New Product Name	STN New Product
JUULpods (Menthol 3.0%)	PM0000864.PD1
JUULpods (Menthol 5.0%)	PM0000872.PD1

JUULpods (Virginia Tobacco 3.0%)	PM0000874.PD1
JUULpods (Virginia Tobacco 5.0%)	PM0000876.PD1
JUUL Device	PM0000878.PD1

### Product Identification

<b>Product Category</b>	Electronic Nicotine Delivery Systems
<b>Product Subcategory</b>	Closed E-Cigarette, Closed E-Liquid
<b>Product Number per Retail Unit</b>	PM0000864.PD1, PM0000872.PD1, PM0000874.PD1, PM0000876.PD1: Blister packs containing 2 or 4 pods each filled with 0.7 mL of e-liquid.  PM0000878.PD1: One kit containing one JUUL device and one JUUL charging dock accessory.
<b>Product Package</b>	PM0000864.PD1, PM0000872.PD1, PM0000874.PD1, PM0000876.PD1: Paper, paperboard, PerfectForm® SkyBlue™ CXB™, foil, and associated adhesive and inks. Pods, of 2 or 4, are contained in the PerfectForm® SkyBlue™ CXB™ and foil which is then contained in a paperboard box.  PM0000878.PD1: Paper, paperboard, paper pulp, biaxially oriented polypropylene, and associated adhesive and inks. Device sits in a paperboard mold and contained in a paperboard box.

## 2. The Need and Purpose for the Proposed Actions

**Purpose:** The applicant wishes to continue marketing the new products in interstate commerce for commercial distribution in the United States and submitted to the Agency PMTAs to obtain marketing orders. Upon receipt of a PMTA, FDA considers the submission, using criteria detailed in section 910(c) of the FD&C Act, to make a finding as to whether a marketing order for the new products would be appropriate for the protection of public health.

**Need:** FDA's responsibility to review a PMTA, make a finding as described in the previous paragraph, and subsequently determine whether or not to issue a marketing order for the new products is a statutory requirement under section 910(c) of the FD&C Act.

## 3. Proposed Actions and Alternatives

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of section 910(c) of the FD&C Act for introduction or delivery for introduction of tobacco products into interstate commerce in the United States after finding the new products would be appropriate for the protection of public health.

The no-action alternative is FDA does not issue marketing orders for the new products. The new products would not be marketed in the United States and, for the purposes of the analysis in this programmatic environmental assessment, it is assumed that there would be no changes to the current ENDS market and no changes to the current or future use of tobacco products.

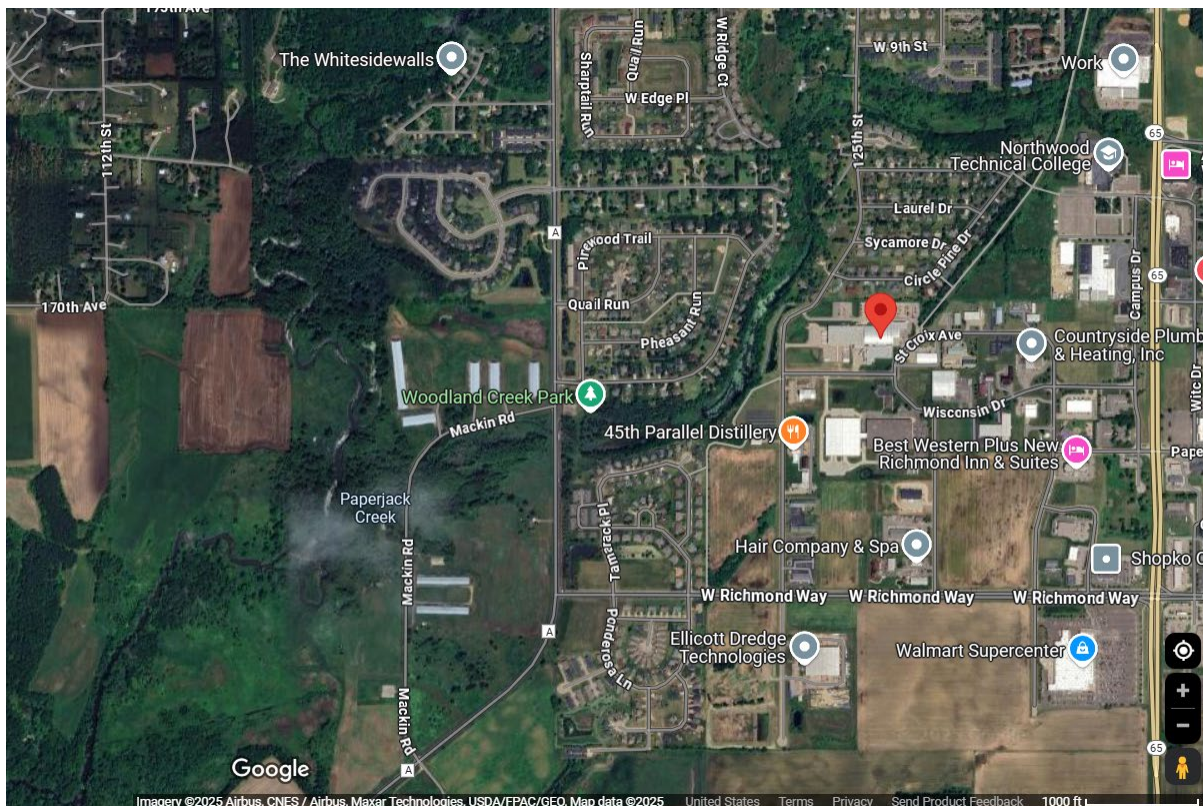
#### 4. Potential Environmental Effects of the Proposed Actions and Alternatives – Manufacturing the New Products

The applicant stated that the AsteelFlash and Pegatron manufacturing facilities in China are in compliance with applicable environmental requirements. The applicant also stated that manufacturing the new products at the identified facilities are not anticipated to impact any species or critical habitat of any species identified under the Endangered Species Act (ESA). However, because both facilities are located outside the United States, environmental effects associated with manufacturing the new products at those sites will not be discussed. The analyses in sections 4.1 through 4.9 focus on the manufacturing facilities at PMC-New Richmond and PMC-Hudson located within the United States.

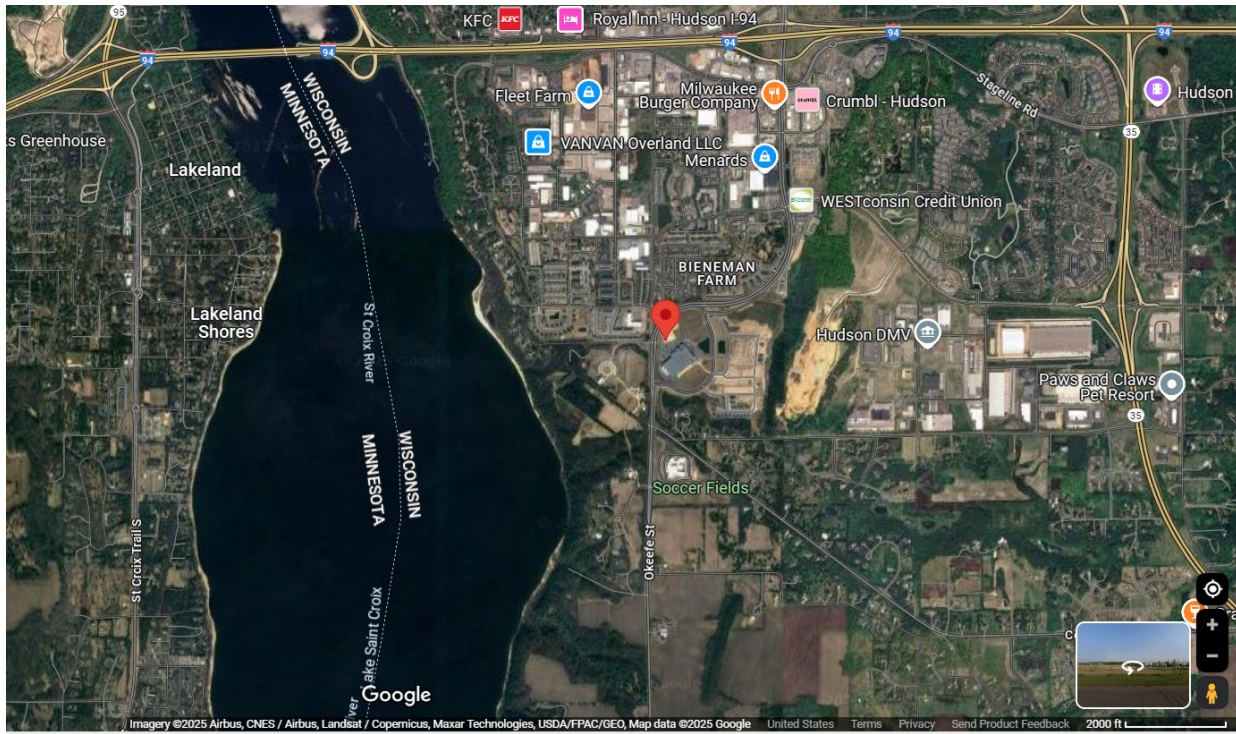
##### 4.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facilities. The applicant stated that the finished Juulpods are manufactured by PMC-New Richmond located at 705 Wisconsin Drive, New Richmond, WI 54017, U.S. (Figure 1) and at PMC-Hudson located at 2202 Carmichael Road, Hudson, WI 54016, U.S. (Figure 2). The facilities are located in light industrial zones and business parks with surrounding residential neighborhoods. Additionally, PMC-Hudson is located approximately 2000 feet from the St. Croix river.

**Figure 1. Location of the PMC-New Richmond Manufacturing Facility (Google Maps, 2025)**



**Figure 2. Location of the PMC–Hudson Manufacturing Facility (Google Maps, 2025)**



The applicant stated that manufacturing the new products will not (1) require expansion of the manufacturing facilities and (2) release any new chemicals or new types of emissions into the environment. Additionally, the applicant stated that the PMC-New Richmond facility meets each of the criteria specified in Wisconsin’s “Natural Minor Source Exemption” within NR 407.03(1s) and, therefore, is exempt from the requirement to obtain an air operation permit from the Wisconsin Department of Natural Resources. However, the PMC-Hudson facility anticipates applying for a Registration Construction Permit / Registration Operation Permit for future operational flexibility. The applicant also stated that the manufacturing facilities are not located within a habitat, critical or otherwise, of a threatened or endangered species.

#### **4.2 Air Quality**

The Agency does not anticipate that manufacturing the new products would lead to release of new chemicals into the air. The applicant stated that manufacturing the new products is not expected to result in changes in air emissions. Accordingly, the applicant indicated that manufacturing the new products would not require any additional environmental controls for air emissions.

#### **4.3 Water Resources**

The Agency does not anticipate that manufacturing the new products will cause the discharge of any new chemicals into water. The applicant stated that (1) manufacturing the new products will not lead to changes in water quality, (2) there is little wastewater discharge from the facilities and (3) there will be no impacts on water resources from manufacturing.

#### **4.4 Soil, Land Use, and Zoning**

The Agency does not anticipate that manufacturing the new products will lead to changes in soil, land use, or zoning. The applicant stated that construction projects that may impact the environment, such as development of a manufacturing site or modification to a manufacturing site, would require an assessment of the environmental effects and approval prior to the construction or expansion of an existing project. Therefore, there will be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

#### **4.5 Biological Resources**

The Agency does not anticipate manufacturing the new products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the ESA. The applicant stated that construction projects that may impact the environment, such as development of a manufacturing site or modification to a manufacturing site, would require an assessment of the environmental effects and approval prior to the construction or expansion of an existing project. In addition, the agency reviewed the U.S. Fish and Wildlife Service's critical habitat and endangered species maps and found no critical habitats identified within the vicinity of the manufacturing facilities (*U.S. FWS, 2025*).

#### **4.6 Regulatory Compliance**

The Agency's search of the EPA's Enforcement and Compliance History Online database did not retrieve any information for the manufacturing facilities (*U.S. EPA, 2025*). The applicant stated that (1) there will be no anticipated impacts on regulatory compliance from manufacturing, and (2) the manufacturing facilities are in compliance with local, state, and federal environmental regulations.

#### **4.7 Solid Waste and Hazardous Materials**

The Agency does not foresee that the introduction of the new products will notably affect the current manufacturing waste generated from the facilities' production of tobacco products. The Agency anticipates the waste generated due to manufacturing the new products will be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facilities. The applicant stated that (1) the amount of waste attributed to the manufacture of the new products would be minimal and (2) the waste generated by the facilities is removed for disposal by third-party waste handlers and therefore ends up in solid waste landfills rather than accumulating in the environment.

#### **4.8 Floodplains, Wetlands, and Coastal Zones**

The applicant stated that construction projects that may impact the environment, such as development of a manufacturing site or modification to a manufacturing site, would require an assessment of the environmental effects and approval prior to the construction or expansion of an existing project. Additionally, the applicant did not propose any land disturbance; therefore, there will be no effects on floodplains, wetlands, or coastal zones.

#### **4.9 Impacts of No-Action Alternative**

The environmental effects of the no-action alternative will not change the existing condition of manufacturing ENDS products as many similar tobacco products would continue to be marketed in the United States.

### **5. Potential Environmental Effects of the Proposed Actions and Alternatives – Use of the New Products**

The Agency considered potential impacts to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes (Confidential Appendix 1) for the first- and fifth-year of marketing of the new products.

#### **5.1 Affected Environment**

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new products to be sold to consumers in the United States.

#### **5.2 Air Quality**

The impacts from use of the new products include exposure to second and thirdhand vapor. Secondhand vapor is created when an ENDS user exhales mainstream vapor into the environment (Czogala et al., 2014). Thirdhand vapor is created when an ENDS is inhaled and the chemicals in the vapor, exhaled by the user, deposit on surrounding surfaces (Goniewicz & Lee, 2015) and clothing (Nath & Geraghty, 2020). Recent studies have shown that secondhand ENDS vapor contains chemicals such as propylene glycol, glycerol, volatile organic compounds (VOCs), nicotine, particulate matter, and other tobacco-specific nitrosamines (TSNAs) (Tan et al., 2016; Visser et al., 2019). In addition, studies suggest that for every 70mL puff, 0.019% of the e-liquid byproduct can deposit on metal (Davis et al., 2017), floors, wood, windows, and walls (Goniewicz & Lee, 2015).

Exposure to secondhand and thirdhand ENDS vapor may have short- and long-term, adverse effects on human and environmental health. Exposure to nicotine from secondhand vapor may cause an increase in blood pressure and palpitations (Visser et al., 2019). Heavy metals found in secondhand vapor from ENDS include chromium, iron, aluminum, lead, copper, nickel, and cadmium (Li et al., 2020) and silver (Hess et al., 2016). These metals may cause irritation to the respiratory system and respiratory damage. The aromatic VOCs found in exhaled vapor include benzene and toluene, listed by the International Agency for Research on Cancer (IARC) as a human carcinogen and a potential neurotoxin, respectively. The carbonyls include formaldehyde (a known carcinogen), acetaldehyde (a potential carcinogen), acetone, acrolein, and propanal. These are considered cytotoxic aldehydes that cause damage to the respiratory system (Li et al., 2020). Exposure to propylene glycol (PG) and glycerol from secondhand vapor may cause respiratory irritation (Visser et al., 2019). Over time, as PG levels build up in the body, it can cause hemolysis, hypoglycemia, lactic acidosis, seizures, coma, and central nervous system depression (Nath & Geraghty, 2020). Tobacco-specific nitrosamines found in secondhand vapor, such as nicotine-derived nitrosamine ketone (NNK) and N-nitrosornicotine (NNN), are known to cause increased risk of tumor development and cancer (Visser et al., 2019). The levels of nicotine and other chemicals released to the air differ depending on a number of factors including type of device,

composition of the e-liquid used, temperature of the heating coil, and power voltage of the device (Li et al., 2020).

Secondhand ENDS vapor impacts indoor air quality and is not risk-free to bystanders (Palmisani et al., 2019). Although room size, temperature, air exchange rate, and relative humidity have an effect on vapor dilution, these vapors do not dilute in the air of enclosed locations (i.e. cars, homes, workplaces) as compared to outdoors (Li et al., 2020). Independent of the e-liquid chosen by the user, the concentration of ultrafine particles found in ENDS vapor exhaled from the user can be up to 3800 times more concentrated than secondhand smoke from a combustible cigarette (Palmisani et al., 2019). Higher concentrations of smaller particles may place bystanders at increased risk due to the particles' high penetration capacity of the respiratory system (Davis et al., 2017; Palmisani et al., 2019). This may pose a greater risk to vulnerable populations such as pregnant women, children, and adolescents (Hess et al., 2016; Palmisani et al., 2019). Short-term exposure to secondhand vapor may cause respiratory and cardiovascular disease and may adversely affect susceptible populations with respiratory complications such as asthma (Li et al., 2020).

Route of exposure to thirdhand vapor is achieved through ingestion, inhalation, and touch (Goniewicz & Lee, 2015; Nath & Geraghty, 2020). Nicotine exposure from thirdhand vapor may place children and infants at higher risk of adverse health effects (Goniewicz & Lee, 2015). Studies show thirdhand vapor from ENDS including those from e-liquids that do not contain nicotine may compromise immune response, brain, and spleen development (Chen et al., 2020), placing infants at increased risk of disrupting brain development (Nath & Geraghty, 2020).

More research is required to determine the full health implications that secondhand and thirdhand exposure from ENDS vapor has on public and environmental health.

As of July 2023, 23 states and three territories had implemented state- and territory-level bans on the use of ENDS in many public spaces. Sixteen states had state-level regulation on the use of ENDS while at least 40 states and the District of Columbia had city or county-level restriction on ENDS. Such laws are expected to reduce the levels of non-users' exposure to secondhand and thirdhand vapor (American Nonsmokers' Rights Foundation, 2021).

The Agency does not anticipate new chemicals would be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other ENDS products already on the market because (1) the new products are expected to compete with other currently marketed ENDS products, and (2) the ingredients in the new products are used in other currently marketed ENDS products.

### **5.3 Impacts from the No-Action Alternative**

The environmental effects of the no-action alternative would not change the existing condition of use of ENDS products because many similar tobacco products would continue to be used in the United States.

## **6. Potential Environmental Effects of the Proposed Actions and Alternatives – Disposal of the New Products**

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new products and found no significant impacts based on Agency-gathered information

and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes (Confidential Appendix 1) for the first- and fifth-year of marketing of the new products.

### **6.1 Affected Environment**

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new products to be sold to consumers nationwide who would dispose of the used products and packaging as municipal solid waste (MSW), recycled material, or litter.

### **6.2 Air Quality**

The Agency does not anticipate disposal of the new products or the packaging material would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the new products. The chemicals in the new ENDS devices, tanks, and batteries are commonly used in other currently marketed ENDS products. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other ENDS products disposed of in the United States. Additionally, although littering of the cartridges containing e-liquid may cause some of the e-liquid to leach into the environment, the majority of e-liquid will be consumed by the user, leaving only trace amounts left in the cartridges that may leach out and be emitted to the air.

No changes in air quality from disposal of the new products' package materials would be expected because (1) the paper and plastic components of the packages are more likely to be recycled, or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste in the United States (*U.S. EPA, 2025f*) based on the projected market volume of the new products. In addition, the applicant stated there will be no air quality impacts from product disposal.

### **6.3 Biological Resources**

Proper disposal of the used products and packaging in the MSW stream will not affect biological resources. Improper disposal (littering) of the used products could lead to terrestrial wildlife having direct exposure to the used products and hazardous substances leaching to aquatic environments and soils. E-liquid is composed of several chemicals that may leach into the environment if not properly disposed. In general, e-liquids are composed of a base, which is typically propylene glycol and vegetable glycerin, as well as nicotine and flavorants, (Dai et al., 2018; DeVito & Krishnan-Sarin, 2018) vanillin, ethyl maltol, and ethyl butyrate being the most common flavoring ingredients (Krüsemann et al., 2021). Leaching of chemical constituents in e-liquids from the disposal or littering of used cartridges is of environmental concern (Baran et al., 2020; Chang, 2014; Panitz et al., 2015). Further, transfer of metals from the cartridge or device into the e-liquid also raises potential environmental concerns (Hess et al., 2017; Zervas et al., 2020). At the time of writing this environmental assessment, studies identifying and characterizing environmental effects of ENDS leachate are not available. While other flavorants and chemicals may be present in e-liquids, their concentration is typically low. Furthermore, although users may dispose of used cartridges improperly as litter, the majority of e-liquid will be consumed, leaving only trace amounts to potentially leach into the environment. Therefore, to the best of our knowledge, no significant environmental effects are expected due to disposal of the new products. In addition, the applicant stated there will not be any significant impacts on biological resources from use of the new

products as released materials during product use would not be expected to generate substantial volumes of harmful constituents that could result in adverse impacts on ecological receptors from decreased air quality (for respiration) and water quality (ingestion or exposure).

#### **6.4 Water Resources and Water Quality**

Proper disposal of the used products and packaging in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of the used tobacco products could result in hazardous substances leaching into water systems. However, the new products will be consumed leaving only trace amounts that may be littered into the environment. Therefore, no significant environmental impacts are expected. In addition, the applicant stated there would be no impacts on water resources related to product use as released materials from the device during use by the consumer would not be expected to generate substantial volumes of harmful constituents that could deposit to waterbodies and result in decreased water quality or other impairments.

#### **6.5 Solid Waste and Hazardous Materials**

Requirements for disposal of e-liquid bottles and ENDS components containing nicotine vary by state and collecting entity responsible for disposal. EPA has the authority to control hazardous waste from “cradle-to-grave” under the Resource Conservation and Recovery Act (RCRA) in 40 CFR Parts 260 through 273 (*U.S. EPA, 2024*). Under Subtitle C of RCRA, nicotine (including nicotine salts) is regulated as an acute hazardous waste (*Public Health Law Center, 2023*). ENDS components containing nicotine must be handled according to applicable federal, state, and local regulations. Additional laws may apply, including 40 CFR Part 266 Subpart P, where ENDS products containing nicotine must be managed as hazardous waste pharmaceuticals (*U.S. EPA, 2025d*).

Non-residential disposal of e-liquid bottles containing nicotine is the responsibility of the collecting entity (e.g. schools, airports, etc.), which EPA considers “generators” of hazardous waste by accumulating RCRA-listed chemicals (*Public Health Law Center, 2023*). Due to nicotine being considered an acute hazardous waste, generators are registered as either a very small quantity generator (VSQG) or large quantity generator (LQG) based on a threshold of one kilogram generated per month (*Public Health Law Center, 2023*). Following collection by state or local authorities, hazardous waste is recycled, treated, stored, or disposed (*U.S. EPA, 2025e*). As hazardous waste generators, VSQGs and LQGs have specific handling requirements such as delivering waste to a hazardous waste collection facility.

Residential disposal (household hazardous waste) of e-liquids containing nicotine is excluded from Subtitle C of RCRA residential disposal and is regulated under Subtitle D of RCRA as non-hazardous solid waste, 40 CFR parts 239 through 259 (*U.S. EPA, 2025b*). Additional state and local laws may apply for disposal.

Improper disposal of e-liquids can pose a threat to the environment; therefore, ENDS components containing nicotine or nicotine residue should not be rinsed (*U.S. FDA, 2020*). As of February 2025, the Agency did not find any data reporting the amount of ENDS products containing nicotine collected or littered in the United States. However, the Marine Debris Tracker mobile application allows individuals to track debris in the United States (*Marine Debris Tracker App, 2021*).

Lithium-ion batteries in ENDS products are regulated under subtitle C of the RCRA as both ignitable hazardous waste and reactive hazardous waste (*Public Health Law Center, 2021*). More specifically, lithium-ion batteries are a type of hazardous waste classified under RCRA as universal waste and must be disposed of according to applicable federal, state and local regulations (*U.S. EPA, 2025a*).

Residential disposal (household hazardous waste) of lithium-ion batteries is excluded from Subtitle C of RCRA and is regulated under Subtitle D, 40 CFR parts 239 through 259 as solid waste (*U.S. EPA, 2025b*). Disposing of lithium-ion batteries in MSW and traditional recycling streams is prohibited due to risk of explosion (*U.S. EPA, 2025c*). Used lithium-ion batteries that have been separated from the device may be disposed of at retailers participating in takeback programs or at specialized battery destination facilities; additional state and local laws may apply (*U.S. EPA, 2025c*). ENDS devices where the battery cannot be separated must be disposed of as nicotine-containing hazardous waste and are subject to certain requirements under RCRA (*Public Health Law Center, 2021*).

Non-residential entities that accumulate or transport universal waste and specialized universal waste destination facilities are considered by EPA as universal waste "handlers" (*U.S. EPA, 2025a*). Handling and disposal requirements depend on how much universal waste a handler accumulates at any one time; handlers are classified as either small quantity handlers or large quantity handlers based on a threshold of 5,000 or more kg of accumulated universal waste. Once it reaches a universal waste destination facility, universal waste is recycled, treated, or disposed of (*U.S. EPA, 2025a*).

As of May 2021, the Agency did not find any data reporting the amount of ENDS products containing lithium-ion batteries collected or littered in the United States. However, a 2020 survey conducted by the Truth Initiative on disposal habits of adolescent and young adult ENDS users revealed that 43% disposed of used ENDS batteries in the trash compared to 18% who pursued proper disposal channels (*Truth Initiative, 2021*).

The Agency does not foresee that the introduction of the new products into the U.S. market would notably affect the nationwide waste generated from the use of ENDS products. The distribution of waste generated due to disposal of the new products and packaging is anticipated to correspond to the pattern of the products use in the United States. Therefore, no net increase in littering would be expected.

## **6.6 Impacts from the No-Action Alternative**

The environmental effects of the no-action alternative would not change the existing condition of disposal of ENDS products and their packaging, as many other similar tobacco products would continue to be disposed of in the United States.

## **7. List of Preparers**

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

### ***Preparer:***

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Eleven years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

### ***Reviewer:***

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-seven years in various scientific activities including thirteen years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

## 8. A Listing of Agencies and Persons Consulted

Not applicable.

## 9. References

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**CONFIDENTIAL APPENDIX 1: First- and Fifth-Year Market Volume Projections for the New Products**

