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Programmatic Environmental Assessment for Marketing Orders for Multiple ENDS Tobacco Products by R.J. Reynolds Vapor Company

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

July 9, 2024

Table of Contents

CONFIDENTIAL APPENDIX 1: Market Volume Projections for the New Products 21

1. Introduction

Background

On September 4, 2020, R.J. Reynolds Vapor Company (RJRV) submitted premarket tobacco product applications (PMTAs) for an electronic nicotine delivery system (ENDS) component (Vuse Alto power unit) and six closed e-liquids (Vuse Alto e-liquid cartridges). In the PMTAs, R.J. Reynolds Vapor Company 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 impacts 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. The Agency did not identify any significant environmental impacts from the proposed actions.

Applicant and Manufacturer Information

Applicant Name:	R.J. Reynolds Vapor Company		
Applicant Address:	401 North Main Street, Winston-Salem, North Carolina 27101		
Manufacturer Information:	Manufacturer Name	Product Manufacturing Location	Product Manufactured
	(b) (4)		Vuse Alto power unit and Finished Products
			Vuse Alto e-liquid cartridges
			E-liquids in the cartridges

Product Information

New Product Names and Submission Tracking Numbers (STNs)

New Product Name	STN New Product
PM0000973.PD1	VUSE ALTO POWER UNIT
PM0000973.PD2	VUSE ALTO POD GOLDEN TOBACCO 5%
PM0000973.PD3	VUSE ALTO POD RICH TOBACCO 5%
PM0000973.PD6	VUSE ALTO POD GOLDEN TOBACCO 2.4%
PM0000973.PD7	VUSE ALTO POD RICH TOBACCO 2.4%
PM0000973.PD10	VUSE ALTO POD GOLDEN TOBACCO 1.8%
PM0000973.PD11	VUSE ALTO POD RICH TOBACCO 1.8%

Product Identification

Product Category	Electronic Nicotine Delivery System (ENDS) (VAPES)
Product Subcategory	ENDS Component, Closed E-Liquid
Product Number per Retail Unit	PM0000973.PD1: One power unit containing a UL 1642 certified lithium-ion battery, puff sensor, and LED indicator; with a USB accessory charger. PM0000973.PD2, PM0000973.PD3: One or two e-liquid cartridges containing 5% nicotine in 1.9mL of e-liquid, sold separately. PM0000973.PD6, PM0000973.PD7: One or two e-liquid cartridges, 2.4% nicotine content, 1.9mL of e-liquid, sold separately. PM0000973.PD10, PM0000973.PD11: One or two e-liquid cartridges, 1.8% nicotine content, 1.9mL of e-liquid, sold separately.
Product Package	PM0000973.PD1: The power unit parts are contained within an aluminum outer tube. The power unit and USB charger are seated in a paperboard tray. The tray and a paper instruction insert are enclosed in a paperboard box, shrink-wrapped with polyethylene/polypropylene film. Packs of power units are bundled in paperboard cartons and cardboard cases for shipping and distribution. PM0000973.PD2, PM0000973.PD3, PM0000973.PD6, PM0000973.PD7, PM0000973.PD10, PM0000973.PD11: sold in packs of one or two cartridges. The cartridges are individually sealed in a polyvinyl chloride/polychlorotrifluoroethylene barrier film blister forming web with a foil lid. The blister pack is seated in a two-piece sliding paperboard box. The pack is shrink wrapped with polyethylene/polypropylene film. The retail packs of cartridges are further bundled in paperboard cartons and cardboard cases for shipping and distribution.

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 product 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 tobacco product 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 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 Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new products and found no significant impacts[1] based on the Agency-gathered information and the following applicant-submitted information:

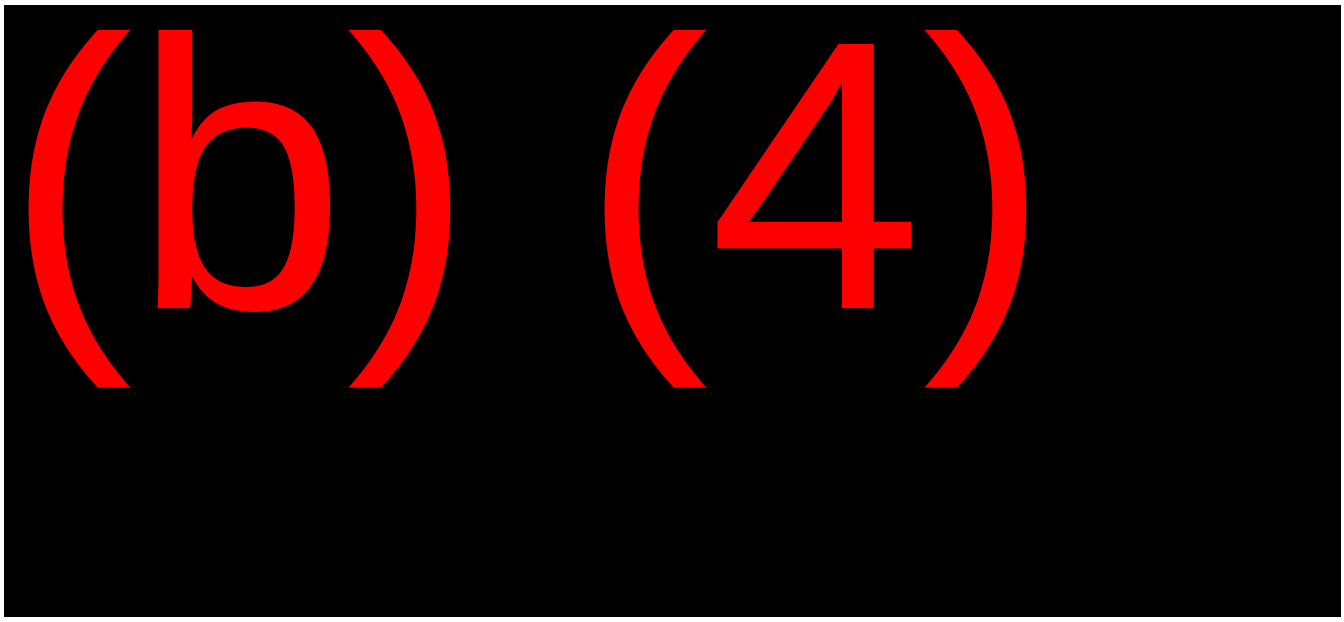
- No additional equipment or facility expansion is expected due to manufacturing the new products.
- Manufacturing the new products will not require additional environmental controls.
- The manufacturing facility complies with federal, state, and local regulations.

4.1. Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facilities listed in section 1.2 of this document.

[1] This environmental assessment only assessed environmental impacts due to manufacturing the new products at the U.S. manufacturing facility.

Figure 1. Location of the E-liquid Manufacturing Facility (Google Maps, 2024)



The manufacturing facility is located in (b) (4) The manufacturing facility is located in a mixed-use area. This includes residential, commercial (e.g. Produce wholesaler, collision center, printing equipment supplier), and industrial land.

4.2. Air Quality

There were no TRI-reportable chemicals released to air from the (b) (4) manufacturing facility.

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals into the environment. The applicant stated that manufacturing the e-liquids does not result in the release of significant emissions to the environment; therefore, the applicant concluded that manufacturing the new products would not require any additional environmental controls for air emissions.

4.3. Water Resources

There were no TRI-reportable chemicals released to water from the manufacturing facility.

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The applicant stated that manufacturing the new products would not require any additional environmental controls for water discharges.

4.4. Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, or zoning. The applicant stated that there would be no expected facility expansion due to manufacturing the new products. Therefore, there would 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 that 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 Endangered Species Act (ESA). The applicant stated that manufacturing the new products would not require expansion of the manufacturing facility. Additionally, U.S. Fish and Wildlife Service (FWS) maps show that the facility are not within or near a critical habitat, or endangered animal and plant species (Data Basin, 2024).

The U.S. FWS identifies 21 vertebrates, two invertebrates, and two plants in Collier County as endangered, proposed endangered, or threatened (US fish and Wildlife Service, 2024).
Because the proposed actions do not require expansion of the manufacturing facility, and the listed species are not found in the immediate vicinity of the facility, there would be no impacts to protected species or their potential habitat. Additionally, no TRI-reportable chemicals were released from the (b) (4) manufacturing facility, and the TRI-reporting status of the facility is not anticipated to change as a result of manufacturing the new products.

4.6. Regulatory Compliance

The applicant stated that the manufacturing facilities outside the United States are in compliance with all applicable local or national environmental and waste regulations.

The e-liquids for the cartridges are manufactured by (b) (4) at the address listed in section 1.2 of this document. The applicant stated that the manufacturer is registered as a large quantity generator for disposal of hazardous waste containing nicotine. The facility does not discharge chemicals to air, water or land because the e-liquid manufacturing waste is transported as hazardous waste to off-site waste management facility. In addition, the applicant stated the e-liquid manufacturer does not require a watershed permit and does not have an on-site treatment facility for wastewater prior to discharge. The e-liquid manufacturer is also not required to report to the Environmental Protection Agency's (EPA's) Toxic Release Inventory (TRI), which was verified by the Agency's search of the TRI data base (U.S. Environmental Protection Agency, 2024a). The e-liquid manufacturing location was last inspected by the Florida Department of Environmental Protection (DEP) in October 2019, and the manufacturer stated it had corrected all findings from that inspection. The Agency reviewed EPA's Enforcement and Compliance History Online (ECHO) database and verified that since then, there were no additional reported violations for the e-liquid manufacturer (U.S. Environmental Protection Agency, 2024a).

4.7. Socioeconomics and Environmental Justice

No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the of the device and cartridges, only the e-liquids are manufactured in the United States.

Manufacturing the new products would not disproportionately impact minority and low-income populations, because according to 2010 U.S. Census and 2017 – 2021 American Community Survey data, only 27% and 23% of the population within a three-mile radius of the (b) (4) manufacturing facility are minority and low-income, respectively (U.S. Environmental Protection Agency, 2024a). The Agency does not anticipate manufacturing the new products would disproportionately impact minority and low-income populations because no TRI-reportable chemicals were released from the manufacturing facility, and the TRI-reporting status of the facility is not anticipated to change as a result of manufacturing the new products. In addition, the manufacturing facility is not located in or near Native American lands.

4.8. Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all tobacco products. The Agency anticipates the waste generated due to manufacturing the new products would 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 facility. The applicant stated that liquid waste and solid materials that contain or come in contact with nicotine or nicotine residue are disposed of as hazardous waste. The Agency's search of EPA's ECHO database did not reveal any Resource Conservation and Recovery Act (RCRA) violations at the (b) (4) manufacturing facility (U.S. Environmental Protection Agency, 2024a). Therefore, no significant changes in pattern, amount, or type of waste generated due to manufacturing the new products are anticipated.

4.9. Floodplains, Wetlands, and Coastal Zones

There would be no anticipated facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

4.10. Impacts from the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing tobacco products at the listed facility, as many similar tobacco products would continue to be manufactured.

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

Exposure to secondhand and thirdhand ENDS aerosol may have short- and long-term, adverse effects on human and environmental health. Exposure to nicotine from secondhand aerosol may cause an increase in blood pressure and palpitations (Visser et al., 2019). Heavy metals found in secondhand aerosol from ENDS include chromium, iron, aluminum, lead, copper, nickel, 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 aerosol 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 and glycerol from secondhand aerosol 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 aerosol, such as nicotine-derived nitrosamine ketone (NNK) and N-nitrosonornicotine (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 aerosol 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 aerosol dilution, these aerosols 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 aerosol 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 aerosol 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 aerosol is achieved through ingestion, (Goniewicz & Lee, 2015), inhalation, and touch (Goniewicz & Lee, 2015; Nath & Geraghty, 2020). Nicotine exposure from thirdhand aerosol may place children and infants at higher risk of adverse health effects (Goniewicz & Lee, 2015). Studies show thirdhand aerosol 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 in order to determine the full health implications that secondhand and thirdhand exposure from ENDS aerosol has on public and environmental health.

As of January 2024, 26 states and the District of Columbia had implemented state-level bans on the use of electronic nicotine delivery systems (ENDS) in many public spaces (American Nonsmokers' Rights Foundation, 2024; Public Health Law Center, 2023). Twenty-six states had state-level regulations on the use of ENDS while at least 40 states had city or county level restrictions on ENDS. Such laws are also expected to reduce the levels of non-users' exposure to secondhand and thirdhand aerosol.

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, (2) the ingredients in the new products are used in other currently marketed tobacco products, and (3) the applicant expects the power units to remain intact during use.

5.3. Environmental Justice

Recent studies suggest that ENDS use prevalence is lower among minorities compared to non-Hispanic whites (NHW). (Centers for Disease Control and Prevention, 2019) (Du et al., 2019) (Bello et al., 2019) (Roberts et al., 2022) (McCabe et al., 2020) (Gilbert et al., 2021) Data from the 2014 and 2018 National Health Interview Survey showed an increase in ENDS ever use among adults in the United States for all races, with the highest prevalence rates observed among NHW adults for both years. (Centers for Disease Control and Prevention, 2019) Prevalence rates among minority youth also appear to be lower compared to NHW youth. (Bello et al., 2019) (McCabe et al., 2020) (Gilbert et al., 2021) Data from national surveys show significantly higher use prevalence among NHW adolescents and at schools with higher proportions of NHW students. (McCabe et al., 2020) (Gilbert et al., 2021) Two studies analyzing data from local and regional surveys reported higher prevalence of ENDS ever use among Hispanics compared to NHW. (Springer et al., 2018) (Barrington-Trimis et al., 2019) One nationally representative survey reporting higher odds of ENDS use among Hispanics also reported lower odds of use among non-Hispanic Blacks and Asians compared to NHW. (Yu & Lippert, 2017)

Studies describing ENDS use by socioeconomic status (SES) reveal inconclusive results. While some studies analyzing nationally representative survey data report inverse associations with household income and educational attainment (Stallings-Smith & Ballantyne, 2019; Assari et al., 2020), other studies analyzing data from regional and product-specific surveys report positive association with high SES. (Du et al., 2019; Roberts et al., 2022; Vallone et al., 2020) Among adolescents, lower parental education and school subjective societal status have been reported to be associated with increased odds of past or current use of ENDS. (Bello et al., 2019) Also, ENDS retail landscape poses environmental health risks to youth. (Bostean et al., 2016; Giovenco et al., 2016; Venugopal et al., 2020) A recent national analysis reported that specialty vape shops are more densely distributed, and are in closer proximity to schools, in school districts with higher proportions of Asian and Black or African American populations, raising environmental justice and health equity concerns. However, vape shops were further away from schools in school districts with higher proportions of the population in poverty. (Venugopal et al., 2020)

At this time, these data do not show disproportionately high ENDS use prevalence among minorities and low-income groups. Therefore, the agency does not anticipate potential disproportionate environmental impacts on Environmental Justice populations from using the new products.

5.4. Impacts from the No-Action Alternative

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

6. Potential Environmental Impacts 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 years of marketing 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 ENDS device, cartridges, and batteries are not likely to be emitted to the air in any distinguishable amount because these are closed systems. Although, littering of the e-liquid cartridges 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 remaining in the cartridges that may leach out and be emitted to the air. Additionally, the batteries in the new products are similar to other lithium-ion batteries used in many other devices on the market and the projected market volume of the new products is a miniscule fraction of other electronic currently on the market.

No changes in air quality from disposal of the packaging materials in the new products 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 packaging is a minuscule portion of the MSW based on the projected market volume of the new products.

6.3. Biological Resources

Proper disposal of the used new products and packaging in the MSW stream would not affect biological resources. Improper disposal (littering) of the used new products could lead to terrestrial wildlife having direct exposure to the used products and hazardous substances leaching to aquatic environments and soils. The applicant anticipates unused e-liquid from cartridges dropped and crushed onto the ground to be infrequent and localized. 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; vanillin, ethyl maltol, and ethyl butyrate being the most common flavoring ingredients. (Krüsemann et al., 2021; Dai et al., 2018; DeVito & Krishnan-Sarin, 2018) Leaching of chemical constituents in e-liquids from the disposal or littering of used cartridges is of environmental concern (Baran et al., 2020; Panitz et al., 2015; Chang, 2014). 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 impacts 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 impacts are expected due to disposal of the new products.

6.4. Water Resources and Water Quality

Proper disposal of the used new products and packaging in the MSW stream would not affect water resources. Improper disposal (littering) of the used new products could result in hazardous substances leaching into water systems. However, no net increase in littering would be expected because the new products will continue to compete for the same market share occupied by other currently marketed ENDS products. Additionally, although littering of the e-liquid cartridges 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 in the cartridges. Nicotine is especially concerning because it is considered hazardous waste (U.S. Environmental Protection Agency, 2023a), however, little is expected to remain in littered cartridges and nicotine has a very short half-life on the order of hours to days (Seckar et al., 2008), depending on the media it is in. Therefore, these impacts are not considered significant.

6.5. Solid Waste and Hazardous Materials

Requirements for disposal of e-liquid cartridges containing nicotine vary by state and collecting entity responsible for disposal. EPA has the authority to control hazardous waste from “cradle-to-grave” under RCRA in 40 CFR Parts 260 through 273 (U.S. Environmental Protection Agency, 2024c). Under Subtitle C of RCRA, nicotine (including nicotine salts) is regulated as an acute hazardous waste (U.S. Environmental Protection Agency, 2023a). Cartridges 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. Environmental Protection Agency, 2023a).

Non-residential disposal of e-liquid cartridges 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 (U.S. Environmental Protection Agency, 2023b). Due to nicotine being considered an acute hazardous waste, generators are registered as either a very small quantity generator or large quantity generator based on a threshold of one kilogram generated per chemicals (U.S. Environmental Protection Agency, 2023b). Following collection by state or local authorities, hazardous waste is recycled, treated, stored, or disposed (U.S. Environmental Protection Agency, 2023c).

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. Environmental Protection Agency, 2023c). Additional state and local laws may apply for disposal and these laws vary by state and municipality.

Improper disposal of e-liquids can pose a threat to the environment; therefore, cartridges containing nicotine or nicotine residue should not be rinsed (U.S. Food and Drug Administration, 2024). Additionally, cartridges should be stored in a cool, temperature-controlled environment (U.S. Food and Drug Administration, 2024) and separated from the ENDS device prior to disposal as nicotine is combustible when exposed to heat (National Institute for Occupational Safety and Health, 2011) and lithium-ion batteries have been linked to explosions during MSW transportation (U.S. Food and Drug

Administration, 2024). As of May 2021, the Agency did not find any data reporting the amount 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 (National Oceanic and Atmospheric Administration, 2024). At this time, the Agency does not anticipate any significant impacts due to cartridge disposal.

Lithium-ion batteries in ENDS products are regulated under subtitle C of the RCRA as both ignitable hazardous waste and reactive hazardous waste (U.S. Environmental Protection Agency, 2024d). 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. Environmental Protection Agency, 2024d).

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. Environmental Protection Agency, 2024b). Disposing of lithium-ion batteries in MSW and traditional recycling streams is prohibited due to risk of explosion (U.S. Environmental Protection Agency, 2024d). 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. Environmental Protection Agency, 2024d). 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 (U.S. Environmental Protection Agency, 2023a).

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. Environmental Protection Agency, 2023b). 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 (U.S. Environmental Protection Agency, 2023b).

As of March 2024, 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 (The Truth Initiative, 2021). At this time, the Agency does not anticipate any significant impacts due to ENDS battery disposal.

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 products use in the United States. Therefore, no net increase in littering would be expected.

6.6. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products would be handled in the same manner as the waste generated from disposal of other ENDS products in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

6.7. Impacts from the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of ENDS products and their packaging, as many other similar ENDS 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:

Susana Addo Ntim, Ph.D., Center for Tobacco Products

Education:	Ph.D. in Environmental Science
Experience:	Twelve years in various scientific activities including six years in NEPA practice
Expertise:	NEPA analysis; fate, transport, and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

Reviewer:

Rudaina Alrefai-Kirkpatrick, Center for Tobacco Products

Education:	Ph.D. in Plant Molecular Biology and Virology
Experience:	Forty-three 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.

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CONFIDENTIAL APPENDIX 1: Market Volume Projections for the New Products

STN	Product	Unit	Market Volume (Thousands)		
			Current (2019)	Projections	
				First Year	Fifth Year
PM0000973.PD1	VUSE ALTO POWER UNIT	One Power Unit	(b) (4)		
PM0000973.PD2	VUSE ALTO POD GOLDEN TOBACCO 5%	One or Two Cartridges			
PM0000973.PD3	VUSE ALTO POD RICH TOBACCO 5%	One or Two Cartridges			
PM0000973.PD6	VUSE ALTO POD GOLDEN TOBACCO 2.4%	One or Two Cartridges			
PM0000973.PD7	VUSE ALTO POD RICH TOBACCO 2.4%	One or Two Cartridges			
PM0000973.PD10	VUSE ALTO POD GOLDEN TOBACCO 1.8%	One or Two Cartridges			
PM0000973.PD11	VUSE ALTO POD RICH TOBACCO 1.8%	One or Two Cartridges			
Total					