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

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1. Introduction

1.1 Background

On April 2, 2020 and April 15, 2020, R.J. Reynolds Vapor Company (RJRV) submitted premarket tobacco product applications (PMTAs) for multiple electronic nicotine delivery system (ENDS) components (Vuse Vibe and Ciro power units) and multiple closed e-liquids (Vuse Vibe e-liquid tanks and Vuse Ciro 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.

1.2 Applicant and Manufacturer Information[1,2]

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	Products Manufactured
	(b) (4)		

[1] The applicant used two batteries in the Vuse Vibe power units, PM0000635 represents the battery manufactured by [redacted] and PM0004287 represents the battery manufactured by (b) (4) [redacted]

[2] The applicant used two batteries in the Vuse Ciro power units, PM0000646 represents the manufactured by [redacted] and PM0004293 represents the battery manufactured by (b) (4) [redacted].

	(b) (4)		
	R.J. Reynolds Tobacco Company	950 Reynolds Blvd, Winston-Salem, North Carolina 27105 7855 King Tobaccoville Road, Tobaccoville, North Carolina 27050	E-liquids in the tanks and cartridges

1.3 Product Information

New Product Names and Submission Tracking Numbers (STNs)

New Product Name	STN New Product
Vuse Vibe Power Unit	PM0000635
Vuse Vibe Power Unit	PM0004287
Vuse Vibe Tank Original 3.0%	PM0000636
Vuse Ciro Power Unit	PM0000646
Vuse Ciro Power Unit	PM0004293
Vuse Ciro Cartridge Original 1.5%	PM0000712

Product Identification

Product Category	Electronic Nicotine Delivery System (ENDS) (VAPES)
Product Subcategory	ENDS Component, Closed E-Liquid
Product Number per Retail Unit	PM0000635, PM0004287: Vuse Vibe Power Unit, non-removable Underwriter Laboratories (UL) certified lithium-ion battery, and universal serial bus (USB) cable. PM0000636: Two Vuse Vibe Original 3.0% e-liquid tanks, 3.0% nicotine content, 1.9mL of e-liquid, sold as a ready-to-use vapor pen. PM0000646, PM0004293: Vuse Ciro Power Unit, non-removable UL certified lithium-ion battery, and USB cable. PM0000712: Three Vuse Ciro Original e-liquid cartridges, 1.5% nicotine content, 0.9mL of e-liquid, sold as a ready-to-use vapor pen.

Product Package	PM0000635, PM0000646, PM0004287, PM0004293: power units and USB charger seated in a molded pulp tray. The tray and an instruction insert are enclosed in a paperboard box. Packs of power units are bundled in paperboard cartons and cardboard cases for shipping and distribution. PM0000636 (Vuse Vibe tanks): sold in packs of two tanks, which are individually sealed in a blister forming web with a foil lid. The packs of Vuse Vibe tanks are bundled in paperboard cartons and cardboard cases for shipping and distribution. PM0000712 (Vuse Ciro cartridges): sold in packs of three cartridges, which are individually sealed in a blister forming web with a foil lid. The packs of Vuse Ciro cartridges are 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 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 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

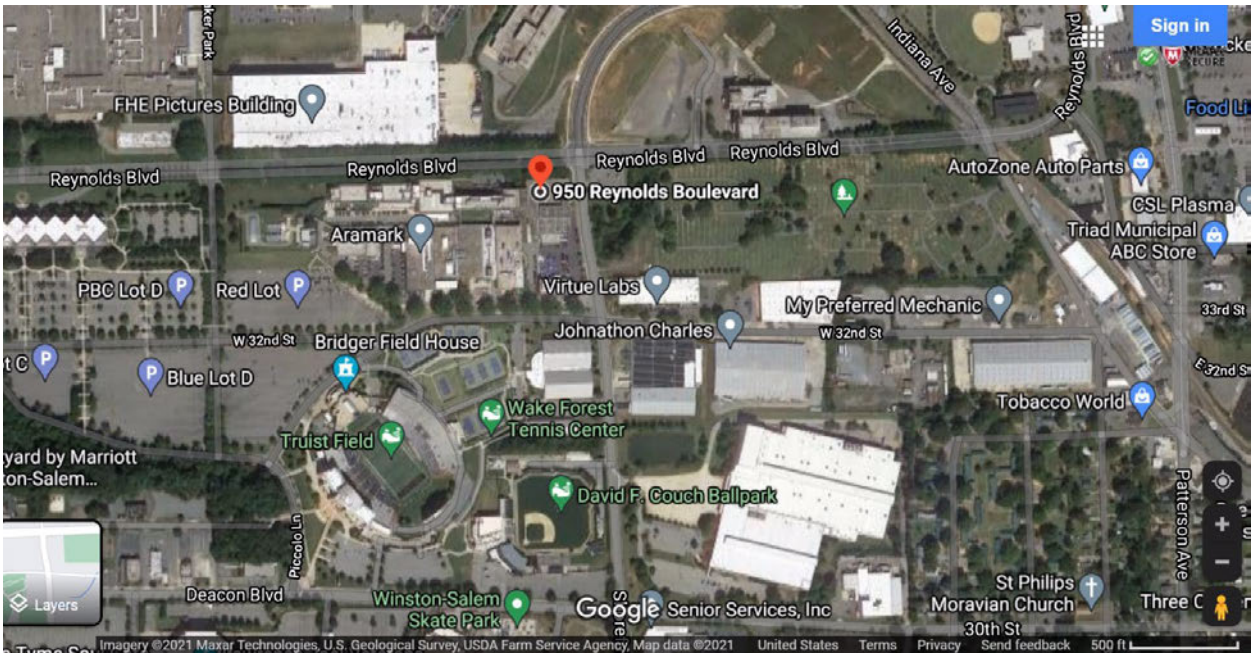
The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new products and found no significant impacts[3] based on the Agency-gathered information and the following applicant-submitted information:

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

4.1 Affected Environment

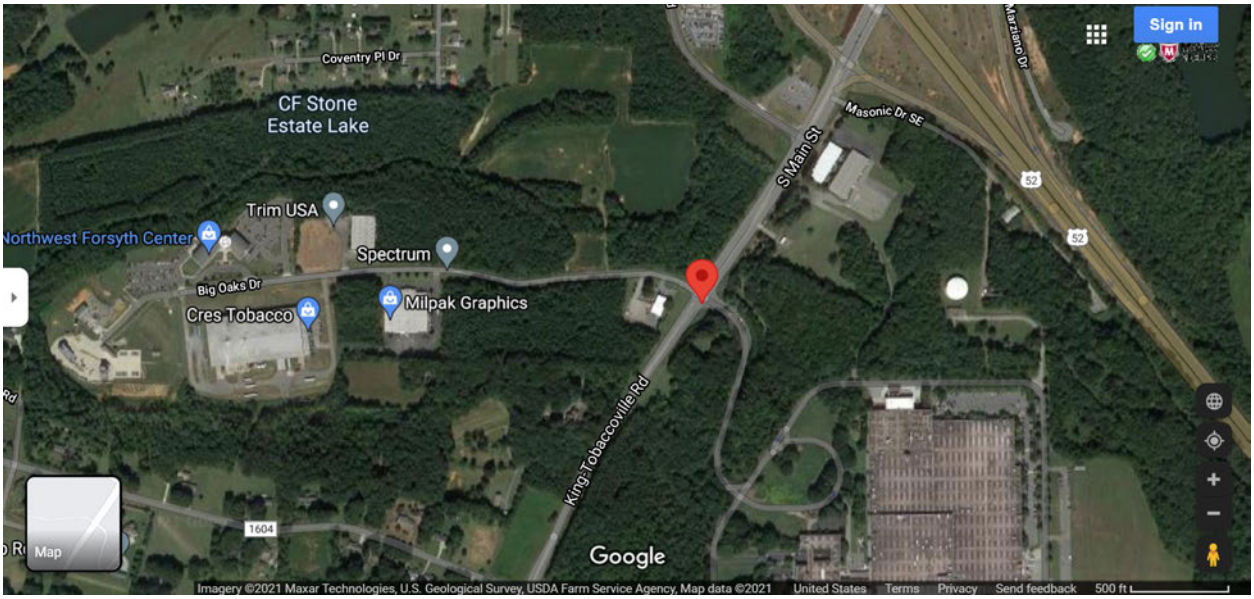
The affected environment includes human and natural environments surrounding the U.S. facilities. The e-liquids in the new products are manufactured in the U.S., which are the subject of this evaluation. All manufacturing addresses are listed in section 1.2 of this document.

Figure 1. Location of the Whitaker Park Manufacturing Facility in Winston-Salem, North Carolina:



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

Figure 2. Location of the Tobaccoville Manufacturing Facility in Tobaccoville, North Carolina:



The manufacturing facilities are located in Forsyth County, North Carolina (NC) in Headwaters Muddy Creek watershed, [4] hydrologic unit code 03040101, which is the largest of the Yadkin River tributaries (United States Geological Survey, 2022). The Whitaker Park manufacturing facility is located in a mixed-use area. This includes residential, commercial (e.g. sports complex, beverage company), and industrial land (e.g. beauty care manufacturer). The Tobaccoville manufacturing facility is surrounded by woodlands; bounded by the city of King, NC to the north; US 52 (a four-lane, divided highway) to the east; and mixed use residential, commercial, and agricultural land to the south and west.

4.2. Air Quality

There were no TRI-reportable chemicals for the Whitaker Park manufacturing facility in 2020. A search in EPA's TRI database showed that in 2020, R.J. Reynolds Tobacco Company manufacturing facility in Tobaccoville, NC released 6,673 pounds of ammonia and 14,999 pounds of nicotine and nicotine salts to air (totaling 21,672 pounds) and transferred 536 pounds of ammonia and 3,520 pounds of nicotine and nicotine salts (totaling 4,056 pounds) offsite (Table 1) (U.S. Environmental Protection Agency, 2022a). The TRI database search did not show that the R.J. Reynolds manufacturing facility released into the environment any other reportable toxicants associated with manufacturing tobacco products. No other hazardous air pollutants were reported. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

[4] A watershed is an area of land where all bodies of water drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. Such bodies of water include the following: surface water from lakes, streams, reservoirs and wetlands; the underlying ground water; and rainfall. See https://water.usgs.gov/edu/watershed.html.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Product at R.J. Reynolds Tobaccoville Manufacturing Facility in 2020

Production-Related Waste Managed or Released		Chemical Mass (pounds)
Recycled		0
Energy Recovery		0
Treated		6,604
Subtotal Waste Managed		*6,604*
On-site Release	Ammonia	6,673
	Nicotine and Nicotine Salts	14,999
Off-site Release	Ammonia	536
	Nicotine and Nicotine Salts	3,520
Subtotal Waste Released		*25,728*
Total Production-Related Waste		**32,332**

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 facilities.

According to the North Carolina Department of Environmental Quality, water quality in Headwaters Muddy Creek watershed where the facility is located is relatively good compared to other sub basins in the greater Yadkin-Pee Dee River basin (North Carolina Department of Environmental Quality, 2010). 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 facilities. Additionally, U.S. Fish and Wildlife Service (FWS) maps show that the facilities are not within or near a critical habitat, or endangered animal and plant species (Data Basin, 2022).

The U.S. FWS identifies two vertebrates, one clam, and one flowering plant as being present in Forsyth County (U.S. Fish and Wildlife Service, 2022) as listed in Table 1:

Table 1. Species Identified by USFWS in Forsyth County, North Carolina

Species	Status
Bald eagle (*Haliaeetus leucocephalus)*	Protected*
Bog turtle (*Glyptemys muhlenbergii)*	Threatened (S/A)**
James spinymussel (*Pleurobema collina*)	Endangered
Schweinitz's sunflower (*Helianthus schweinitzii*)	Endangered
*Protected under the Bald and Golden Eagle Protection Act	
**Threatened due to similarity of appearance	

Because the proposed actions do not require expansion of the manufacturing facilities, and the listed species are not found in the immediate vicinity of the facilities, there would be no impacts to protected species or their potential habitat.

4.6. Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The agency verified the applicant statement, including review of the following permits:

(1) Permit for discharge of stormwater at the manufacturing site in a regulated outfall issued by the State of North Carolina Department of Environmental Quality Division of Energy, Mineral, and Land Resources with number NCG060079 (U.S. Environmental Protection Agency, 2022b).
(2) Permit for management of hazardous waste generated in the manufacturing facility issued by the North Carolina Department of Environmental and Natural Resources with number NCD982076739 (U.S. Environmental Protection Agency, 2022b).

Additionally, the Tobaccoville manufacturing facility submits release data to the EPA under the provisions of the Toxic Release Inventory (TRI) program (permit # 27050RJRYN7855A).

The Agency's search of EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations at the Whitaker Park and Tobaccoville manufacturing facilities (U.S. Environmental Protection Agency, 2022b).

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 devices, tanks, and cartridges, only the e-liquids are manufactured in the United States.

Manufacturing the new products would not disproportionately impact minority populations, because only 11% of the population within a three-mile radius of the Tobaccoville manufacturing facility is minority per 2010 U.S. Census and American Community Survey data (U.S. Environmental Protection Agency, 2022b). In a three-mile radius of the Whitaker Park manufacturing facility, 68% is minority. However, the Agency does not anticipate manufacturing new products would disproportionately impact

minority populations because there were no TRI-reportable chemicals in 2020, 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 facilities are 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 Enforcement and Compliance History Online (ECHO) database did not reveal any Resource Conservation and Recovery Act (RCRA) violations at the Whitaker Park and Tobaccoville manufacturing facilities (U.S. Environmental Protection Agency, 2022b). Therefore, there would be no significant changes in pattern, amount, or type of waste generated due to manufacturing the new products.

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 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, 2014) and clothing

(Nath & Geraghty, 2020). Recent 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, Mello, Sanders-Jackson, & Bigman, 2016) (Visser, Klerx, & Hans, 2019). In addition, studies suggest that for every 70 mL puff, 0.019% of the e-liquid byproduct can deposit (Davis, Sassano, Goddell, & Tarran, 2017) on metal, floors, wood, windows, and walls (Li, Lin, Xia, & Zhu, 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, Klerx, & Hans, 2019). Heavy metals found in secondhand aerosol from ENDS include chromium, iron, aluminum, lead, copper, nickel, cadmium (Li, Lin, Xia, & Zhu, 2020), and silver (Hess, Lachireddy, & Capon, 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, Lin, Xia, & Zhu, 2020). Exposure to propylene glycol (PG) and glycerol from secondhand aerosol may cause respiratory irritation (Visser, Klerx, & Hans, 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, Klerx, & Hans, 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, Lin, Xia, & Zhu, 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, Lin, Xia, & Zhu, 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 (Palmisani, et al., 2019; Davis, Sassano, Goddell, & Tarran, 2017). This may pose a greater risk to vulnerable populations such as pregnant women, children, and adolescents (Palmisani, et al., 2019; Hess, Lachireddy, & Capon, 2016). 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, Lin, Xia, & Zhu, 2020).

Route of exposure to thirdhand aerosol is achieved through ingestion (Goniewicz & Lee, 2014), inhalation, and touch (Goniewicz & Lee, 2014; Nath & Geraghty, 2020). Nicotine exposure from thirdhand aerosol may place children and infants at higher risk of adverse health effects (Goniewicz & Lee, 2014). 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 2021, 22 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, 2021; Public Health Law Center, 2021). Twenty-five 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 tobacco 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) (QuickStats, 2019; Du, Shah, Weber, & Lightstone, 2019; Bello, et al., 2019; Roberts, Keller-Hamilton, Ferketich, & Berman, 2020; McCabe, Boyd, Evans-Polce, McCabe, & Veliz, 2020; Gilbert, Kava, & Afifi, 2020). 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 (QuickStats, 2019). Prevalence rates among minority youth also appear to be lower compared to NHW youth (Bello, et al., 2019; McCabe, Boyd, Evans-Polce, McCabe, & Veliz, 2020; Gilbert, Kava, & Afifi, 2020). Data from national surveys show significantly higher use prevalence among NHW adolescents and at schools with higher proportions of NHW students (McCabe, Boyd, Evans-Polce, McCabe, & Veliz, 2020; Gilbert, Kava, & Afifi, 2020). 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, Mistry, & Bazargan, 2020), other studies analyzing data from regional and product-specific surveys report positive association with high SES (Du, Shah, Weber, & Lightstone, 2019; Roberts, Keller-Hamilton, Ferketich, & Berman, 2020; 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).

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 EJ 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-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 ENDS devices, tanks, cartridges, and batteries are not likely to be emitted to the air in any distinguishable amount because these are closed systems. Additionally, although littering of the e-liquid tanks and 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 tanks and 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 cardboard 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 municipal solid waste 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 tanks and 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 (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, Madej-Knysak, Sobczak, & Adamek, 2019; Panitz, Swamy, & Nehrke, 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 municipal solid waste 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 tanks and 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 tanks and cartridges. Nicotine is especially concerning because it is considered hazardous waste (Public Health Law Center, 2019), however, only trace amounts are expected to remain in littered tanks and 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 tanks and 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 the Resource Conservation and Recovery Act (RCRA) in 40 CFR Parts 260 through 273 (U.S. Environmental Protection Agency, 2020). Under Subtitle C of RCRA, nicotine (including nicotine salts) is regulated as an acute hazardous waste (U.S. Environmental Protection Agency, 2021a). Tanks and 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, 2021a).

Non-residential disposal of e-liquid tanks and 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, 2021b). 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 month (U.S. Environmental Protection Agency, 2021b). Following collection by state or local authorities, hazardous waste is recycled, treated, stored, or disposed (U.S. Environmental Protection Agency, 2021c).

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, 2021d). Additional state and local laws may apply for disposal.

Improper disposal of e-liquids can pose a threat to the environment; therefore, tanks and cartridges containing nicotine or nicotine residue should not be rinsed (U.S. Food and Drug Administration, 2020). Additionally, tanks and cartridges should be stored in a cool, temperature controlled environment (U.S. Food and Drug Administration, 2020) 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, 2020). 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 (U.S. National Oceanic and Atmospheric Administration, 2021). At this time, the Agency does not anticipate any significant impacts due to tank and 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, 2021e). 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, 2021f).

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, 2021d). Disposing of lithium-ion batteries in MSW and traditional recycling streams is prohibited due to risk of explosion (U.S. Environmental Protection Agency, 2021e). 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, 2021e). 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, 2021a).

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, 2021f). 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. Environmental Protection Agency, 2021f).

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). 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 the 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:

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- Education: B.S. in Biological Sciences
- Experience: Four years in various scientific activities
- Expertise: NEPA analysis, forestry, ecology, evolutionary, and sustainability studies

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

8. A Listing of Agencies and Persons Consulted

Not applicable.

9. References

American Nonsmokers' Rights Foundation. (2021). *States and municipalities with laws regulating use of electronic cigarettes.* Retrieved May 25, 2021, from https://no-smoke.org/wp-content/uploads/pdf/ecigslaws.pdf

Assari, S., Mistry, R., & Bazargan, M. (2020). Race, Educational Attainment, and E-Cigarette Use. *Journal of Medical Research and Innovation, 4*(1), 10.

Baran, W., Madej-Knysak, D., Sobczak, A., & Adamek, E. (2019). The influence of waste from electronic cigarettes, conventional cigarettes and heat-not-burn tobacco products on microorganisms. *Journal of Hazardous Materials, 385*, 121591.

Barrington-Trimis, J. L., Bello, M. S., Liu, F., Leventhal, A. M., Kong, G., Mayer, M., . . . McConnell, R. (2019). Ethnic Differences in Patterns of Cigarette and E-Cigarette Use Over Time Among Adolescents. *J Adolesc Health*.

Bello, M., Khoddam, R., Stone, M., Cho, J., Yoon, Y., Lee, J., & Leventhal, A. (2019). Poly-product drug use disparities in adolescents of lower socioeconomic status: Emerging trends in nicotine products, marijuana products, and prescription drugs. *Behaviour Research and Therapy, 115*, 103-110.

Chang, H. (2014). Research gaps related to the environmental impacts of electronic cigarettes. *Tobacco Control, 23*, ii54.

Chen, H., Li, G., Allam, V., Wang, B., Chan, Y., Scarfo, C., . . . Oliver, B. (2020). Evidence from a mouse model on the dangers of thirdhand electronic cigarette exposure during early life. *ERJ Open Research, 6*(2), 00022-2020.

Czogala, J., Goniewicz, M., Fidelus, B., Zielinska-Danch, W., Travers, M., & Sobczak, A. (2014). Secondhand exposure to vapors from electronic cigarettes. *Nicotine & Tobacco Research, 16*(6), 655-662.

Dai, J., Kim, K., Szulejko, J., Jo, S., Kwon, K., & Choi, D. (2018). Quantification of nicotine and major solvents in retail electronic cigarette fluids and vaped aerosols. *Microchemical Journal, 140*, 262-268.

Data Basin. (2022). *Critical Habitat Map*. Retrieved from https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449

Davis, E., Sassano, M., Goddell, H., & Tarran, R. (2017). E-liquid autofluorescence can be used as a marker of vaping deposition and third-hand vape exposure. *Scientific Reports, 7*(1), 7459.

DeVito, E., & Krishnan-Sarin, S. (2018). E-cigarettes: Impact of E-Liquid Components and Device Characteristics on Nicotine Exposure. *Current Neuropharmacology, 16*(4), 438–459.

Du, Y. S., Shah, M., Weber, M., & Lightstone, A. (2019). Prevalence and sociodemographic disparities in ever E-cigarette use among adults in Los Angeles County. *Preventive Medicine Reports, 3*(2).

Gilbert, P. A., Kava, C., & Afifi, R. (2020). High school students rarely use e-cigarettes alone: A socio-demographic analysis of poly-substance use among adolescents in the USA. *Nicotine & Tobacco Research, 23*(3), 505-510.

Goniewicz, M., & Lee, L. (2014). Electronic cigarettes are a source of thirdhand exposure to nicotine. *Oxford Journals: Nicotine and Tobacco Research, 17*(2), 256-258.

Hess, C. A., Olmedo, P., Navas-Acien, A., Goessler, W., Cohen, J. E., & Rule, A. (2017). E-cigarettes as a source of toxic and potentially carcinogenic metals. *Environmental Research, 152*, 221-225.

Hess, I., Lachireddy, K., & Capon, A. (2016). A systematic review of the health risks from passive exposure to electronic cigarette vapour. *Public Health Research & Practice, 26*(2), e2621617.

Krüsemann, E., Havermans, A., Pennings, J., de Graaf, K., Boesveldt, S., & Talhout, R. (2021). Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid's flavour category. *Tobacco Control, 30*, 185-191.

Li, L., Lin, Y., Xia, T., & Zhu, Y. (2020). Effects of electronic cigarettes on indoor air quality and health. *Annual Review of Public Health, 41*, 363-380.

McCabe, S., Boyd, C., Evans-Polce, R., McCabe, V., & Veliz, P. (2020). School-Level Prevalence and Predictors of e-Cigarette Use in 8th, 10th, and 12th Grade U.S. Youth: Results From a National Survey (2015–2016). *Journal of Adolescent Health, 67*(4), 531-541.

Nath, S., & Geraghty, P. (2020). Should we worry about children's exposure to third-hand by-products generated from electronic nicotine delivery systems? *ERJ Open Research, 6*(2).

National Institute for Occupational Safety and Health. (2011). *Nicotine: Systemic Agent*. Retrieved May 19, 2021, from https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750028.html

North Carolina Department of Environmental Quality. (2010). *Yadkin River Headwaters*. Retrieved from https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Yadkin/Yadkin%20Plans/2010%20Plan/2_03040101%20Yadkin%20River%20Headwaters-2010.pdf

Palmisani, J., Di Gilio, A., Palmieri, L., Abenavoli, C., Famele, M., Draisci, R., & de Gennaro, G. (2019). Evaluation of second-hand exposure to electronic cigarette vaping under a real scenario: measurements of ultrafine particle number concentration and size distribution and comparison with traditional tobacco smoke. *Toxics, 25*(7), 59.

Panitz, D., Swamy, H., & Nehrke, K. (2015). A C. elegans model of electronic cigarette use: Physiological effects of e-liquids in nematodes. *BMC Pharmacology Toxicology, 16*, 32.

Public Health Law Center. (2019). *Disposing of E-Cigarette Waste: FAQ for Schools and Others.* Retrieved March 25, 2021, from https://www.publichealthlawcenter.org/sites/default/files/resources/Disposing-of-E-Cigarette-Waste.pdf

Public Health Law Center. (2021). *U.S. E-cigarette regulation: A 50-state review*. Retrieved May 25, 2021, from https://www.publichealthlawcenter.org/resources/us-e-cigarette-regulations-50-state-review

QuickStats. (2019). Age-Adjusted Percentage of Adults Who Had Ever Used an E-cigarette, by Race and Ethnicity — National Health Interview Survey, United States, 2014 and 2018. *MMWR Morbidity and Mortality Weekly Report, 68*(1102).

Roberts, M., Keller-Hamilton, B., Ferketich, A., & Berman, L. (2020). Juul and the upsurge of e-cigarette use among college undergraduates. *Journal of American College Health*, 1-4.

Seckar, J., Stavanja, M., Harp, P., Yi, Y., Garner, C., & Doi, J. (2008). Environmental fate and effects of nicotine released during cigarette production. *Environmental Toxicology and Chemistry, 27*, 1505-1514.

Springer, A. E., Davis, C., Van Dusen, D., Grayless, M., Case, K. R., Craft, M., & Kelder, S. H. (2018). School socioeconomic disparities in e-cigarette susceptibility and use among central Texas middle school students. *Preventive Medicine Reports*, 105-108.

Stallings-Smith, S., & Ballantyne, T. (2019). Ever Use of E-Cigarettes Among Adults in the United States: A Cross-Sectional Study of Sociodemographic Factors. *Inquiry, 56*.

Tan, A., Mello, S., Sanders-Jackson, A., & Bigman, C. (2016). Knowledge about chemicals in e-cigarette secondhand vapor and perceived harms of exposure among a national sample of U.S. adults. *Risk Analysis: An International Journal, 37*(6), 1170-1180.

Truth Initiative. (2021). *A Toxic, Plastic Problem: E-cigarette Waste and the Environment*. Retrieved April 12, 2021, from https://truthinitiative.org/research-resources/harmful-effects-tobacco/toxic-plastic-problem-e-cigarette-waste-and-environment

U.S. Environmental Protection Agency. (2020). *Resource Conservation and Recovery Act (RCRA) Overview*. Retrieved March 19, 2021, from https://www.epa.gov/rcra/resource-conservation-and-recovery-act-rcra-overview

U.S. Environmental Protection Agency. (2021a). *Where are the Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine in Effect?* Retrieved April 15, 2021, from https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075

U.S. Environmental Protection Agency. (2021b). *Categories of Hazardous Waste Generators*. Retrieved from https://www.epa.gov/hwgenerators/categories-hazardous-waste-generators

U.S. Environmental Protection Agency. (2021c). *Learn the Basics of Hazardous Waste*. Retrieved May 19, 2021, from https://www.epa.gov/hw/learn-basics-hazardous-waste

U.S. Environmental Protection Agency. (2021d). *Household Hazardous Waste*. Retrieved April 14, 2021, from https://www.epa.gov/hw/household-hazardous-waste-hhw

U.S. Environmental Protection Agency. (2021e). *Used Lithium-ion Batteries*. Retrieved April 6, 2021, from https://www.epa.gov/recycle/used-lithium-ion-batteries#:~:text=Additionally%2C%20if%20the%20battery%20or,equipment%2C%20creating%20a%20fire%20hazard

U.S. Environmental Protection Agency. (2021f). *Overview of the Universal Waste Program*. Retrieved March 25, 2021, from https://www.epa.gov/hw/universal-waste

U.S. Environmental Protection Agency. (2022a). *TRI Facility Report*. Retrieved from https://enviro.epa.gov/facts/tri/ef-facilities/#/Facility/27050RJRYN7855A

U.S. Environmental Protection Agency. (2022b). *Enforcement and Compliance History Online*. Retrieved from https://echo.epa.gov/

U.S. Fish and Wildlife Service. (2022). *Listed species believed to or known to occur in North Carolina*. Retrieved from https://ecos.fws.gov/ecp/report/species-listings-by-state?stateAbbrev=NC&stateName=North%20Carolina&statusCategory=Listed

U.S. Food and Drug Administration. (2020). *Tips for Safe Disposal of E-Cigarettes and E-Liquid Waste*. Retrieved March 19, 2021, from https://www.fda.gov/tobacco-products/products-ingredients-components/tips-safe-disposal-e-cigarettes-and-e-liquid-waste

U.S. National Oceanic and Atmospheric Administration. (2021). *Marine Debris Tracker App*. Retrieved May 19, 2021, from https://marinedebris.noaa.gov/partnerships/marine-debris-tracker

United States Geological Survey. (2022). *National Water Information System: Mapper*. Retrieved April 14, 2022, from https://maps.waterdata.usgs.gov/mapper/index.html

Vallone, D. M., Cuccia, A., Briggs, J., Xiao, H., Schillo, B., & Hair, E. (2020). Electronic Cigarette and JUUL Use Among Adolescents and Young Adults. *JAMA Pediatrics, 174*(3), 277-286.

Visser, W., Klerx, W., & Hans, W. (2019). The Health Risks of Electronic Cigarette Use to Bystanders. *International Journal of Environmental Research and Public Health, 16*(9), 1525.

Yu, E., & Lippert, A. M. (2017). Race/ethnicity modifies the association between school prevalence of e-cigarette use and student-level use: Results from the 2014 US National Youth Tobacco Survey. *Health Place*, 114-120.

Zervas, E., Matsouki, N., Kyriakopoulos, G., Poulopoulos, S., Ioannides, T., & Katsaounou, P. (2020). Transfer of metals in the liquids of electronic cigarettes. *Inhalation Toxicology, 32*(6), 240-248.

CONFIDENTIAL APPENDIX 1: Market Volume Projections for the New Products

STN	Product	Unit	Market Volume Projections (Year)	
			First-Year (2019)	Fifth-Year (2023)
PM0000635, PM0004287	Vuse Vibe Power Unit[5]	One Device	(b) (4)	
PM0000636	Vuse Vibe Tank Original 3.0%	Two tanks		
PM0000646, PM0004293	Vuse Ciro Power Unit[6]	One Device		
PM0000712	Vuse Ciro Cartridge Original 1.5%	Three cartridges		
	Total			

[5] Includes market volume for PM0●●●635 and PM00●4287.

[6] Includes market volume for PM0●●●646 and PM00●4293.