

**Programmatic Environmental Assessment for
Marketing Orders for
New Nicotine Pouch Products
Marketed by**

Helix Innovations LLC

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

December 16, 2025

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1. Introduction

1.1 Background

On December 23, 2024, and September 25, 2024, Helix Innovations LLC submitted premarket tobacco product applications (PMTAs) for six nicotine pouch (NP) products. In the PMTAs, Helix Innovations LLC requests the U.S. Food & Drug Administration (FDA) 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. The Agency did not identify any significant environmental impacts from the proposed actions.

1.2 Applicant and Manufacturers' Information

Applicant Name:	Helix Innovations LLC
Applicant Address:	601 East Jackson Street, Richmond, VA, 23219
Manufacturer Name:	U.S. Smokeless Tobacco Company LLC (USSTC)
Product Manufacturing Locations:	U.S. Smokeless Tobacco Company LLC 4201 Commerce Road, Richmond, VA 23234

1.3 Product Information

New Product Names and Submission Tracking Numbers (STNs)¹

New Product Name	STN New Product
on! PLUS nicotine pouches 6 mg Mint	PM0009121.PD10
on! PLUS nicotine pouches 9 mg Mint	PM0009121.PD11
on! PLUS nicotine pouches 6 mg Tobacco	PM0009121.PD13
on! PLUS nicotine pouches 9 mg Tobacco	PM0009121.PD14
on! PLUS nicotine pouches 6 mg Wintergreen	PM0009121.PD16
on! PLUS nicotine pouches 9 mg Wintergreen	PM0009121.PD17

¹ STN means submission tracking number including product static identification number (PD). PM means premarket tobacco product application.

Product Identification

Product Category	All STNs	Other
Product Subcategory	All STNs	Other
Product Number per Retail Unit	PM0009121.PD10, PM0009121.PD11, PM0009121.PD13, PM0009121.PD14, PM0009121.PD16, PM0009121.PD17	14 individual pouches per can
Product Package	PM0009121.PD10, PM0009121.PD11, PM0009121.PD13, PM0009121.PD14, PM0009121.PD16, PM0009121.PD17	Individual pouches are packaged in polypropylene cans made of polypropylene with BOPP (Biaxially-Oriented Polypropylene) labels, shrink wrapped (low-density polyethylene [LDPE] film) in groups of five in a log roll, and each shipping case (cardboard box) will have 20 log rolls (100 cans).

2. The Need and Purpose for the Proposed Actions

Purpose: The applicant wishes to introduce 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 new 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 will not be marketed in the United States and, for the purposes of the analysis in this programmatic environmental assessment, it is assumed that there will be no changes to the current NP product market and no changes to the current or future use of NP products.

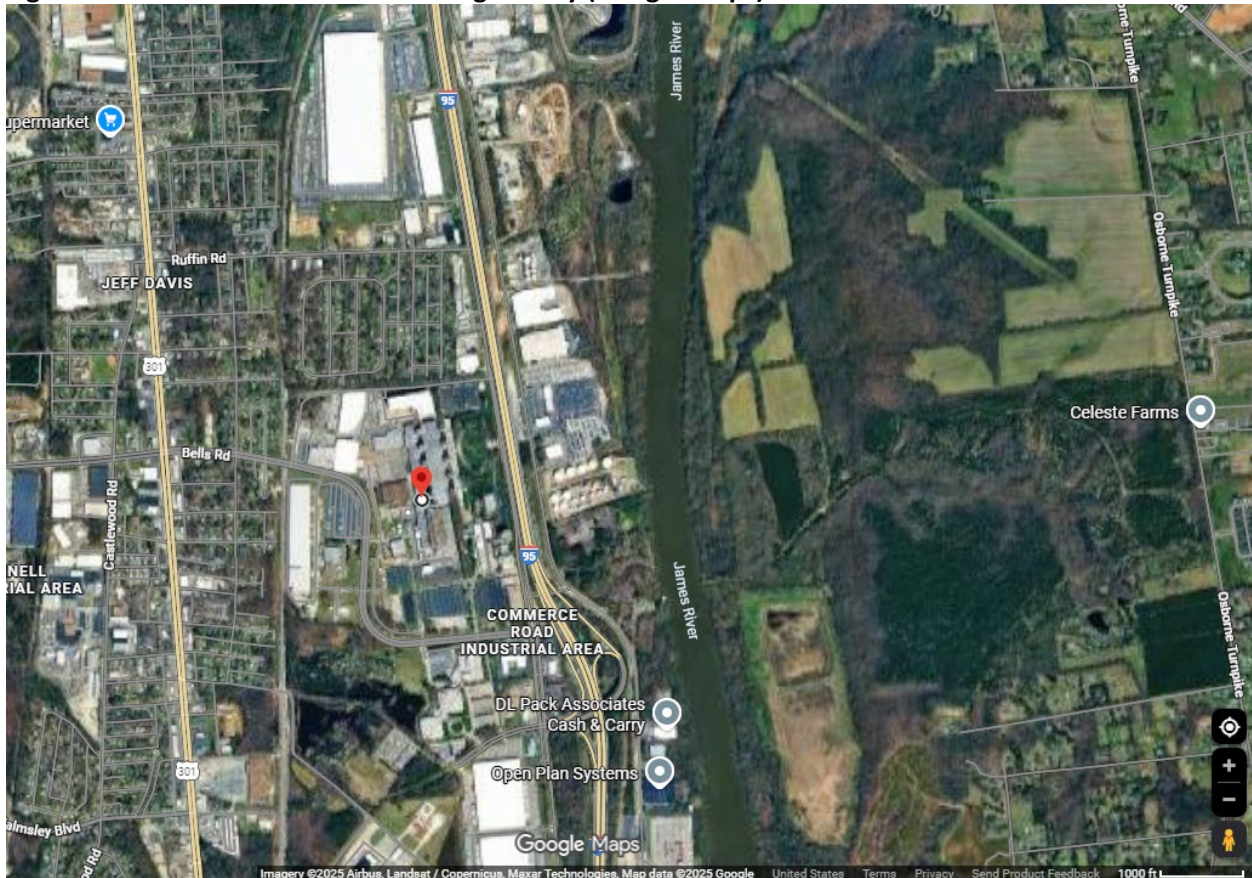
4. Potential Environmental Effects of the Proposed Actions and Alternatives – Manufacturing the New Products

The Agency considered potential environmental effects of manufacturing the new products based on information gathered by the Agency and submitted by the applicant, including projected market volumes for the new products (Confidential Appendix 1), the Agency found no significant environmental impacts from the proposed action.

4.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facilities. The new products are manufactured within the Philip Morris USA (PM USA) manufacturing complex at U.S. Smokeless Tobacco Company LLC (USSTC) at 4201 Commerce Road, Richmond, VA 23234 (Figure 1).

Figure 1. Location of the Manufacturing Facility (Google Maps)



The PM USA manufacturing complex encompasses both USSTC Richmond, VA manufacturing locations and is surrounded by a residential development across a road to the north and west; a two-lane divided road and an interstate freeway (I-95) to the east; two hotels, a fast food restaurant, and a gas station at the southeast corner; undeveloped forested land and a petroleum product pumping station and delivery terminal to the south; and a railroad to the west with a spur into the manufacturing facility (Google Maps).

The PM USA manufacturing complex is located in the James River watershed, which occupies the central portion of Virginia and covers 24% of total land area of the state of Virginia (USGS, 2025; Virginia DCR, 2025). Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area (Virginia DCR, 2025).

4.2 Air Quality

The Agency does not anticipate that manufacturing the new products will cause a significant release of new chemicals or new type of emissions into the environment. The applicant stated that manufacturing the new products does not require any additional environmental controls for air emissions and, therefore, does not require a revised or new air permit.

4.3 Water Resources

The Agency does not anticipate that manufacturing the new products will cause a significant discharge of new chemicals into water. The applicant stated that manufacturing the new products does not

require any additional environmental controls for wastewater discharges and, therefore, does not require a revised or new wastewater discharge permit.

4.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products will lead to changes in land use or zoning. The new products are manufactured within the existing PM USA Richmond, VA manufacturing complex, which currently manufactures other tobacco products. There will be no expected facility expansion, no zone changes 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 will 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. An Agency search of the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species list shows three threatened species and one endangered species listed in the city of Richmond and the bordering counties (Henrico and Chesterfield Counties) (U.S. Fish & Wildlife Service, 2025a, 2025b). The applicant reviewed the U.S. FWS's maps and stated that none of these species are found near the manufacturing facility and the facility is not in a critical habitat area, which was verified by the Agency.

4.6 Regulatory Compliance

The Agency's search of the EPA's Enforcement and Compliance History Online database did not reveal any violations of the environmental laws and regulations for USSTC LLC Richmond, VA manufacturing locations (U.S. Environmental Protection Agency, 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 anticipate that manufacturing the new products will lead to the presence of new chemicals in the manufacturing waste stream. The applicant stated that the manufacturing process utilizes low-volatile raw materials and is expected to result in an insignificant amount of additional compounds to the environment. Thus, manufacturing the new products will not require new or expanded disposal, treatment and recycle capacity or resources. The applicant also stated that the USSTC facility is considered a Large Quantity Generator of Hazardous Waste and is registered for and capable of managing hazardous waste generation.

4.8 Floodplains, Wetlands, and Coastal Zones

The applicant stated that the new products are manufactured within the existing PM USA Richmond, VA complex. The applicant stated that no facility expansions would be expected due to manufacturing the new products. Therefore, no effects to floodplains, wetlands, or coastal zones are anticipated.

4.9 Effects from the No-Action Alternative

The environmental effects of the no-action alternative will not change the existing conditions of manufacturing NP products, as many similar tobacco products will continue to be manufactured at the same facility.

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

The Agency considered potential effects 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. Furthermore, the new products are smokeless and therefore will not affect air quality in the vicinity of use. Effects on non-users will be minimal given the lack of secondhand or thirdhand exposure to airborne emissions during use. However, there is a potential risk of inadvertent exposure to nicotine from contact with NPs. This risk can be mitigated with childproof container closure systems and proper use of new NPs.

5.1 Affected Environment

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

5.2 Effects from the No-Action Alternative

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

6. Potential Environmental Effects of the Proposed Action – Disposal of the New Products

The Agency evaluated potential effects 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 their packaging material would lead to the release of new or increased chemicals into the air. Currently, there are no studies available that describe the air quality effects resulting from the disposal of used NP products. The applicant provided

information on the material composition of the pouches, which includes synthetic polymers and plastic materials. Some of these materials are known to be non-biodegradable or only slowly biodegradable.

However, no changes in air quality from disposal of the packaging materials of new products are expected because (1) the paper, cardboard, and plastic components of the packages are likely to be recycled, at least partially, (2) these 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

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of their habitat, as prohibited under the United States Endangered Species Act. Proper disposal of the used new products and packaging to MSW would not affect biological resources. If improper disposal as litter occurs, the products are not expected to result in significant concentrations of harmful constituents (e.g., nicotine) being emitted or released to the environment. Further, unlike combusted tobacco products, smoldering of used products is not a concern with disposal of the new products. Therefore, the risk of fires from smoldering tobacco products and associated effects on natural environments from littering are not a concern with disposal of the new products. The Agency does not anticipate that disposal of the new products or their packaging materials, would lead to significant impacts on biological resources.

6.4 Water Resources

Proper disposal of used products and packaging in the MSW stream will not affect water resources. However, improper disposal (littering) of the used new product could result in hazardous substances leaching into water systems. However, introducing the new products into the U.S. market is not expected to increase the nationwide use and disposal of tobacco products based on the Agency's assessment and projected market volumes reported by the applicant.

6.5 Solid Waste and Hazardous Materials

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. However, introducing the new products into the U.S. market is not expected to increase the nationwide use and disposal of tobacco products based on the Agency's assessment. Therefore, no net increase in littering is expected.

Users of the new products, which are intended as spit-free products, are not anticipated to expectorate the new product into the environment. There is a potential risk of inadvertent exposure to nicotine from contact with the new products, as indicated by case reports of young children swallowing used pouches (Olivas, 2025). This risk can be mitigated by proper disposal of the new products.

Improper disposal of the new products (littering) could also pose a risk to aquatic organisms and ecosystems as a result of hazardous substances leaching into water systems. The applicant estimated EICs for chemicals within the new products, including nicotine. The applicant stated the EIC for nicotine was lower than the 1 µg/L de minimis threshold level of concern established by FDA for aquatic ecotoxicity studies with human and veterinary drugs. Three chemicals (cellulose, a sugar and a plastic) exceeded the 1 µg/L de minimis threshold level of concern. Cellulose is insoluble and is expected to

remain in the pouch. Further, biodegradation of cellulose and sugar is expected to be rapid within the environment. The plastic resin comprising the pouch material may potentially persist in the environment. Similar to other plastics and polyester fibers, it would be expected to undergo degradation and leaching through weathering and sunlight. Based on a review of available ecological toxicity data on the new products' substances and the small quantity of product that will be released into the environment as litter, the Agency concludes that incidental exposure to used pouches is unlikely to have significant adverse effects on the environment.

The Agency does not anticipate significant impacts from disposal of packaging materials. The agency estimates that packaging disposal waste represents a minuscule portion (less than 1%) of the overall MSW, consistent with FDA's experience evaluating tobacco product packaging waste. This percentage remains minimal even without accounting for recycling, although some portion will become litter U.S. Environmental Protection Agency. (2018).

6.6 Effects of the No-Action Alternative

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

7. List of Preparers

Preparer:

John Teem, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biology

Experience: 35 years biological research, state agency regulatory compliance, GMO biosafety

Expertise: Environmental risk assessment, regulatory compliance

Reviewer:

Ronald L. Edwards Jr., MS, Center for Tobacco Products

Education: MS in Biology

Experience: Twenty-eight years in environmental regulation and six years in laboratory toxicology

Expertise: NEPA analysis, heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

8. A Listing of Agencies and Persons Consulted

Not applicable.

9. References

Google Maps. Map of the Philip Morris USA (PM USA) manufacturing center at U.S. Smokeless Tobacco Company LLC (USSTC) at 4201 Commerce Road, Richmond, VA 23234 Accessed November 25, 2025.

<https://www.google.com/maps/place/2211+Bells+Rd,+Richmond,+VA+23234/@37.4708801,-77.4360625,566m/data=!3m2!1e3!4b1!4m6!3m5!1s0x89b10e28dd7ec47b:0x6f43de03d857308>

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Confidential Appendix 1: First- and Fifth-Year Market Volume Projections for the New Products

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