

**Programmatic Environmental Assessment for Marketing  
Orders for New Smokeless Tobacco Products  
Manufactured by  
U.S. Smokeless Tobacco Company LLC**

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

**April 20, 2020**

**Table of Contents**

- 1. Applicant and Manufacturer Information .....3**
- 2. Product Information .....3**
- 3. The Need for the Proposed Actions .....3**
- 4. Alternative to the Proposed Actions .....4**
- 5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the New Products .....4**
  - 5.1 Affected Environment..... 4
  - 5.2 Analysis of Potential Environmental Impacts ..... 5
  - 5.3 Cumulative Impacts ..... 6
  - 5.4 Impacts from No-Action Alternative..... 8
- 6. Potential Environmental Impacts of the Proposed Actions and Alternatives - Use of the New Products .....8**
  - 6.1 Affected Environment..... 8
  - 6.2 Analysis of Potential Environmental Impacts ..... 8
  - 6.3 Cumulative Impacts ..... 8
  - 6.4 Impacts from No-Action Alternative..... 8
- 7. Potential Environmental Impacts of the Proposed Actions and Alternative - Disposal of the New Products .....8**
  - 7.1 Affected Environment..... 9
  - 7.2 Analysis of Potential Environmental Impacts ..... 9
  - 7.3 Cumulative Impacts ..... 10
  - 7.4 Impacts from No-Action Alternative..... 10
- 8. List of Preparers.....10**
- 9. List of Agencies and Persons Consulted.....10**
- Confidential Appendix 1: Comparison of the New Products to the Single Predicate Product .....11**
- Confidential Appendix 2: First- and Fifth-Year Market Volume Projections for New Products .....12**

**1. Applicant and Manufacturer Information**

<b>Applicant Name</b>	Altria Client Services LLC
<b>Applicant Address</b>	601 East Jackson Street Richmond, VA, 23219
<b>Manufacturer Name</b>	U.S. Smokeless Tobacco Company LLC
<b>Product Manufacturing Address</b>	800 Harrison Street Nashville, TN 37203  2303 Bells Road Richmond, VA 23234

**2. Product Information**

<b>New Product</b>	<b>STN</b>	<b>Predicate Product</b>
Husky Long Cut Wintergreen	SE0013345	Husky Long Cut Wintergreen
Husky Long Cut Wintergreen	SE0013346	

<b>Product Category</b>	Smokeless
<b>Product Subcategory</b>	Loose Moist Snuff
<b>Product Packages</b>	(SE0013345) 204.12 g of loose moist snuff per tub/can, polypropylene tub/can capped with a polypropylene lid, paper side and bottom label, polyethylene shrink film per 6 tub/can log roll per corrugated board shipping case.  (SE0013346) 408.24 g of loose moist snuff per tub/can, polypropylene tub/can capped with a polypropylene lid, paper side and bottom label, polyethylene shrink film per 6 tub/can log roll per corrugated board shipping case.

**3. The Need for the Proposed Actions**

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States.

The Agency shall issue marketing orders if, after considering the substantial equivalence reports and amendments submitted by the applicant, the new products are found substantially equivalent to the single predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new products differ from the predicate product in a change in quantity (Confidential Appendix 1).

The applicant provided first- and fifth-year market volume projections for the new products (Confidential Appendix 2).

#### 4. Alternative to the Proposed Actions

The no-action alternative is the Agency does not issue marketing orders for the new tobacco products in the United States.

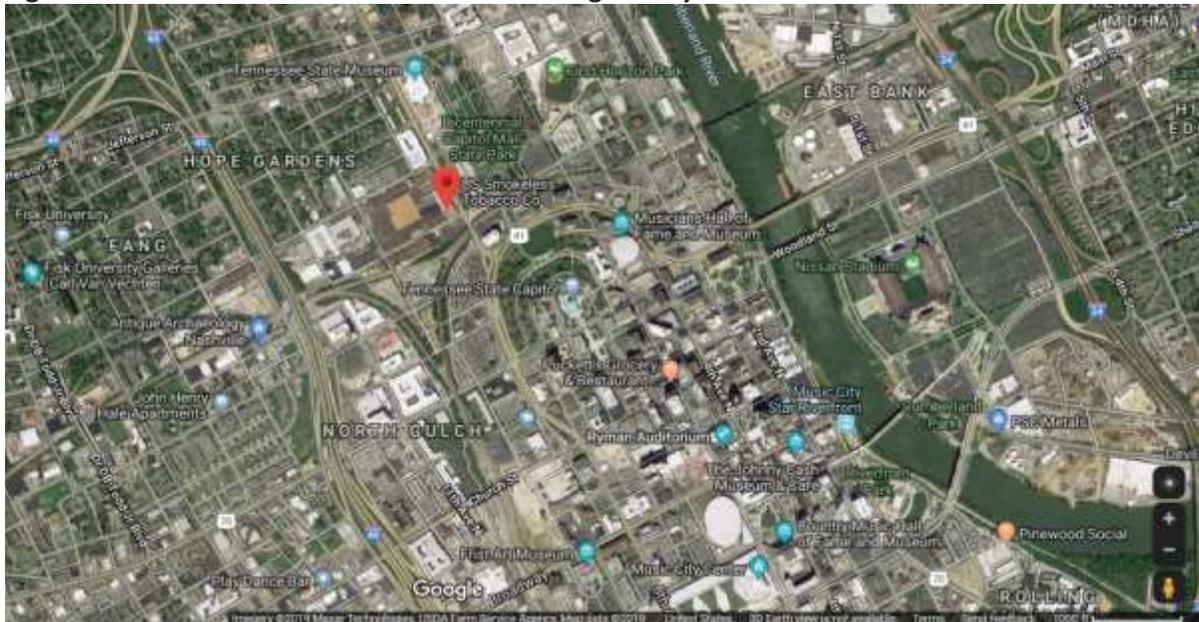
#### 5. Potential Environmental Impacts of the Proposed Actions and Alternatives - Manufacturing the New Products

The Agency evaluated potential environmental impacts that may be caused by manufacturing the new products and found no significant impacts.

##### 5.1 Affected Environment

The new products would be manufactured at U.S. Smokeless Tobacco Company LLC, 800 Harrison Street, Nashville, TN 37203 (Figure 1) and 2303 Bells Road, Richmond, VA 23234 (Figure 2). The Nashville, TN facility is within an industrial park in downtown Nashville, with a railroad spur along its southern perimeter, offices and parking lots to the north, a six-lane highway to the west, a residential neighborhood to the north, and Cumberland River to the east.<sup>1</sup>

Figure 1. Location of the Nashville Manufacturing Facility

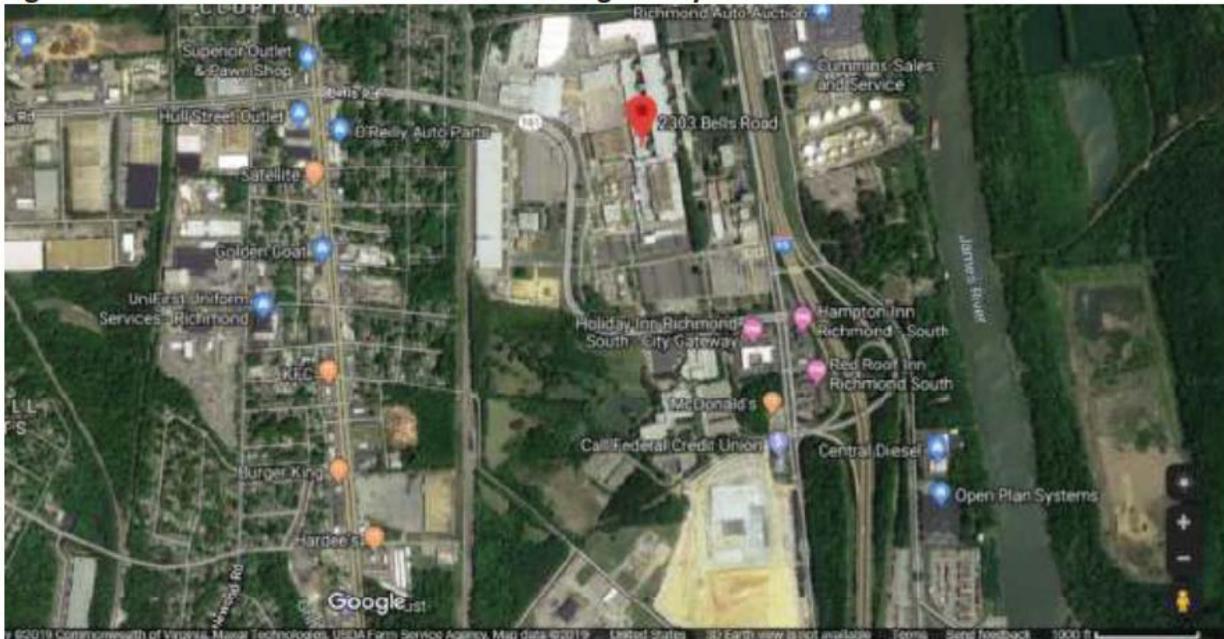


The Richmond, VA manufacturing facility is surrounded by a residential development across a road to the north; a two-lane divided road and an interstate freeway (I-95) to the east; two hotels, a fast food restaurant, and a gas station at the southeast corner; undeveloped forested land and a petroleum

<sup>1</sup> Google. 2019. Map of 800 Harrison Street, Nashville, TN 37203. Retrieved from Google Maps: [www.google.com/maps](http://www.google.com/maps). December 3, 2019.

product pumping station and delivery terminal to the south; and a railroad to the west with a spur into the manufacturing facility.<sup>2</sup>

**Figure 2. Location of the Richmond Manufacturing Facility**



## 5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the new products based on information gathered by the Agency and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products is not expected to result in changes in the types of air emissions from the manufacturing facilities and would not require new or revised permits.
Water resources	The applicant stated that manufacturing the new products is not expected to result in changes in the types of water discharges from the manufacturing facilities and would not require new or revised permits.
Land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed action.

<sup>2</sup> Google. 2019. Map of 2303 Bells Road, Richmond, VA 23234. Retrieved from Google Maps: [www.google.com/maps](http://www.google.com/maps). December 3, 2019.

Environmental Resource	Analysis of Potential Impacts
Biological resources	The applicant stated that there would be no facility expansion due to manufacturing the new products and that manufacturing the new products would not result in changes in types of air emissions or water discharges. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new products.
Soils	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no effects on soils would occur as a direct impact from manufacturing the new products.
Socioeconomic conditions	The applicant stated that there would be no facility expansion or changes in types of air emissions or water discharges at the facilities. Therefore, no socioeconomic effects (beneficial or adverse) would occur as a direct impact from manufacturing the new products.
Solid waste and hazardous materials	The applicant stated that manufacturing the new products is not expected to result in emissions of new or additional compounds from the manufacturing facilities. Additionally, the applicant stated that no material changes in solid waste generation are expected to result from manufacturing the new products. Therefore, the Agency does not anticipate that manufacturing the new products would lead to the presence of new chemicals in the manufacturing waste stream.
Floodplains, wetlands, and coastal zones	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact of manufacturing the new products.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations that live near the manufacturing facilities.
Regulatory compliance	The applicant also stated that their manufacturing facilities are in compliance with all relevant federal, state, and local environmental regulations. The Agency's search for the manufacturing facilities in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of environmental laws and regulations.

### 5.3 Cumulative Impacts

The Agency does not anticipate the proposed actions would incrementally increase or change the chemicals released to the environment from the facilities' tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2018, the U.S. Smokeless Tobacco's manufacturing facility in Nashville, Tennessee no ammonia and 231 pounds of nicotine and nicotine salts to air (Table 1).<sup>3</sup> No other hazardous air pollutants were reported. The Richmond facility was not found in the ECHO database under the address provided, however, the Philip Morris USA facility

---

<sup>3</sup> U.S. Environmental Protection Agency (EPA). TRI Available at: [https://www3.epa.gov/enviro/facts/tri/form\\_ra\\_download.html](https://www3.epa.gov/enviro/facts/tri/form_ra_download.html). Searched March 27, 2019.

occupies the same space but has a different address, 3601 Commerce Road, Richmond, VA 23234. Philip Morris and USSTC are corporate entities under the parent company, Altria. A search in the EPA's TRI database showed that in 2018, the Philip Morris USA manufacturing facility in Richmond, Virginia released no ammonia and 10,313 pounds of nicotine and nicotine salts to air, but released no other hazardous air pollutants at reportable levels (Table 2).<sup>4</sup> Nicotine and nicotine salts have known adverse developmental effects.<sup>5</sup> The TRI database search did not show that the U.S. Smokeless Tobacco manufacturing facilities disposed of, treated, or released into the environment any other toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facilities released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

**Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at Nashville U.S. Smokeless Tobacco Facility in 2018**

Production-Related Waste Managed or Released		Chemical Mass (Pounds)	
Recycled		18,345	
Energy Recovery		0	
Treated		671	
<i>Subtotal Waste Managed</i>		<i>19,016</i>	
On-Site Release	Air	Ammonia	0
		Nicotine and Nicotine Salts	231
Off-Site Disposal/Release		32,382	
<i>Subtotal Waste Released</i>		<i>32,613</i>	
<b>Total Production-Related Waste</b>		<b>51,398</b>	

**Table 2 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Richmond Philip Morris USA Facility in 2018**

Production-Related Waste Managed or Released		Chemical Mass (Pounds)	
Recycled		122,530	
Energy Recovery		0	
Treated		94,266	
<i>Subtotal Waste Managed</i>		<i>216,796</i>	
On-site Release	Air	Ammonia	0
		Nicotine and Nicotine Salts	10,313
Off-site Release		35,528	
<i>Subtotal Waste Released</i>		<i>45,841</i>	
<b>Total Production-Related Waste</b>		<b>262,637</b>	

<sup>4</sup> U.S. Environmental Protection Agency (EPA). TRI Data Form R & A Download. Available at: [https://www3.epa.gov/enviro/facts/tri/form\\_ra\\_download.html](https://www3.epa.gov/enviro/facts/tri/form_ra_download.html). Searched on March 27, 2019.

<sup>5</sup> Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

#### 5.4 Impacts from No-Action Alternative

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

#### 6. Potential Environmental Impacts of the Proposed Actions and Alternatives - Use of the New Products

The Agency evaluated potential environmental impacts that may be caused by use of the new products and found no significant impacts.

##### 6.1 Affected Environment

The affected environment is the entire United States because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

##### 6.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from use of the new products based on Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new products are likely to be used by the same consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no change in impacts to environmental justice populations is expected.

##### 6.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with the new products' use under the proposed actions, would lead to cumulative impacts.

##### 6.4 Impacts from No-Action Alternative

The no-action alternative would not change the existing use of other smokeless tobacco products in the United States, as many similar smokeless tobacco products would continue to be marketed and therefore used.

#### 7. Potential Environmental Impacts of the Proposed Actions and Alternative - Disposal of the New Products

The Agency evaluated potential environmental impacts that may be caused by disposal of the new products and found no significant impacts.

## 7.1 Affected Environment

The affected environment is the entire United States because the marketing orders would allow the new tobacco products to be sold to consumers nationwide who would dispose of the used new products and packaging as municipal solid waste, recycled material, or litter.

## 7.2 Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from disposal based on Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of the used new products and packaging in the municipal solid waste 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 soil. However, no net increase in littering is expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations from disposal of the used new products and packaging waste.
Water resources	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 to water systems. However, no net increase in littering is expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Solid Waste	The distribution of waste generated due to disposal of the new products and packaging is expected to correspond to the pattern of product use in the United States. However, no net increase in solid waste is expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Regulatory compliance	The new products have no features that would lead to a different rate of used product littering compared to currently marketed smokeless tobacco products. Despite state and local ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new products as for currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.

### **7.3 Cumulative Impacts**

The Agency did not identify any actions that, when considered with the new products' disposal under the proposed actions, would lead to cumulative impacts.

### **7.4 Impacts from No-Action Alternative**

The no-action alternative would not change the existing disposal of other smokeless tobacco products in the United States, as many similar smokeless tobacco products would continue to be marketed and therefore disposed of.

## **8. List of Preparers**

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

### ***Preparers:***

Ronald Edwards, MS, Center for Tobacco Products

Education: MS in Biology

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

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

### ***Reviewer:***

Gregory G. Gagliano, MS, Center for Tobacco Products

Education: MS in Environmental Science

Experience: Thirty-seven years in environmental compliance and analysis

Expertise: Environmental toxicology, risk assessment, regulatory compliance, NEPA analysis

## **9. List of Agencies and Persons Consulted**

Not applicable.

**Confidential Appendix 1: Comparison of the New Products to the Single Predicate Product**

<b>SE Report</b>	<b>Characteristic</b>	<b>Change</b>
SE0013345	Package size	Increase from 34.02 g to 204.12 g.
SE0013346	Package size	Increase from 34.02 g to 408.24 g.

**Confidential Appendix 2: First- and Fifth-Year Market Volume Projections for New Products**

STN	Unit	Market Volume	
		First-Year Projection	Fifth-Year Projection
SE0013345	Cans	(b) (4)	
	Metric Tons		
SE0013346	Cans		
	Metric Tons		

The applicant stated that the predicate product is not currently on the market but that they reserve the right to market the predicate product in the future.