

**Environmental Assessment for a Marketing Order for a New  
Smokeless Tobacco Product Manufactured by U.S. Smokeless  
Tobacco Company LLC**

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

**July 16, 2019**

**Table of Contents**

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

### 1. Applicant and Manufacturer Information

<b>Applicant Name</b>	Altria Client Services LLC
<b>Applicant Address</b>	2325 Bells Road Richmond, VA 23234
<b>Manufacturer Name</b>	U.S. Smokeless Tobacco Company LLC
<b>Product Manufacturing Address</b>	800 Harrison Street Nashville, TN 37203

### 2. Product Information

#### New Product Name, Submission Tracking Numbers (STN), and Predicate Product Name

<b>New Product</b>	<b>STN</b>	<b>Predicate Product</b>
Copenhagen Long Cut Straight	SE0015107	Copenhagen Long Cut Straight

#### Product Identification

<b>Product Category</b>	Smokeless
<b>Product Subcategory</b>	Loose moist snuff
<b>Product Packages</b>	34.02 g loose moist snuff per can

### 3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue a marketing order 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 product into interstate commerce for commercial distribution in the United States and submitted to the Agency a substantial equivalence (SE) report to obtain a marketing order. The Agency shall issue a marketing order if the new product is found substantially equivalent to the predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new product differs from the predicate product in the composition of the (b)(4) (b)(4) (Confidential Appendix 1). The applicant provided first and fifth-year market volume projections for the new product (Confidential Appendix 2).

### 4. Alternatives to the Proposed Action

The no-action alternative is the Agency does not issue a marketing order for the new tobacco product in the United States.

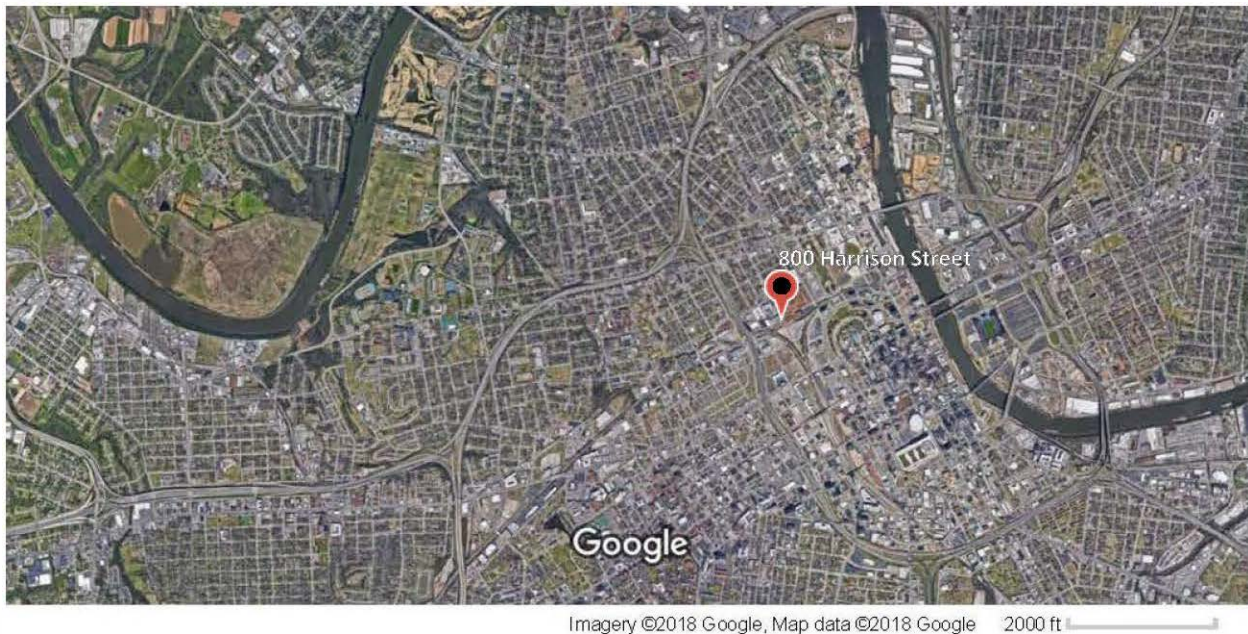
## 5. Potential Environmental Impacts of the Proposed Action and Alternatives - Manufacturing the New Product

The Agency considered potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts based on the Agency-gathered information and the submitted information by the applicant.

### 5.1 Affected Environment

The new product would be manufactured at U.S. Smokeless Tobacco Company LLC, 800 Harrison Street, Nashville, TN 37203 (Figure 1). The facility is within an industrial park in downtown Nashville, with a railroad spur along its southern perimeter, an iron fabricator and Goodwill Industries headquarters to the west and north, offices and parking lots to the north, and a five-lane road to the east with the Nashville Farmers Market building on the other side of the road.

Figure 1. Location of the Manufacturing Facility



### 5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from manufacturing the new product 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 product would have the same or similar air emissions as products currently manufactured at the facility and would not require a new or revised permit.
Water resources	The applicant stated that manufacturing the new product would have the same or similar wastewater discharges as products currently manufactured at the facility and would not require a new or revised permit.

Environmental Resource	Analysis of Potential Impacts
Land use and zoning	The applicant stated that there would be no facility expansion due to the new product. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed actions.
Biological resources	The applicant stated that there would be no facility expansion due to the new product and manufacturing the new product would not change emissions or discharges. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new product.
Soils	The applicant stated that there would be no facility expansion due to the new product. Therefore, no effects on soils would occur as a direct impact from manufacturing the new product.
Socioeconomic conditions	The applicant stated that there would be no facility expansion due to the new product. Therefore, no socioeconomic effects (beneficial or adverse) would occur as a direct impact from manufacturing the new product.
Solid waste and hazardous materials	The applicant stated that the new product would not change solid waste generation at the manufacturing facility and waste would be disposed of in the same manner as waste generated by other smokeless tobacco products manufactured at the same facility. Therefore, no effects to solid waste or change in disposal of hazardous materials would occur as a direct impact from manufacturing the new product.
Floodplains, wetlands, and coastal zones	The applicant stated that there would be no facility expansion due to the new product. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact from manufacturing the new product.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations near the manufacturing facility.
Regulatory compliance	The applicant stated that the manufacturing facility complies with the Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act; the applicant stated that manufacturing the new product would not change the facility's compliance with relevant federal, state, and local environmental regulations. The Agency's search for the manufacturing facility in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online database <sup>1</sup> did not reveal any violations of environmental laws and regulations.

### 5.3 Cumulative Impacts

The Agency does not anticipate the proposed actions to incrementally increase or change the chemicals released to the environment from the facility's tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017, the U.S. Smokeless Tobacco's manufacturing facility in Nashville, Tennessee released 17,153 pounds of ammonia and 235 pounds of nicotine and nicotine salts to air (totaling 17,388 pounds) and transferred 40,409 pounds of ammonia and nicotine

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<sup>1</sup> U.S. Environmental Protection Agency. 2018. ECHO: Enforcement and Compliance History Online. <https://echo.epa.gov/>. Accessed July 8, 2019.

and nicotine salts to Central Wastewater Treatment Plant (Table 1),<sup>2</sup> constituting 14% of TRI releases in Davidson County.<sup>3</sup> No other hazardous air pollutants were reported. Ammonia adversely affects ocular and respiratory systems; nicotine and nicotine salts have known adverse developmental effects.<sup>4</sup> The TRI database search did not show that the U.S. Smokeless Tobacco manufacturing facility 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 facility 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 U.S. Smokeless Tobacco Facility in 2017**

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			17,970
Energy Recovery			0
Treated			102,420
<i>Subtotal Waste Managed</i>			<i>120,390</i>
On-Site Release	Air	Ammonia	17,153
		Nicotine and Nicotine Salts	235
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-Site Disposal/Release			40,409
<i>Subtotal Waste Released</i>			<i>57,797</i>
<b>Total Production-Related Waste</b>			<b>178,187</b>

#### 5.4 Impacts of the No-Action Alternative

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

#### 6. Potential Environmental Impacts of the Proposed Action and Alternatives - Use of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by use of the new product and found no significant impacts.

<sup>2</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 December 20, 2018.

<sup>3</sup> U.S. EPA. <https://myrtk.epa.gov/info/report.jsp?IDT=TRI&ID=37203STBCC800HA>. The site allows for searching the industrial facilities that manage toxic waste chemicals. Accessed December 20, 2018.

<sup>4</sup> Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

### 6.1 Affected Environment

The affected environment includes human and natural environments in the United States. The marketing order will allow for the distribution and sale of the new tobacco product to consumers in the United States.

### 6.2 Analysis of Potential Environmental Impacts

The Agency considered the proposed action for potential environmental impacts from the new product use based on the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new product is 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

No actions were identified that, when considered with the proposed action, would lead to cumulative impacts.

### 6.4 Impacts of the 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 Action and Alternatives - Disposal of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new product and the packaging and found no significant impacts.

### 7.1 Affected Environment

The affected environment includes human and natural environments in the United States. The marketing order would allow the applicant to distribute and sell the new tobacco product to consumers in the United States. Consumers would dispose of the used product and packaging via municipal solid waste landfills, recycling centers, or as litter.

### 7.2 Analysis of Potential Environmental Impacts

The proposed action was 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 product and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of the used new product could lead to terrestrial wildlife having direct exposure to the used product and hazardous substances leaching to aquatic environments and soil. However, no net increase in littering is expected because the new product 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 product and packaging waste.
Water resources	Proper disposal of the used new product and packaging in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of the used new product could result in hazardous substances leaching to water systems. However, no net increase in littering is expected because the new product 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 product has 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 product as for currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.

### 7.3 Cumulative Impacts

No actions were identified that, when considered with the proposed action, 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:*

Mehran Niazi, Ph.D., Center for Tobacco Products  
 Education: M.S. in Environmental Planning and Ph.D. in Environmental Sciences



Experience: Twelve years in environmental fate and transport and environmental modeling  
Expertise: Water quality modeling, environmental fate and transport modeling

***Reviewer:***

Gregory Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: Thirty-six years in environmental toxicology

Expertise: NEPA analysis, ecotoxicology, environmental risk assessment

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

Not applicable.

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

New Product	STN	Predicate Product	Differences Between New Product and Corresponding Predicate Product
Copenhagen Long Cut Straight	SE0015107	Copenhagen Long Cut Straight	<p>Changed composition of (b) (4)</p> <ul style="list-style-type: none"> <li>- Addition of (b) (4) tobacco, (b) (4) and (b) (4) to tobacco blend</li> <li>- Removal of (b) (4) (b) (4) from tobacco blend</li> </ul>

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<sup>5</sup> The generally recognized as safe (GRAS) designation does not apply to ingredients added to tobacco products

**Confidential Appendix 2: Market Volume Projections for the New Product**

STN	Name	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0015107	Copenhagen Long Cut Straight	Can	(b) (4)	
		Metric ton		

The predicate product for SE0015107 is currently on the market. The applicant stated that it does not intend to simultaneously manufacture the new product and the predicate product.