

**Programmatic Environmental Assessment for Two  
Loose Moist Snuff Products by U.S. Smokeless Tobacco  
Company LLC**

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

**October 22, 2018**

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### 1. Applicant and Manufacturer Information

<b>Applicant Name:</b>	U.S. Smokeless Tobacco Company 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 St, Nashville, TN 37203

### 2. Product Information

#### New and Predicate Products

<b>New Product Name</b>	<b>New Product STN</b>	<b>Predicate Product Name</b>	<b>Predicate Product STN</b>
Copenhagen Long Cut Straight	SE0014825	Copenhagen Long Cut Straight	GF1200192
Husky Long Cut Natural	SE0014826	Husky Long Cut Natural	GF1200199

#### Product Identification

<b>Product Category</b>	Smokeless
<b>Product Sub-Category</b>	Loose Moist Snuff
<b>Product Quantity Per Unit of Sale</b>	34.02 grams/Can
<b>Product Package</b>	Polypropylene can bottom, tin-plated steel can lid, paper label, polyethylene shrink film, and cardboard shipping case. The new products are packaged in individual cans that are shrink-wrapped into log rolls of 5 cans per roll and placed 18 log rolls to a shipping case. The new products may be purchased at retail locations in individual cans or in five-can log rolls.

### 3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to the corresponding predicate products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The predicate products are grandfathered products that were on the market as of February 15, 2007.

The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) report and any amendments submitted by the applicant, the new products are found substantially equivalent to the predicate products.

The new and corresponding predicate products are different in packaging materials (Confidential Appendix 1).

#### 4. Alternatives to the Proposed Action

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

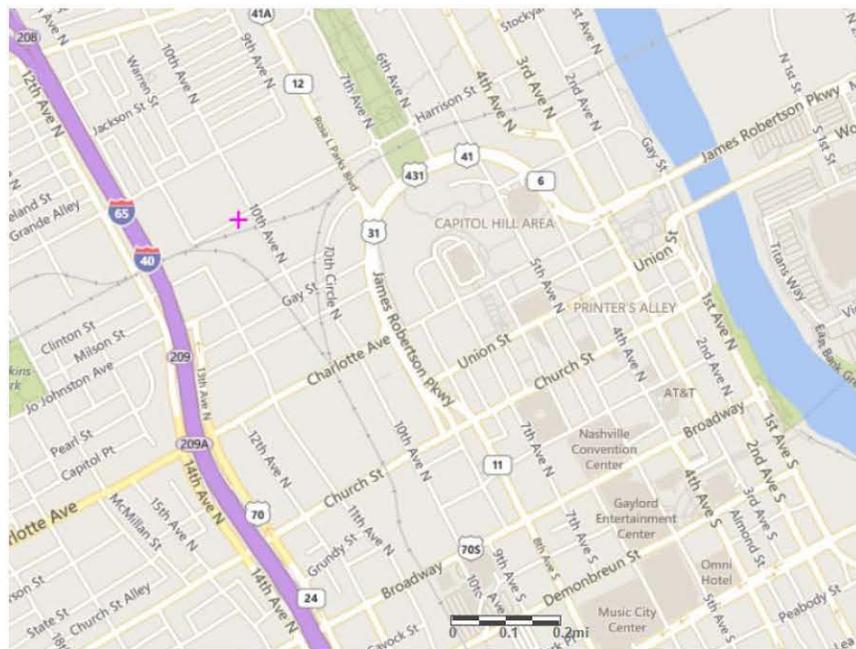
#### 5. Potential Environmental Impacts of the Proposed Action and the Alternatives – Manufacturing the New Products

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 are manufactured at the U.S. Smokeless Tobacco Company LLC facility at 800 Harrison St., Nashville, TN 37203 (Figure 1). The facility is in downtown Nashville, in a mixed-use industrial, commercial and residential area just west of the State Capitol and the Cumberland River and east of interstates 40 and 65. The facility is located in the Lower Cumberland-Sycamore watershed.<sup>1,2</sup>

**Figure 1. Location of the Manufacturing Facility (crosshairs)**



<sup>1</sup> A watershed is an area of land where all bodies of water, such as; surface water from lakes, streams, reservoirs and wetlands, the underlying ground water, and rainfall, drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. See <https://water.usgs.gov/edu/watershed.html>.

<sup>2</sup> USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed Aug 23, 2018.

## 5.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from manufacturing based on Agency-gathered information and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products would lead to the same or similar air emissions as manufacturing the corresponding predicate products and would not require a new or revised permit.
Water resources	The applicant stated that manufacturing the new products would lead to the same or similar wastewater discharges as manufacturing the corresponding predicate products and would not require a new or revised permit.
Land use and zoning	The applicant stated that there would be no facility expansion due to the new products. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed actions.
Biological resources	The search of the U.S. Fish and Wildlife Services’ (U.S. FWS) critical habitat and endangered species list shows twelve endangered species (four clams, four flowering plants, a cray fish and a bat species) and two threatened species (a flowering plant and a bat species) are listed in Davidson County. <sup>3,4</sup> The applicant also reviewed the U.S. FWS maps and stated that the manufacturing facility is not within or near a critical habitat or endangered animal and plant species.
Soils	The applicant stated that there would be no facility expansion due to the new products. Therefore, no effects on soils would occur as a direct impact from manufacturing the new products.
Solid waste and hazardous materials	The applicant stated that manufacturing the new products would have minimal or no impacts on total manufacturing waste. The new products differ from the corresponding predicate products due to changes in packaging and associated ingredients. Based on applicant-provided information, no changes in manufacturing solid waste generation are expected, and no additional environmental controls are needed. 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 the new products. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact manufacturing the new products.
Socioeconomics and environmental justice	No changes on socioeconomics are anticipated due to manufacturing the new product. The Agency does not anticipate any impacts on employment revenue,

<sup>3</sup> U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=47037> Accessed August 23, 2018.

<sup>4</sup> Critical habitats map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed, Aug 23, 2018.

	<p>or taxes because the new product is intended to replace similar tobacco products currently manufactured at the facility.</p> <p>A high percentage minority (60%) and low-income population (48% below poverty level) reside within 3 miles of the manufacturing facility of the new product, per 2010 U.S. Census and American Community Survey data.<sup>5</sup> However, manufacturing the new product is not expected to disproportionately impact minority populations, as no new exposure is anticipated. In addition, the facility is not located in an Indian reservation.</p>
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### 5.3. Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant provided detailed information for the following air permit:

Synthetic Minor Air Pollutant Source Operating Permit, issued in accordance with applicable Metropolitan Government of Nashville and Davidson County regulations, will expire December 2018.

The Agency’s search of EPA’s Enforcement and Compliance History Online (ECHO) did not reveal any violations of the federal environmental laws and regulations.<sup>6</sup> The applicant also stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

### 5.4. 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. A search in the EPA’s Toxic Release Inventory (TRI) database showed that in 2016, the U.S. Smokeless Tobacco’s manufacturing facility in Nashville, Tennessee released 154 pounds nicotine and nicotine salts to the air and transferred 622 pounds of nicotine and nicotine salts to Metro Central Wastewater Treatment Plant (Table 1),<sup>7</sup> constituting less than 1% of TRI releases in Davidson County.<sup>8</sup> No other hazardous air pollutants were reported. Nicotine and nicotine salts have known adverse developmental effects. 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

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<sup>5</sup> EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000370820>. Accessed August 23, 2018

<sup>6</sup> EPA ECHO Detailed Facility Report: U S Smokeless Tobacco Manufacturing Co LLC. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000370820>. Accessed August 23, 2018

<sup>7</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 August 23, 2018.

<sup>8</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 Aug 2, 2018.

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 the U.S. Smokeless Tobacco Facility in 2016**

Production-Related Nicotine and Salts Managed or Released		Chemical Mass (Pounds)
Recycled		4,834
Energy Recovery		0
Treated		403
Subtotal Waste Managed		5,237
On-site Release	Air	154
	Water	0
	Land	0
Off-site Disposal/Release		63,622
Subtotal Waste Released		63,776
Total Production-Related Waste		69,013

### 5.5. Impacts from No Action Alternative

The no-action alternative would not change the existing manufacturing of other smokeless tobacco at the U.S. Smokeless Tobacco Company facility or other manufacturers' facilities, as many similar tobacco products would continue to be marketed and therefore manufactured.

## 6. Potential Environmental Impacts of the Proposed Actions and the Alternative - 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 Justice Impacts

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

<b>Environmental Resource</b>	<b>Analysis of Potential Impacts</b>
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

No actions were identified that would lead to cumulative impacts due to the proposed actions.

### 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 tobacco products would continue to be marketed and therefore used.

## 7. Potential Environmental Impact of the Proposed Actions and the 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 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.

<b>Environmental Resource</b>	<b>Analysis of Potential Impacts</b>
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 and hazardous substances leaching to aquatic environments and soil. However, no net increases in littering are 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 into 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. The total solid waste generated was calculated based on the applicant-provided first- and fifth-year marketing projections for the new products (Confidential Appendix 2). No significant environmental impacts were identified due to the waste disposal as it is a negligible fraction of the total waste reported in the United States (Confidential Appendix 3).
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 existing smokeless tobacco products; therefore, these impacts are not considered significant.

### 7.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the disposal of the new tobacco products.

### 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 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:

#### **Preparer:**

Dilip Venugopal, Ph.D., Center for Tobacco Products  
 Education: M.S. in Ecology and Ph.D. in Entomology  
 Experience: Seventeen years in various scientific activities  
 Expertise: NEPA analysis, ecological risk assessments, applied ecology, geo-statistics

#### **Reviewer:**

Hoshing W. Chang, Center for Tobacco Products  
 Education: Ph.D. in Biochemistry, M.S. in Environmental Science  
 Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

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

Not applicable.

**Confidential Appendix 1: Differences Between the New and Corresponding Predicate Products**

<b>STN</b>	<b>Component</b>	<b>Differences</b>
SE0014825	Can	Replacement of fiberboard can containing interior Parafflex wax coating with a plastic can without interior wax coating
SE0014826	Can Lid	Replacement of plastic lid with a metal lid

**Confidential Appendix 2: Marketing Projections for the New Products**

STN	Name	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0014825	Copenhagen Long Cut Straight	Cans	(b) (4)	
		Metric tons		
SE0014826	Husky Long Cut Natural	Cans		
		Metric tons		

Additionally, the applicant states that the new and predicate products will not be marketed simultaneously after the new product receives a market order.

**Confidential Appendix 3: The First- and Fifth-Year Projection of Waste of Packaging Materials Associated with Marketing the New Products**

To analyze the environmental effects from waste due to the proposed action, the Agency estimated the first- and fifth-year weights of the projected packaging materials waste (in metric tons) that are generated from disposal of the new products. Projected total waste is the summation of the projected paper, plastic, and metal waste from the new products. Projected total paper waste is the summation of the projected recyclable (shipping case) and non-recyclable (coated paper side label) paper waste from the new products. Projected total plastic waste is the summation of the projected recyclable (can bottom) and non-recyclable (shrink wrap) plastic waste from the new products.

(b) (4)



STN	Year	Q	P	O	N	M	L	K	J	I	H	G	F	E	D	C	B	A
SE0014825	First	196	2.08	0.37	8.98	6.82	18	5	(b) (4)									
	Fifth	196	2.08	0.37	8.98	6.82	18	5										
SE0014826	First	196	2.08	0.37	8.98	6.82	18	5										
	Fifth	196	2.08	0.37	8.98	6.82	18	5										

**Total Waste**

If the entire packaging paper, plastic, and metal components are disposed of as waste, which is a conservative approach, the projected cumulative paper, plastic, and metal waste in the first and fifth years of marketing the new products are (b) (4) metric tons and (b) (4) metric tons, respectively. Both are negligible fractions of the 262.4 million metric tons of total waste reported in the United States in 2015 (U.S. EPA, 2018).