

**Programmatic Environmental Assessment for Marketing  
Orders for Nine Loose Moist Snuff Smokeless Tobacco  
Products by Swedish Match USA Inc.**

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

**October 24, 2018**

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**1. Applicant and Manufacturer Information**

<b>Applicant Name:</b>	Swedish Match USA Inc.
<b>Applicant Address:</b>	Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219
<b>Manufacturer Name:</b>	Swedish Match North America LLC
<b>Product Manufacturing Addresses:</b>	1121 Industrial Drive Owensboro, KY 42301 and 1170 Ewing Road Owensboro, KY 42301

**2. Product Information**

**New and Predicate Products**

<b>New Product</b>	<b>STN</b>	<b>Predicate Product</b>
Longhorn Fine Cut Natural 204.12 g	SE0011034	Longhorn Fine Cut Natural 34.02 g
Longhorn Fine Cut Wintergreen 408.24 g	SE0011035	Longhorn Fine Cut Wintergreen 34.02 g
Longhorn Fine Cut Wintergreen 204.12 g	SE0011036	Longhorn Fine Cut Wintergreen 34.02 g
Longhorn Long Cut Natural 408.24 g	SE0011037	Longhorn Fine Cut Natural 34.02 g
Longhorn Long Cut Natural 204.12 g	SE0011038	Longhorn Fine Cut Natural 34.02 g
Longhorn Long Cut Straight 204.12 g	SE0011040	Longhorn Long Cut Straight 34.02 g
Longhorn Long Cut Wintergreen 204.12 g	SE0011042	Longhorn Long Cut Wintergreen 34.02 g
Longhorn Long Cut Mint 408.24 g	SE0011043	Longhorn Long Cut Mint 37.42 g
Longhorn Long Cut Mint 204.12 g	SE0011044	Longhorn Long Cut Mint 37.42 g

**Product Identification**

<b>Product Category</b>	Smokeless
<b>Product Subcategory</b>	Loose Moist Snuff
<b>Product Quantity per Retail Unit</b>	204.12 g or 408.24 g loose moist snuff per can, eight cans per case
<b>Product Package</b>	Polypropylene cans with linear low-density polyethylene lids, with additional empty polypropylene cans and lids for refills that hold 34.02 g.

**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 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 and submitted to the Agency nine substantial equivalence (SE) reports to obtain marketing orders. After considering the SE Reports, the

Agency shall issue marketing orders if the new products are found substantially equivalent to the corresponding predicate products.

Five of the predicate products were previously found substantially equivalent by the FDA and granted marketing orders: SE0003404 on April 21st, 2017; SE0000098, SE0000099 and SE0000100 on September 25th, 2017; and SE0000101 on March 01, 2018. The predicate product GF1200021 was granted grandfather status by the FDA on October 1, 2012.

The new products differ from the corresponding predicate products in product quantity and packaging design by the addition of a refillable empty can (Appendix 1).

#### **4. Alternative to the Proposed Actions**

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 Actions and the Alternatives - Manufacturing the New Products**

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

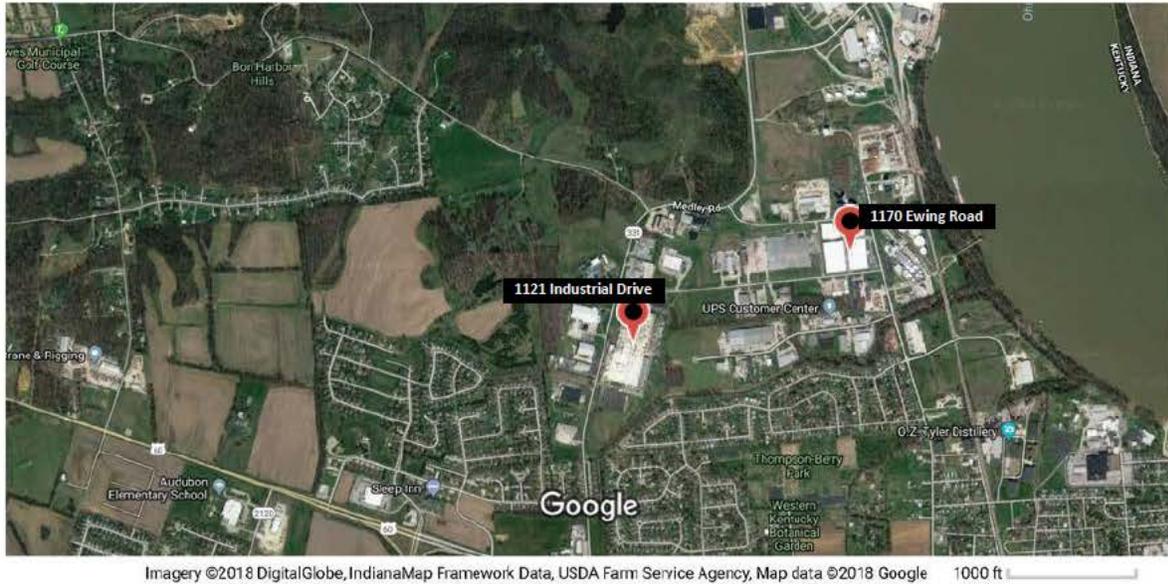
##### **5.1 Affected Environment**

The new products are manufactured at two Swedish Match North America LLC facilities, at 1121 Industrial Drive, Owensboro, KY 42301 and 1170 Ewing Road, Owensboro, KY 42301 (Figure 1).<sup>1</sup> The Industrial Drive facility is at the edge of a manufacturing district, with a power plant equipment fabricator and a beverage distributor to the north, a rubber products supplier and a steel fabricator to the east, a plastic fabrication company and a vending machine supplier to the west, a metal stamping facility to the southwest, and a housing development buffered by a row of trees to the south. The Ewing Road facility is one mile east of the Industrial Drive facility, with a county wastewater treatment facility to the north, a vegetable oil refinery to the east, a brick showroom and a marine supplier warehouse to the south, and a storage and warehousing operation to the west. The Ohio River is 0.2 miles east of the Ewing Road facility, beyond the vegetable refinery, a railroad, and a 200-foot buffer zone of mature deciduous trees.

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<sup>1</sup> Google. (2018). *Maps of 1121 Industrial Drive and 1170 Ewing Road, Owensboro, KY 42301*. Retrieved March 30, 2018, from Google Maps: [www.google.com/maps](http://www.google.com/maps).

**Figure 1. Location of the Manufacturing Facilities**



**5.2 Analysis of Potential Environmental Impacts**

The proposed actions were evaluated for potential environmental impacts from manufacturing based on Agency-gathered information and the applicant’s submitted information, including projected market volumes for the new and predicate products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products would not lead to changes in air emissions to the environment from the manufacturing facility and would not require a new or revised permit.
Water resources	The applicant stated that manufacturing the new products would not lead to changes in wastewater discharges from the manufacturing facility 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 applicant stated that there would be no facility expansion due to the new products and manufacturing the new products would result in no changes in emissions or discharges. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new products.
Geological features and soils	No effects on geological features or soils are expected because no facility expansion is anticipated.
Socioeconomic conditions	No facility expansion is anticipated; therefore, no impacts are expected on employment, state or municipal revenue and taxes, or on police force and fire department resources.
Solid waste and hazardous materials	The applicant stated that manufacturing the new products would not increase total manufacturing waste based on the trend of waste disposal at the manufacturing facility, which showed a slight decrease from 2009 to 2017. The

	product modifications do not include any changes to material composition. 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 are anticipated.
Environmental justice	No significant environmental impacts associated with the proposed actions were identified, therefore no disproportionate impacts to environmental justice populations near the manufacturing facility are anticipated.
Regulatory compliance	The applicant stated that the manufacturing facility is in compliance with all relevant federal, state, and local environmental regulations.

### 5.3 Cumulative Impacts

The applicant stated that there would be no facility expansion due to the new product. However, construction is underway at the Industrial Drive facility and is projected to be completed by mid-2019. The company described the construction in news reports as buildout of a 16,000-square-foot area for another product (referred to as “ZYN”) and a 34,000-square-foot expansion of its current facility. The Swedish Match North America Director of Operations was quoted as saying, “We recently decided to invest in larger scale production capacity to more fully capitalize on the progress of some of our newer smokeless products. This capacity project will expand our existing facility for smokeless products in the US and will primarily cater to US demand but could potentially address future launches in other markets.”<sup>2</sup> Therefore, the new products that are the subject of this programmatic environmental assessment (PEA) would have contributed to the identified need for expanding this facility.

Satellite imagery did not reveal any undeveloped land at or immediately adjacent to this location that would have been newly disturbed by the construction.<sup>3</sup> In addition, FDA reviewed potential impacts from this construction project on the following environmental resources that are typical of a developed area like the vicinity of the manufacturing facility at 1121 Industrial Drive:

- Cultural and historic resources: The nearest historic resource is a single dwelling more than 0.6 miles from the site.<sup>4</sup>
- Floodplains: The location is not in a floodplain.<sup>5</sup>

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<sup>2</sup> Owensboro Living Magazine. (2017, September 1). Owensboro, KY, USA: Tanner Publishing. Retrieved April 12, 2018, from <https://www.owensboroliving.com/the-buzz/swedish-match-set-expand-owensboro-operation/>.

<sup>3</sup> Google (2018).

<sup>4</sup> National Park Service. (1992). National Register of Historic Places Registration Form: Moorman House. Owensboro, Kentucky, USA: U.S. Department of the Interior.

<sup>5</sup> Federal Emergency Management Agency. (2018, April 13). National Flood Hazard Layer FIRMette. *1121 Industrial Drive, Owensboro, KY*. U.S. Department of Homeland Security.

- Soils and erosion: The applicant obtained a Construction General Permit from the State of Kentucky committing to compliance with the state’s master general permit for storm water discharges that would occur during construction.<sup>6</sup>
- Water resources: This site has no sole source aquifers, wetlands, or streams.<sup>7, 8, 9</sup>

Based on this limited review, no cumulative impacts were identified from expanding the manufacturing facility at 1121 Industrial Drive.

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

The no-action alternative would not change the existing manufacturing of other smokeless tobacco products at the Swedish Match North America LLC facility or other manufacturers’ facilities as many similar smokeless tobacco products would continue to be marketed and therefore manufactured.

The ongoing construction described in Section 5.3 would be completed under both the no-action alternative and the proposed actions to support future manufacturing of other products at the same facility. No cumulative impacts were identified from expanding the manufacturing facility at 1121 Industrial Drive.

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

The Agency considered 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 the applicant’s submitted information.

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<sup>6</sup> Kentucky Department for Environmental Protection. (2018, January 11). Letter re: KYR1- Coverage Acknowledgement. Frankfort, KY, USA.

<sup>7</sup>U.S. Environmental Protection Agency. (2018). Sole Source Aquifers for Drinking Water. *SSA Locations*. Retrieved April 13, 2018, from <https://www.epa.gov/dwssa>.

<sup>8</sup>U.S. Fish and Wildlife Service. (2018, April 13). National Wetlands Inventory. *Map of 1121 Industrial Drive, Owensboro, KY*.

<sup>9</sup> Google (2018).

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new products are expected 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 are expected.

### 6.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with product 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 the Alternatives - Disposal of the New Products

The Agency considered 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 product and packaging as municipal solid waste, recycled material, or litter.

### 7.2 Analysis of Potential Environmental Impacts

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

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of used product and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of used product 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 other currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.

Solid waste and hazardous materials	Although the new products contain additional empty plastic cans, waste generated from use of the new products would account for a small fraction of the municipal solid waste generated in the United States. <sup>10</sup> Additionally, introducing the new products is not expected to increase waste due to nationwide use of smokeless tobacco products because the new products would compete for market share with other smokeless tobacco products.
Environmental justice	No significant environmental impacts associated with the disposal of the used products and packaging were identified, therefore no disproportionate impacts to environmental justice populations are anticipated.
Water resources	Proper disposal of used product and packaging materials in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of used product could result in hazardous substances leaching to water systems. However, no net increases in littering are expected because the new products would compete for the same market share occupied by other 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 product 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**

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this PEA.

**Preparer:**

Susana Addo Ntim, PhD, Center for Tobacco Products  
 Education: PhD in Environmental Science

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<sup>10</sup> U.S. Environmental Protection Agency. (2016). Advancing Sustainable Material Management: Facts and Figures.

Experience: Six years in various scientific activities  
Expertise: Fate, transport and ecotoxicology of new and emerging contaminants, applications and environmental implications of nanotechnology

**Reviewer:**

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: MS in Environmental Science and PhD in Biochemistry

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.

**Appendix 1: Difference between New and Predicate Products**

STN	Product Quantity (g)		Packaging Design Change
	New Product	Predicate Product	
SE0011034	204.12	34.02	Additional empty plastic can with lid for refills that holds 34.02 g
SE0011035	408.24		
SE0011036	204.12		
SE0011037	408.24		
SE0011038	204.12		
SE0011040	204.12		
SE0011042	204.12	37.42	
SE0011043	408.24		
SE0011044	204.12		

**Confidential Appendix 1: Marketing Projections for the New and Predicate Products**

STN	Unit	Market Volume					
		Current Year		First-Year Projection		Fifth-Year Projection	
		New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0011034	Cans	(b) (4)					
	Pounds						
SE0011035	Cans						
	Pounds						
SE0011036	Cans						
	Pounds						
SE0011037	Cans						
	Pounds						
SE0011038	Cans						
	Pounds						
SE0011040	Cans						
	Pounds						
SE0011042	Cans						
	Pounds						
SE0011043	Cans						
	Pounds						
SE0011044	Cans						
	Pounds						
<b>Total Market Volume</b>	<b>Cans</b>						
	<b>Pounds</b>						

Except for the grandfathered predicate product, the applicant intends to continue marketing the predicate products after receiving marketing orders for the new products. However, introducing the new products is not expected to increase nationwide use of smokeless tobacco products because the new products would compete for market share with other smokeless tobacco products.