

**Programmatic Environmental Assessment for One Chewing
Tobacco Product and Three Loose Moist Snuff Products by
Swedish Match USA Inc.**

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

August 24, 2018

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1. Applicant and Manufacturer Information

Applicant Name:	Swedish Match USA Inc.
Applicant Address:	Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219
Manufacturer Name:	Swedish Match North America LLC
Product Manufacturing Address:	1121 Industrial Drive Owensboro, KY 42301

2. Product Information

New and Predicate Products

New Product	STN	Predicate Product
J.D.'s Blend 9 oz	SE0005816	J.D.'s Blend December 31, 2006
Longhorn Fine Cut Natural 408.24 g	SE0005826	Longhorn Fine Cut Natural February 10, 2007
Longhorn Long Cut Wintergreen 408.24 g	SE0005828	Longhorn Long Cut Wintergreen December 31, 2006
Longhorn Long Cut Straight 408.24 g	SE0005830	Longhorn Long Cut Straight December 31, 2006

Product Identification

Product Category	Smokeless
Product Subcategories	Chewing tobacco and loose moist snuff
Product Packages	255.15 g chewing tobacco per pouch 408.24 g moist loose snuff per can, with refillable empty can

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.

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 corresponding predicate products. The predicate products were on the market as of February 15, 2007.

The new chewing tobacco product differs from the corresponding predicate product due to a change in product quantity from 85.05 g to 255.15 g (9 oz.) per pouch and changes in ingredient amounts (Confidential Appendix 1). The three new loose moist snuff products differ from the corresponding predicate products due to changes in product quantity from 37.42 g to 408.24 g per can and packaging design by addition of a refillable empty can for consumers to carry. Two of the new loose moist snuff products also differ in ingredient amounts, ingredient sources, or product moisture range (Confidential Appendix 1).

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

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not authorize marketing of the new tobacco products in the United States.

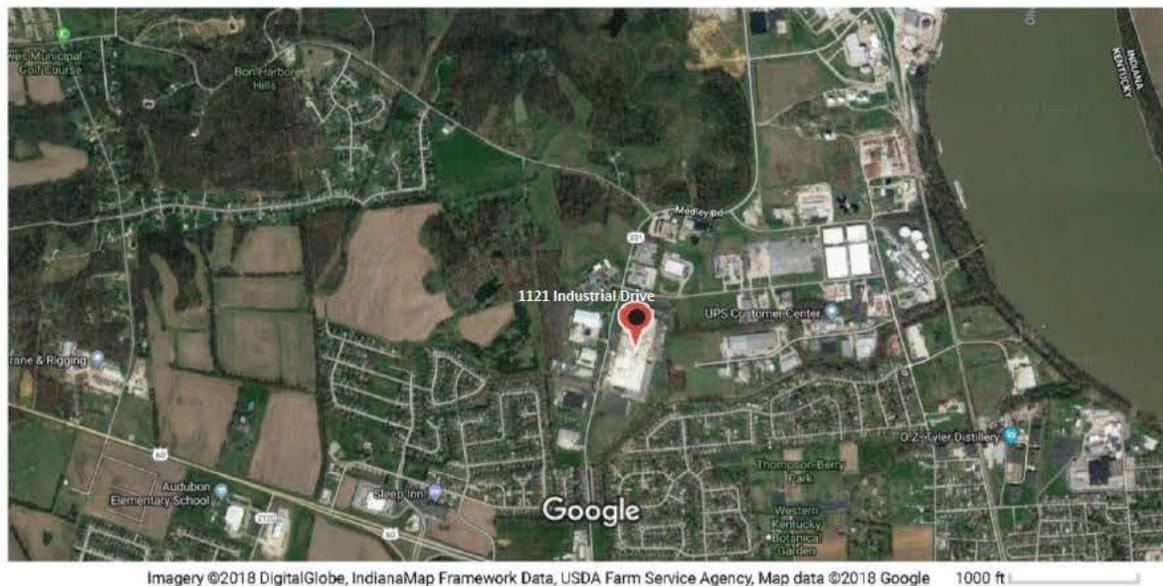
5. Potential Environmental Impacts of the Proposed Actions and the Alternative - Manufacturing the New Products

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 Swedish Match North America LLC at 1121 Industrial Drive, Owensboro, KY 42301 (Figure 1).¹ The 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.

Figure 1. Location of the Manufacturing Facility



¹ Google. (2018). *Map of 1121 Industrial Drive, Owensboro, KY 42301*. Retrieved March 30, 2018, from Google Maps: www.google.com/maps.

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.

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.
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.
Socioeconomic conditions	The applicant stated that there would be no facility expansion due to the new products. 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 would not increase total manufacturing waste. The changes in material composition consist of changes in the amounts of existing ingredients or replacement with like material having the same chemical identity from another manufacturer. Therefore, the Agency does not anticipate that manufacturing the new products would introduce new chemicals to 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 from manufacturing the new products.
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 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 products. 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.”² Therefore, the new products that are the subject of this programmatic environmental assessment 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.³ In addition, the Agency 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.⁴
- Floodplains: The location is not in a floodplain.⁵
- 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.⁶
- Water resources: This site has no sole source aquifers, wetlands, or streams.^{7, 8, 9}

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

² 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/>.

³ Google (2018).

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

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

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

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

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

⁹ Google (2018).

facility. No cumulative impacts were identified from expanding the manufacturing facility at 1121 Industrial Drive.

6. Potential Environmental Impact 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 Impacts

The proposed actions were evaluated for potential environmental impacts from use 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 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 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.

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 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 to water systems. 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.
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

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

Preparers:

Christine M. Modovsky, Center for Tobacco Products (product-specific analyses, primary author)

Education: M.S. in Environmental Science

Experience: Twenty-nine years in environmental compliance and analysis

Expertise: NEPA analysis, regulatory compliance, evaluation of environmental health and ecological effects

Shannon K. Hanna, Center for Tobacco Products (impact analysis framework)

Education: Ph.D. in Environmental Science and Management

Experience: Four years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment, and water quality

Reviewer:

Hoshing W. Chang, Center for Tobacco Products

Education: Ph.D. in Biochemistry, M.S. in Environmental Science

Experience: Nine 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 New and Predicate Products

All four of the new products are different from the corresponding predicate products in product quantity and packaging design. Three of the new products also differ in ingredient amounts, ingredient sources, or product moisture range.

The following table lists the differences between the new and corresponding predicate products.

STN	New Product	Predicate Product	Differences Between New Product and Corresponding Predicate Product
SE0005816	J.D.'s Blend 9 oz	J.D.'s Blend December 31, 2006	<ul style="list-style-type: none"> - (b) (4) - product quantity increased from 85.05 g to 255.15 g per pouch
SE0005826	Longhorn Fine Cut Natural 408.24 g	Longhorn Fine Cut Natural February 10, 2007	<ul style="list-style-type: none"> - final product moisture target and upper and lower range limits increased - amounts of some ingredients slightly changed - some materials replaced with like material with the same chemical identity from another supplier - product quantity increased from 37.42 g to 408.24 g per can - new product as packaged includes an empty can (identical to the smaller can used for the predicate product) that consumers can refill themselves
SE0005828	Longhorn Long Cut Wintergreen 408.24 g	Longhorn Long Cut Wintergreen December 31, 2006	<ul style="list-style-type: none"> - final product moisture upper and lower range limits increased - material replaced with like material with the same chemical identity from another supplier - product quantity increased from 37.42 g to 408.24 g per can - new product as packaged includes an empty can (identical to the smaller can used for the predicate product) that consumers can refill themselves
SE0005830	Longhorn Long Cut Straight 408.24 g	Longhorn Long Cut Straight December 31, 2006	<ul style="list-style-type: none"> - product quantity increased from 37.42 g to 408.24 g per can - new product as packaged includes an empty can (identical to the smaller can used for the predicate product) that consumers can refill themselves

Confidential Appendix 2: Market Volumes and Marketing Projections for the New Products

STN	Name	Unit	Market Volumes		
			Current Year	Projected First Year	Projected Fifth Year
SE0005816	J.D.'s Blend 9 oz	Pouch	(b) (4)		
		Pound			
SE0005826	Longhorn Fine Cut Natural 408.24 g	Can			
		Pound			
SE0005828	Longhorn Long Cut Wintergreen 408.24 g	Can			
		Pound			
SE0005830	Longhorn Long Cut Straight 408.24 g	Can			
		Pound			

The predicate products are not currently marketed and the applicant stated that no sales are projected for any of the predicate products.