

**Environmental Assessment for One Loose Moist Snuff Product
by Swedish Match USA Inc.**

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

August 7, 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 Addresses:	1121 Industrial Drive Owensboro, KY 42301 and 1170 Ewing Road Owensboro, KY 42301

2. Product Information

New and Predicate Products

New Product	STN	Predicate Product
Timber Wolf Long Cut Wintergreen 408.24 g	SE0013001	Timber Wolf Long Cut Wintergreen 34.02 g

Product Identification

Product Category	Smokeless
Product Subcategory	Loose Moist Snuff
Product Package	408.24 g loose moist snuff per can plus a small empty can for refills that holds approximately 34 g

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 after finding the new tobacco product substantially equivalent to the predicate product. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States.

The Agency shall issue a marketing order if, after considering the substantial equivalence report and amendments submitted by the applicant, the new product is found substantially equivalent to the predicate product. The predicate product was previously found substantially equivalent and received a marketing order on November 15, 2013.

The new product differs from the predicate product due to changes in product quantity from 34.02 g to 408.24 g and packaging design by addition of a refillable empty can for consumers to carry.

The applicant provided first- and fifth-year marketing projections for the new product (Confidential Appendix 1).

4. Alternative to the Proposed Action

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

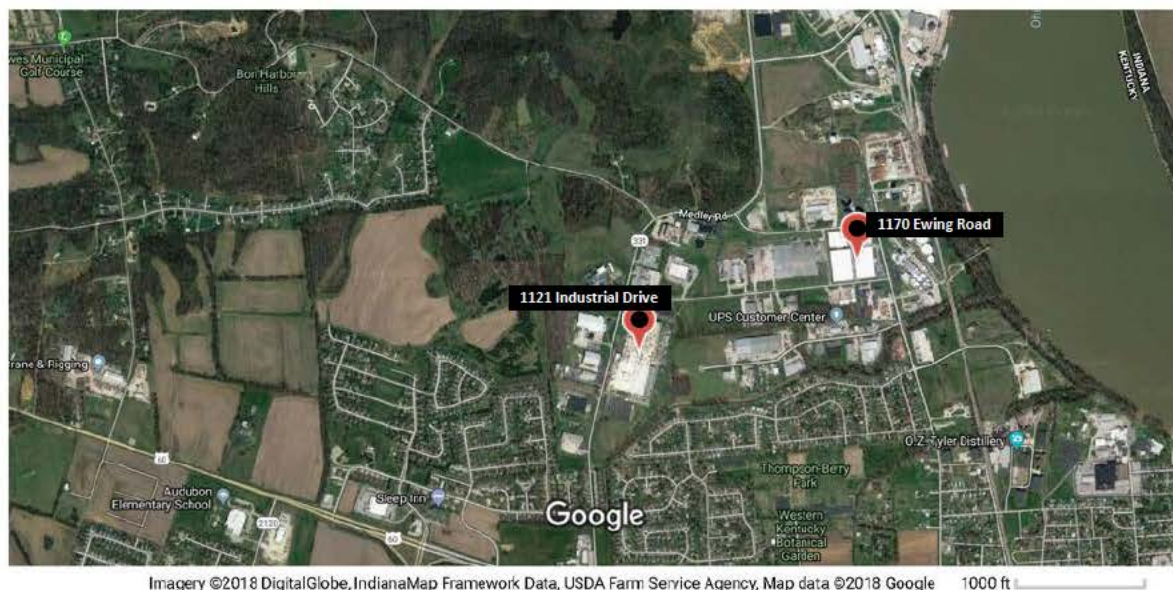
5. Potential Environmental Impacts of the Proposed Action and the Alternative - Manufacturing the New Product

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

5.1 Affected Environment

The new product is 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).¹ 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.

Figure 1. Location of the Manufacturing Facilities



¹ 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.

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 product 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 product 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 product. Therefore, no changes in land use or zoning would occur as a direct impact from the proposed action.
Biological resources	The applicant stated that there would be no facility expansion due to the new product and manufacturing the new product 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 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 manufacturing the new product would not increase total manufacturing waste. The differences between the new and predicate products do not include any changes to material composition. Therefore, the Agency does not anticipate that manufacturing the new product 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 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 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.”² Therefore, the new product that is the subject of this EA 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 action 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 Action and the Alternative - Use of the New Product

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

6.1 Affected Environment

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

6.2 Analysis of Potential Environmental Impacts

The proposed action was 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 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

The Agency did not identify any actions that, when considered with product use under the proposed action, 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 Action and the Alternative - Disposal of the New Product

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

7.1 Affected Environment

The affected environment is the entire United States because the marketing order would allow the new tobacco product 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 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 and hazardous substances leaching to aquatic environments and soil. However, no net increases in littering are 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 increases in littering are 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

The Agency did not identify any actions that, when considered with product disposal under 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 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: Marketing Projections for the New and Predicate Products

STN	Name	Unit	Projected Market Volume		
			Current Year	First Year	Fifth Year
SE0013001	Timber Wolf Long Cut	408.24 g can	(b) (4)		
	Wintergreen 408.24 g	Metric ton	(b) (4)		
Predicate	Timber Wolf Long Cut	34.02 g can	(b) (4)		
	Wintergreen 34.02 g	Metric ton	(b) (4)		

The applicant intends to continue marketing the predicate products after receiving marketing orders for the new products.