

**Environmental Assessment for
Marketing Order for New Smokeless Tobacco Product by
Swedish Match USA Inc.**

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

November 5, 2019

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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 USA Inc.
Product Manufacturing Addresses:	Swedish Match North America LLC 1121 Industrial Drive Owensboro, KY 42301

2. Product Information

New Product Name, Submission Tracking Number (STN), and Predicate Product Name

New Product	STN	Predicate Product
Timber Wolf Pouches Peach	SE0015504	Timber Wolf Pouches Wintergreen

Product Identification

Product Category	Smokeless
Product Subcategory	Portioned Moist Snuff
Product Quantity per Retail Unit	23.25 g per can, wrapped in 5 can rolls, 18 rolls (90 cans) per shipping case.
Product Package	Polypropylene can, lid, and label; polyvinyl chloride shrink film; and paperboard case.

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 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 was previously found SE and issued a marketing order on December 31, 2015.

The new product differs from the predicate product in product quantity (Appendix 1).

4. Alternatives to the Proposed Action

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

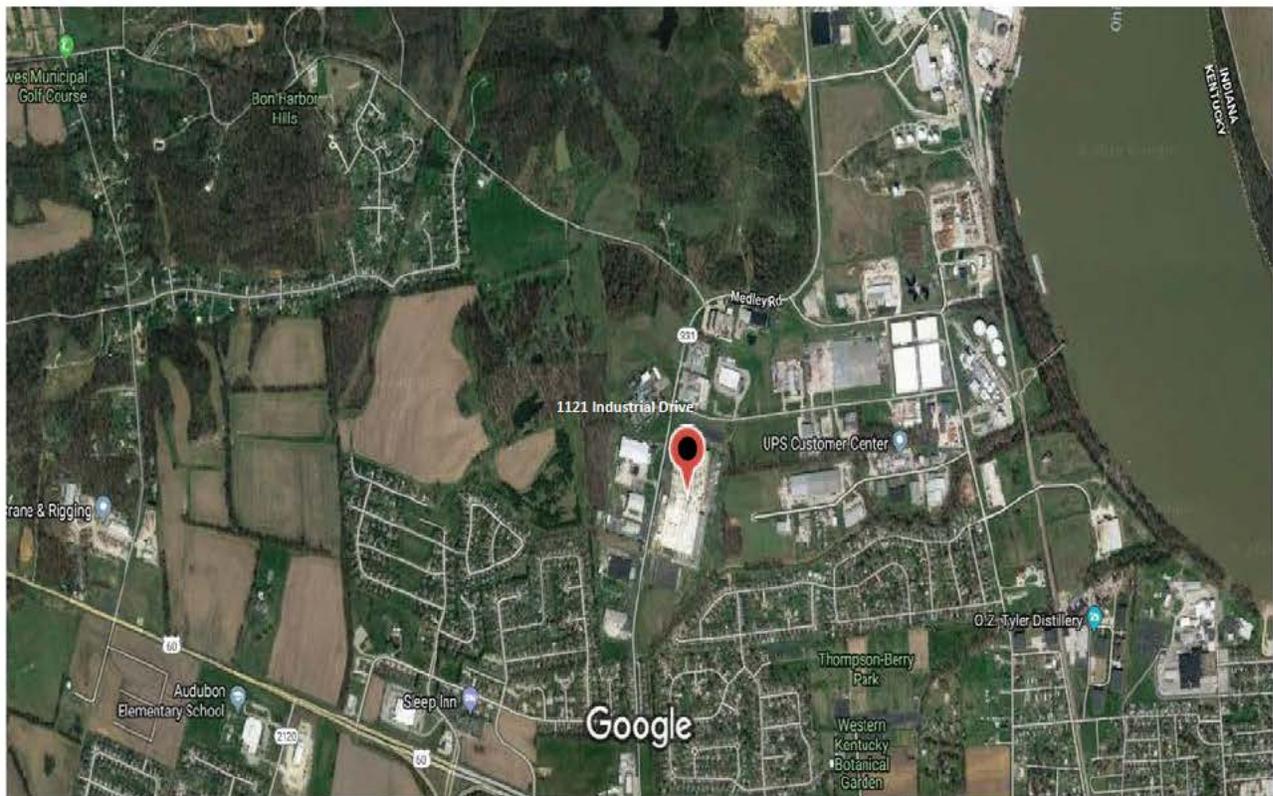
5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

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

5.1 Affected Environment

The new product is manufactured at Swedish Match North America LLC facility, 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 product 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 Manufacturing Facility



Imagery ©2018 DigitalGlobe, IndianaMap Framework Data, USDA Farm Service Agency, Map data ©2018 Google 1000 ft

¹ Google. (2018). *Maps of 1121 Industrial Drive and 1170 Ewing Road, Owensboro, KY 42301*. Retrieved May 30, 2019, 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 the new product 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 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 manufacturing 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 and no expected changes in emissions or discharges due to manufacturing the new product. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new product.
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 product would not require additional resources for total manufacturing waste disposal and no additional environmental controls would be needed. 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 manufacturing the new product. Therefore, no effects to floodplains, wetlands, or coastal zones are anticipated.
Environmental justice	No significant environmental impacts associated with the proposed action were identified; therefore, no disproportionate impacts to environmental justice populations near the manufacturing facility are anticipated.
Regulatory compliance	The applicant provided details on the permits and compliance of the manufacturing facility relevant to different environmental regulations. The applicant also stated that the facility complies with the Endangered Species Act and the Convention on International Trade in Endangered Species of Wild Fauna and Flora. The Agency's search for the manufacturing facility in the Environmental Protection Agency's Enforcement and Compliance History Online

	database did not reveal any current violations of the environmental laws and regulations. ²
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5.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with manufacturing the new product under the proposed action, would lead to cumulative impacts.

5.4 Impacts from the No-Action Alternative

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

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

The Agency considered 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 includes human and natural environments in the United States because the marketing order would allow for the new tobacco product to be sold to consumers in the United States.

6.2 Analysis of Potential Environmental Impacts

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

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new product is expected to be used by consumers that use existing smokeless tobacco product, competing for the same market share. Therefore, no change in impacts to environmental justice populations are expected.

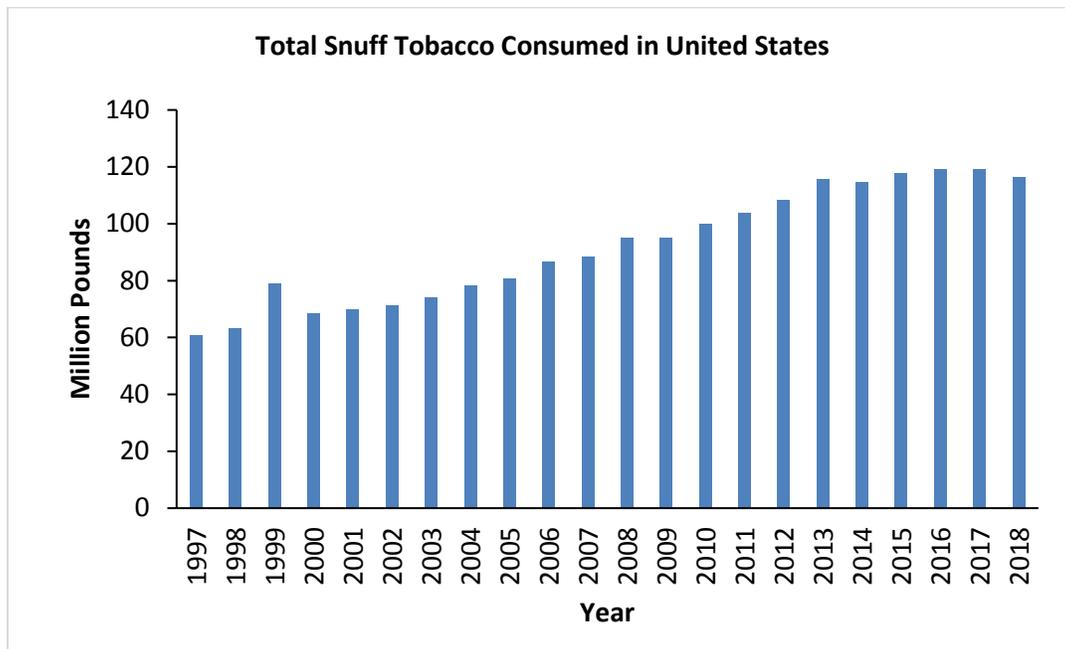
6.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with product use under the proposed action, would lead to cumulative impacts. Since 1997, snuff tobacco use (which includes snus tobacco use) in the United States has increased overall. However, in recent years snuff tobacco use has leveled

² U.S. Environmental Protection Agency (EPA). ECHO: Enforcement and Compliance History Online. Detailed Facility Report Available at: <https://echo.epa.gov/detailed-facility-report?fid=110013765559>. Searched on May 30, 2019.

off (Figure 2).³ The Agency does not expect the new tobacco product to significantly increase snus use in the United States.

Figure 2. Use of Snuff Tobacco in the United States, 1997-2018



6.4 Impacts from 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 in the United States.

7. Potential Environmental Impacts of the Proposed Action and Alternatives – Disposal of the New Product

The Agency considered 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 includes human and natural environments in the entire United States because the marketing order would allow the new tobacco product to be sold to consumers in the United States

³ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 6, 2019.

who would dispose of the used product and packaging as municipal solid waste (MSW), recycled material, or litter.

7.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from disposal of the new product based on Agency-gathered information and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of used new product and packaging in the MSW would not affect biological resources. Improper disposal (littering) of 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 increases in littering would be expected because the new product would be disposed of by consumers who use other currently marketed smokeless tobacco products. Therefore, these impacts are not considered significant.
Environmental justice	No significant environmental impacts associated with the disposal of the used product and packaging were identified; therefore, no disproportionate impacts to environmental justice populations are anticipated.
Solid waste and hazardous materials	Waste generated from use of the new product would account for a small fraction of the MSW generated in the United States. ⁴ Additionally, introducing the new product is not expected to increase the nationwide use and disposal of smokeless tobacco products because the new product would compete for market share with other smokeless tobacco products.
Water resources	Proper disposal of used product and packaging materials in the MSW 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 would be expected because the new product 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 product has no features that would lead to a different rate of littering for the used product 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 disposal of the new product under the proposed action, would lead to cumulative impacts.

⁴ U.S. Environmental Protection Agency. (2016). Advancing Sustainable Material Management: Facts and Figures.

7.4 Impacts from the 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 environmental assessment:

Preparer:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Five years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. 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.

Confidential Appendix 1: Difference between New and Predicate Products

SE Report	Characteristic	Change
SE0015504	Total tobacco content	<ul style="list-style-type: none">• Decrease in total amount of tobacco
	Tobacco composition	<ul style="list-style-type: none">• Decrease in 14 ingredients• Increase in (b) (4)• Removal of (b) (4)• Addition of (b) (4)

Confidential Appendix 2: Marketing Projections for the New and Predicate Products

STN	Product	Unit	Projected Market Volume		
			Current	First Year	Fifth Year
SE0015504	New Product	Cans	(b)	(4)	
		Metric tons			
	Predicate Product	Cans			
		Metric tons			