

**Programmatic Environmental Assessment for Marketing
Orders for Three Smokeless Chewing Tobacco Products by
Swedish Match USA Inc.**

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

April 15, 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 North America LLC
Product Manufacturing Addresses:	1121 Industrial Drive Owensboro, KY 42301

2. Product Information

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

New Product	STN	Predicate Product
Granger Select 16 oz.	SE0011047	Granger Select 3 oz.
J.D.'s Blend 16 oz.	SE0011048	J.D.'s Blend 3 oz.
Southern Pride 16 oz.	SE0011050	Southern Pride 3 oz.

Product Identification

Product Category	Smokeless
Product Subcategory	Loose chewing tobacco
Product Quantity per Retail Unit	453.6 g loose chewing tobacco per pouch
Product Package	Foil pouch

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. 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 previously found substantially equivalent by the FDA and received marketing orders March 1, 2018; SE0000083 - predicate product for SE0011047, SE0000088 – predicate product for SE0011048, and SE0000089 – predicate product for SE0011050.

The new products differ from the corresponding predicate products in product quantity (Appendix 1).

4. Alternatives to the Proposed Actions

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

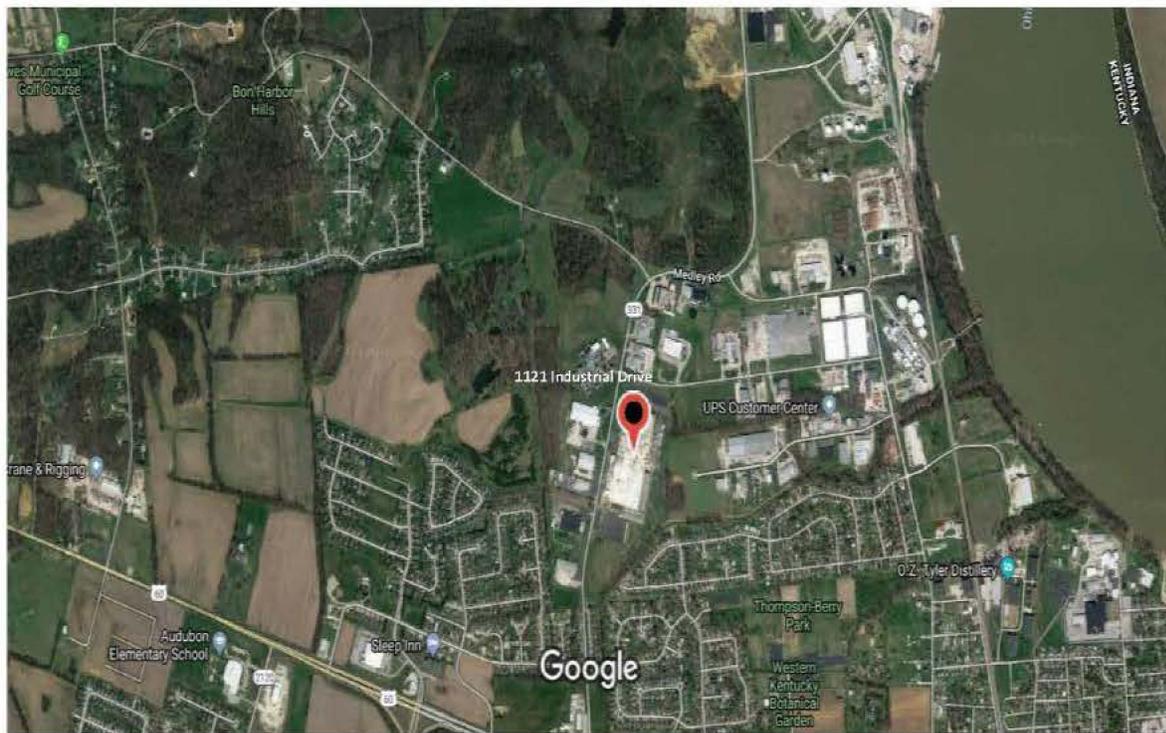
5. Potential Environmental Impacts of the Proposed Actions and the Alternatives - Manufacturing the New Products

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 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 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



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 February 20, 2019, 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, 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 manufacturing 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 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 manufacturing 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. 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

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 Feb 20, 2019.

5.3 Cumulative Impacts

The Agency does not anticipate that the proposed actions would incrementally increase or change the chemicals released to the environment from the facility's tobacco manufacturing. The manufacturing facility was not listed in EPA's Toxic Release Inventory (TRI), indicative of a minor facility.³

The applicant stated that manufacturing the new products would not require revised or new air, waste water, or storm water permits. 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."⁴ 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.⁵ 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 mile from the site.⁶
- Floodplains: The location is not in a floodplain.⁷
- 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.⁸

³ U.S. Environmental Protection Agency (EPA). *TRI Data Form R & A Download*. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched on Feb 20, 2019.

⁴ Owensboro Living Magazine. (2017, September 1). Owensboro, KY, USA: Tanner Publishing. Retrieved Feb 25, 2019, from <https://www.owensboroliving.com/the-buzz/swedish-match-set-expand-owensboro-operation/>.

⁵ Google (2018).

⁶ National Park Service. (1992). National Register of Historic Places Registration Form: Moorman House. Owensboro, Kentucky, USA: U.S. Department of the Interior.

⁷ Federal Emergency Management Agency. (2018, April 13). National Flood Hazard Layer FIRMette. *1121 Industrial Drive, Owensboro, KY*. U.S. Department of Homeland Security.

⁸ Kentucky Department for Environmental Protection. (2018, January 11). Letter re: KYR1- Coverage Acknowledgement. Frankfort, KY, USA. http://dep.gateway.ky.gov/eSearch/Search_AI_Detail.aspx?AgencyID=963

- Water resources: This site has no sole source aquifers, wetlands, or streams.^{9,10}

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 as similar smokeless tobacco products would continue to be 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.

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.

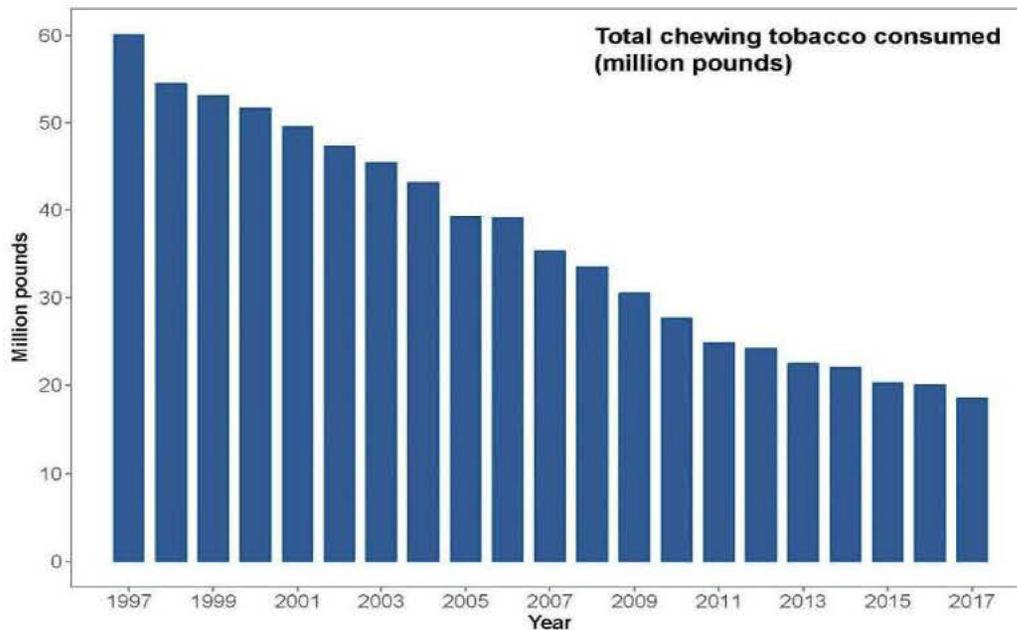
⁹U.S. Environmental Protection Agency. (2018). Sole Source Aquifers for Drinking Water. *SSA Locations*. Retrieved April 13, 2018, from <https://www.epa.gov/dwssa>.

¹⁰U.S. Fish and Wildlife Service. (2018, April 13). National Wetlands Inventory. *Map of 1121 Industrial Drive, Owensboro, KY*.

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. This is broadly due to the declining trend of chewing tobacco use in the United States, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports, (Figure 2).¹¹

Figure 2. Use of chewing tobacco in the United States, 1997 – 2017



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.

¹¹ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed March 7, 2018.

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 the used products and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of used 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 and predicate 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 foil pouches, waste generated from use of the new and predicate products would account for a small fraction of the municipal solid waste generated in the United States. ¹² Additionally, introducing the new products is not expected to increase waste due to nationwide decrease in the use of smokeless tobacco products, and 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 products and packaging materials in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of used products could result in hazardous substances leaching to water systems. However, no net increases in littering are expected because the new and predicate 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.

¹² U.S. Environmental Protection Agency. (2016). Advancing Sustainable Material Management: Facts and Figures.

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:

Dilip Venugopal, PhD, Center for Tobacco Products

Education: MS in Ecology and PhD in Entomology

Experience: Sixteen years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis and risk assessment, applied ecology, geostatistics

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)	
	New Product	Predicate Product
SE0011047	453.6	85.05
SE0011048		
SE0011050		

Confidential Appendix 1:

First- and Fifth-Year Market Volume Projections for the New and Predicate Products and Percentage of Chewing Tobacco Use in the United States Projected to be Attributed to the New and Predicate Products

First- and fifth-year market volume projections for the new and predicate products were compared to the total forecasted use of chewing tobacco in the United States.¹³ The applicant intends to continue marketing the predicate products after receiving marketing orders for the new products. The new and predicate products account for a minor percentage (b) (4) respectively, for first year and fifth year) of the total forecasted smokeless chewing tobacco use in the United States. Additionally, the new products would compete for market share with other smokeless tobacco products.

STN	Projected Market Volume			
	First Year		Fifth Year	
	Market Volume (pounds)	Percent of Total Chewing Smokeless Tobacco Used ¹⁴	Market Volume (pounds)	Percent of Total Chewing Smokeless Tobacco Used ¹⁵
SE0011047	(b)		(4)	
SE0000083 (Predicate to SE0011047)				
SE0011048				
SE0000088 (Predicate to SE0011048)				
SE0011050				
SE0000089 (Predicate to SE0011050)				
Total				

¹³ The Agency used historical data regarding total use of smokeless chewing tobacco from 1997 to 2017 to mathematically estimate the total amount of smokeless chewing tobacco used in the United States. Using the trend line from a polynomial regression model with an R² value of 0.99, the forecasted number of smokeless chewing tobacco that would be used in the United States is estimated at 14.45 million pounds in the first year and 9.67 million pounds in the fifth year of marketing the new and predicate products.

¹⁴ Projected Market Occupation of the Product in the United States (%) = $\frac{\text{Projected Market Volume of the Products (pounds)}}{\text{Projected Use of smokeless chewing tobacco in United States (pounds)}} \times 100$

¹⁵ Ibid