

**Environmental Assessment for a Marketing Order for
New Chewing Tobacco Product
Manufactured by Swedish Match USA Inc.**

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

June 12, 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 Name, Submission Tracking Number (STN), and Predicate Product Name

New Product	STN	Predicate Product
Red Man Golden Blend	SE0015215	Red Man Golden Blend

Product Identification

Product Category	Smokeless
Product Subcategory	Loose chewing tobacco
Product Quantity per Retail Unit	255.15 g loose chewing tobacco per pouch
Product Package	Foil pouch

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 a 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 the marketing order. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product.

The applicant intends to commercially market both the new and predicate products. The predicate product was previously found substantially equivalent by the FDA (SE0000085) and received a marketing order on January 30, 2019.

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

4. Alternative to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for 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 considered potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. 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 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). 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 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 increase total manufacturing waste and no additional environmental controls would be needed. The product modifications 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 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 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 The applicant also stated

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.

	that the facility complies with the Endangered Species Act and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.
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5.3 Cumulative Impacts

The Agency does not anticipate that the proposed action 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 there would be no facility expansion and manufacturing the new product would not require revised or new air, waste water, or storm water permits. However, construction of a 16,000-square-foot area for another product (referred to as "ZYN") and a 34,000-square-foot expansion of the Industrial Drive facility was completed in May 2019.⁴

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

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 May 30, 2019.

⁴ Messenger Inquirer. Swedish Match unveiling \$100M expansion. Available at: https://www.messenger-inquirer.com/news/local/swedish-match-unveiling-m-expansion/article_86fbddac-c044-5a44-a0e2-78f3dd574f5c.html. Accessed June 7, 2019.

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.

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

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

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

5.4 Impacts from the No-Action Alternative

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

6. Potential Environmental Impacts of the Proposed Action and the Alternative – 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.

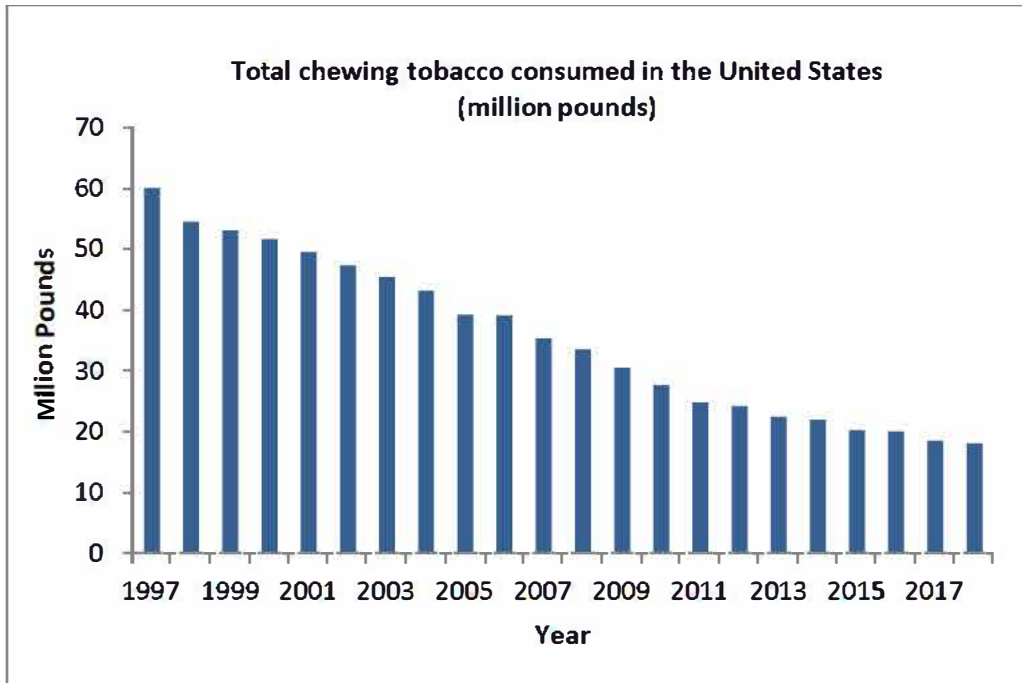
Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new product is expected to be used by consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no change in impacts to environmental justice populations are expected.

6.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with product use under the proposed action, 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 – 2018

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, 2019.



6.4 Impacts from the No-Action Alternative

The no-action alternative would not change the existing use of smokeless tobacco products in the United States, as many similar smokeless tobacco products would continue to be used in the United States.

7. Potential Environmental Impacts of the Proposed Action and the Alternative – 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 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 (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 the used product and packaging in the MSW stream 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 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 product contains additional foil pouches, waste generated from the new product use would account for a small fraction of the MSW generated in the United States. ¹² 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.
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.
Water resources	Proper disposal of used product and packaging materials in the MSW stream would not affect water resources. Improper disposal (littering) of used new product could result in hazardous substances leaching to water systems. However, no net increase in littering is 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 the new product disposal under the proposed action, would lead to cumulative impacts.

7.4 Impacts from the No-Action Alternative

The no-action alternative would not change the existing disposal of smokeless tobacco products in the United States, as many similar smokeless tobacco products would continue to be marketed and therefore disposed of.

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

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:

Dilip Venugopal, Ph.D., Center for Tobacco Products

Education: M.S. in Ecology and Ph.D. in Entomology

Experience: Sixteen years in various scientific activities

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

Reviewer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-two years in various scientific activities including eight years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

9. List of Agencies and Persons Consulted

Not applicable.

Appendix 1: Differences between New and Predicate Products

STN	Product Quantity (g)	
	New Product	Predicate Product
SE0015215	(b) (4)	

Confidential Appendix 1:

Market Volumes 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

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

STN	Market Volumes				
	Current Year (pounds)	First-Year Projection		Fifth-Year Projection	
		Market Volume (pounds)	Percent of Total Smokeless Chewing Tobacco Used ¹⁴	Market Volumes (pounds)	Percent of Total Smokeless Chewing Tobacco Used ¹⁵
SE0015215 (new product)	(b) (4)	(b) (4)			
SE0000085 (predicate product)					
Total					

¹³The Agency used historical data regarding total use of smokeless chewing tobacco from 1997 to 2018 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 15.378 million pounds in the first year and 11.314 million pounds in the fifth year of marketing the new products.

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

¹⁵Ibid.