

**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**

March 2, 2020

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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 tobacco product Name

New Product	STN	Predicate Product
Big Duke Sweet Blend	SE0015538	Southern Pride Blackberry Blend

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 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 tobacco 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 tobacco product is found substantially equivalent to the predicate tobacco product.

The applicant intends to commercially market both the new and predicate tobacco products. The predicate tobacco product is a grandfathered product (GF1702236) that was commercially marketed in the United States as of February 15, 2007.

The new tobacco product differs from the predicate tobacco 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 Tobacco Product

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

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. The new tobacco 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 tobacco products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new tobacco 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 tobacco 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 tobacco 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 tobacco product. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new tobacco 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 tobacco 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 tobacco 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 tobacco 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 November 20, 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 did not identify any actions that, when considered with manufacturing the new tobacco 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 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 Tobacco Product

The Agency considered potential environmental impacts that may be caused by use of the new tobacco 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 tobacco product based on the applicant’s submitted information.

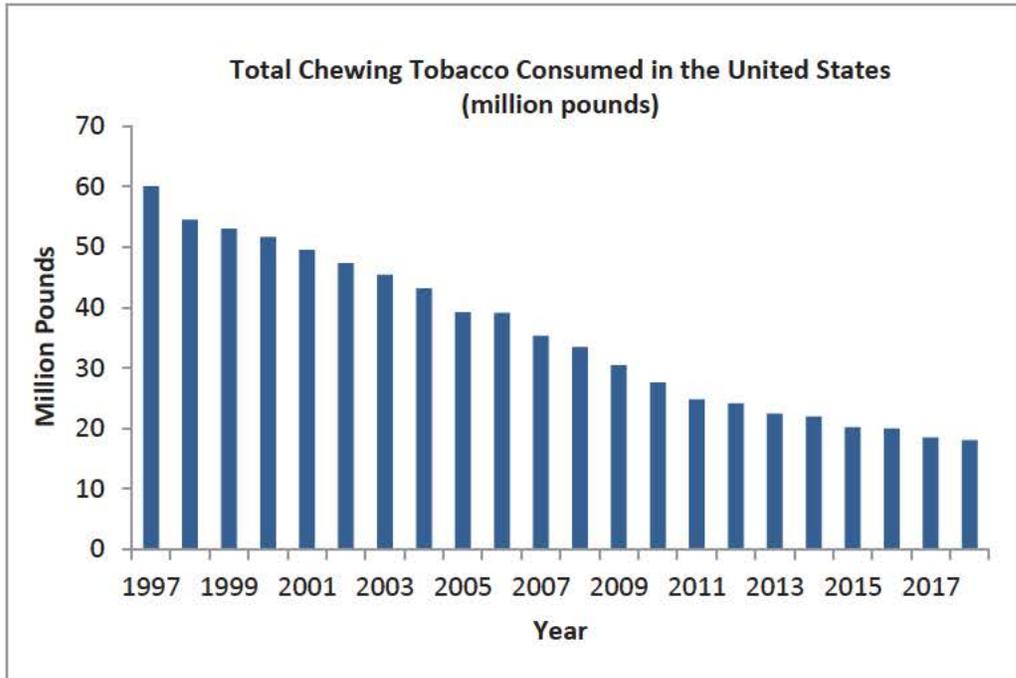
Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new tobacco product is expected to be used by consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no change in impacts to environmental justice populations are expected.

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).³

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 7, 2019.

Figure 2. Use of Chewing 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 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 Tobacco Product

The Agency considered potential environmental impacts that may be caused by disposal of the new tobacco 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 tobacco 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 tobacco 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 tobacco 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 tobacco product contains additional foil pouches, waste generated from the new tobacco product use would account for a small fraction of the MSW generated in the United States. ⁴ Additionally, introducing the new tobacco product is not expected to increase the nationwide use and disposal of smokeless tobacco products because the new tobacco 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 tobacco product could result in hazardous substances leaching to water systems. However, no net increase in littering is expected because the new tobacco 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 tobacco 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 tobacco 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 tobacco 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.

⁴ 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: Seventeen years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis and risk assessment, applied ecology, geo-statistics

Reviewer:

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

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

Experience: Eleven 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: Differences Between New and Predicate Tobacco Products

STN	Product Quantity (g)	
	New Product	Predicate Product
SE0015528	453.06	85.05

Confidential Appendix 1:

Market Volumes for the New and Predicate Tobacco Products and Percentage of Chewing Tobacco Use in the United States Projected to be Attributed to the New and Predicate Tobacco Products

The applicant intends to continue marketing the predicate tobacco product after receiving a marketing order for the new tobacco product. First- and fifth-year market volume projections for the new and predicate tobacco products were compared to the total forecasted use of chewing tobacco in the United States.⁵ The new and predicate tobacco products account for a minor percentage (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 tobacco 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 ⁶	Market Volumes (pounds)	Percent of Total Smokeless Chewing Tobacco Used ⁷
SE0015538 (new product)	(b) (4)				
GF1702236 (predicate product)					
Total					

⁵ The 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.

⁶ Projected Market Occupation of the Product in the United States (%) = $\frac{\text{Projected Market Volume of the Product (pounds)}}{\text{Projected Use of smokeless chewing tobacco in United States (pounds)}} \times 100$

⁷ Ibid.