

**Environmental Assessment for a Marketing Order for
One Loose Chewing Smokeless Tobacco Product
By
Swedish Match USA, Inc.**

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

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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 Address:	1121 Industrial Drive Owensboro, KY 42301

2. Product Information

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

New Product Name	STN	Predicate Product Name
J.D.'s Blend 2.5 oz.	SE0012725	J.D.'s Blend 3.0 oz.

Product Identification

Product Category	Smokeless
Product Subcategory	Loose Chewing Tobacco
Product Number Per Retail Unit	2.5 oz. (70.87 g) loose leaf tobacco per pouch and 12 pouches per carton
Product Package	Foil pouches coated one side paper/polyethylene/aluminum foil/polyethylene overcoat with zipper closure; pouches are contained in paperboard carton

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for 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. After considering the SE Report, 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 substantially equivalent and received a marketing order on March 1, 2018. The new product differs from the predicate product due to changes in the product quantity from 3.0 oz. (85.05 g) to 2.5 oz. (70.87 g) of loose leaf chewing tobacco per foil pouch.

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 new product is manufactured at Swedish Match USA, Inc. 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. The Ohio River is 1.2 miles east of the facility.

Figure 1. Location of the Manufacturer



¹ Google. (2018). *Maps of 1121 Industrial Drive and 1170 Ewing Road, Owensboro, KY 42301*. Retrieved August 22, 2018, from Google Maps: www.google.com/maps.

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action 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 because (1) the new product is expected to replace similar tobacco products currently manufactured in the facility and (2) the differences between the new and predicate products do not include any changes to material composition.
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 water discharge 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 from manufacturing the new product.
Biological Resources	The applicant stated that no facility expansion, or changes in air emission or water discharges would be expected from manufacturing the new product. Therefore, no adverse effects to biological resources would occur from manufacturing the new product.
Soils	The applicant stated that there would be no facility expansion due to the new products. Therefore, no effects on soils would occur as a direct impact from manufacturing the new products.
Socioeconomic Conditions	The applicant stated that the new product is expected to replace other chewing tobacco products currently on the market. There would be no expected facility expansion due to manufacturing the new product. Therefore, no adverse effects on socioeconomic conditions would occur from manufacturing the new product.
Solid Waste and Hazardous Materials	The applicant stated that manufacturing the new product would not notably affect the current waste generated from the manufacturing facility because (1) the new product is expected to replace other currently-manufactured chewing tobacco products in the manufacturing line at this facility; (2) the differences between the new and predicate products do not include any changes to material composition; and (3) the waste generated due to manufacturing the new product would be handled in the same manner as the waste generated from any other products manufactured in the same facility and in a similar manner to other smokeless tobacco manufactured in the United States. Therefore, the Agency does not anticipate that manufacturing the new product would introduce new chemicals to the manufacturing waste stream
Floodplains, Wetlands, and Coastal Zones	There would be no facility expansion due to manufacturing the new product. Therefore, there would be no effects on floodplains, wetlands, or coastal zones. (See also section 5.3 of this document.)

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 applicable environmental laws, regulations, and local ordinances.

5.3 Cumulative Impacts

The applicant stated that there would be no facility expansion due to the new product. However, construction projected to be completed by mid-2019 is underway at the Industrial Drive facility. 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 USA 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 environmental assessment (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

² Owensboro Living Magazine. (2017, September 1). Owensboro, KY, USA: Tanner Publishing. Retrieved August 24, 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. Available at: <http://www.nationalregisterofhistoricplaces.com/ky/daviess/state.html>. Accessed August 24, 2018.

⁵ Federal Emergency Management Agency. (2018, August 24). National Flood Hazard Layer FIRMette. 1121 Industrial Drive, Owensboro, KY. U.S. Department of Homeland Security. Available at: <https://hazards-fema.maps.arcgis.com/apps/webappviewer/index.html?id=8b0adb51996444d4879338b5529aa9cd>.

⁶ Kentucky Department for Environmental Protection. (2018, January 11). Letter re: KYR1- Coverage Acknowledgement. Frankfort, KY, USA.

- 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 No-Action Alternative

The no-action alternative would not change the existing condition of manufacturing smokeless tobacco products at the Swedish Match North America LLC facility or other manufacturers’ facilities, as many similar 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 facility. No cumulative impacts were identified from expanding the manufacturing facility at 1121 Industrial Drive.

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

The Agency considered potential environmental impacts 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 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 would likely be used by the same consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, there would be no expected change in impacts to environmental justice populations.

⁷ U.S. Environmental Protection Agency. (2018). Sole Source Aquifers for Drinking Water. SSA Locations. Retrieved August 24, 2018, from <https://www.epa.gov/dwssa>.

⁸ U.S. Fish and Wildlife Service. (2018, August 24). National Wetlands Inventory. Map of 1121 Industrial Drive, Owensboro, KY.

⁹ Google (2018).

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. No-Action Alternative

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

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 is the entire United States because the marketing order would allow for the new tobacco product to be sold to consumers nationwide. Consumers 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 action for potential environmental impacts from disposal of the new product based on the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Air Quality	The Agency does not anticipate disposal of the product or the packaging material would lead to the release of new or increased chemicals into the air because (1) introducing the new product into the U. S. market is not expected to increase the nationwide use and eventual disposal of smokeless tobacco products; (2) the new product is expected to replace similar tobacco products currently on the market; (3) the paper components of the packages are more likely to be recycled, or at least a portion of the packaging waste is likely to be recycled; and (4) the packaging materials are commonly used and disposed of in the United States.
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 change on the environmental impacts on water quality due to disposal of the new product would be expected because (1) the new product would replace similar tobacco products currently on the market and (2) the use of chewing tobacco continues to decline. 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. No-Action Alternative

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

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this EA:

Preparer:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products
 Education: Ph.D. in Plant Molecular Biology and Virology
 Experience: Twenty-five years in various scientific activities including seven years in NEPA practice
 Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products
 Education: M.S. in Environmental Science and Ph.D. in Biochemistry
 Experience: Ten years in NEPA practice
 Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1

Current Year Market Volume and First- and Fifth-Year Market Volume Projections for the New and Predicate Products

STN	Market Volume					
	Unit	Current Year Production	First-Year Projection		Fifth-Year Projection	
		Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0012725	Number of foil pouches	(b) (4)	0	(b) (4)	0	(b) (4)
	Metric Tons		0		0	

The applicant intends to continue marketing the predicate (provisional) product after receiving a marketing order for the new product.