

**Programmatic Environmental Assessment for Marketing
Orders for Three Portioned Moist Snuff Products by U.S.
Smokeless Tobacco Company LLC**

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

February 28, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	Altria Client Services LLC
Applicant Address:	2325 Bells Road, Richmond, VA 23234
Manufacturer Name:	U.S. Smokeless Tobacco Company LLC
Product Manufacturing Address:	800 Harrison Street Nashville, TN 37203

2. Product Information

New Product Names, Submission Tracking Numbers (STN), and Predicate Product Names

New Product Name	STN	Predicate Product Name
Skoal Pouches Mint	SE0015017	Skoal Pouches Mint
Skoal Pouches Wintergreen	SE0015020	Skoal Pouches Wintergreen
Skoal Pouches Berry Tobacco Blend	SE0015022	Skoal Pouches Berry

Product Identification

Product Category	Smokeless
Product Sub-Category	Portioned moist snuff
Product Quantity Per Unit of Sale	23.25 grams tobacco in 15 portions per can; 1.55 grams per portion
Product Package	Polypropylene can bottom with a metal lid.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the U.S. 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 after finding the new tobacco products substantially equivalent to the corresponding predicate products. The applicant wishes to introduce three new tobacco products into interstate commerce for commercial distribution in the United States.

The applicant submitted to the Agency three substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) reports submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products. The corresponding predicate products are either grandfathered products commercially marketed in the United States as of February 15, 2007, or previously found by FDA to be substantially equivalent.

The new products differ from the corresponding predicate products in the composition of the fermented tobacco (Confidential 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.

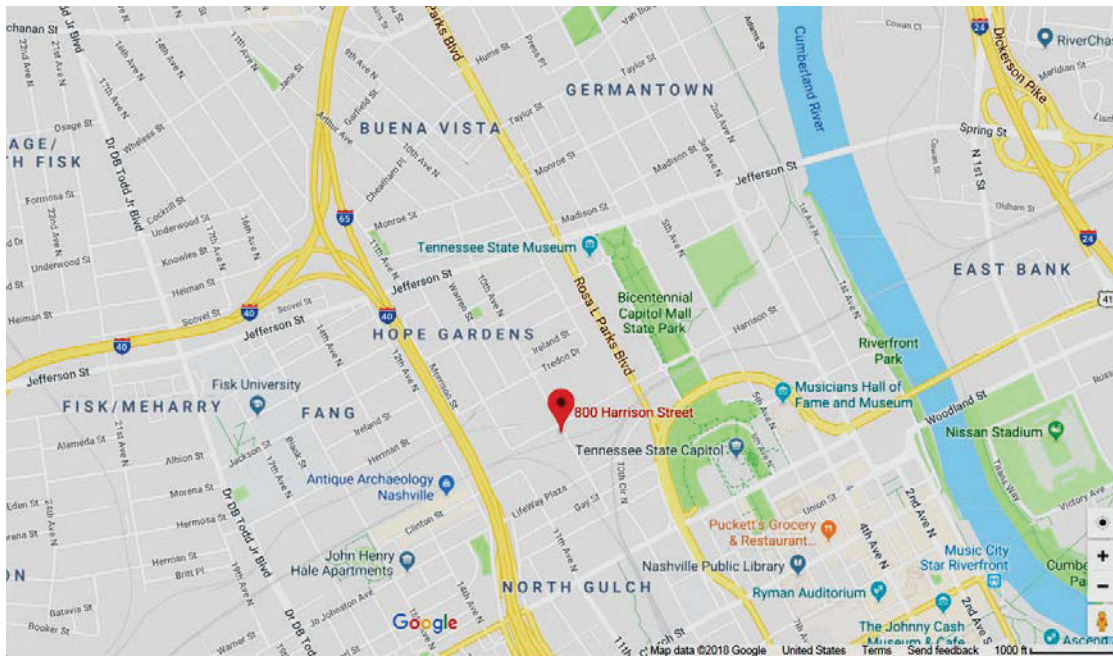
5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

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

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. The new products are manufactured at the U.S. Smokeless Tobacco Company LLC facility at 800 Harrison Street, Nashville, TN 37203 (Figure 1). The facility is in downtown Nashville, in a mixed-use industrial, commercial and residential area just west of the State Capitol and the Cumberland River and east of interstates 40 and 65. The facility is located in the Lower Cumberland-Sycamore watershed.^{1,2}

Figure 1. Location of the Manufacturing Facility



¹ A watershed is an area of land where all bodies of water, such as; surface water from lakes, streams, reservoirs and wetlands, the underlying ground water, and rainfall, drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. See <https://water.usgs.gov/edu/watershed.html>.

² USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed December 20, 2018.

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from manufacturing the new products based on information gathered by the Agency and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new products would have the same or similar air emissions as those associated with current smokeless tobacco products manufactured at the facility and would not require a new or revised permit.
Water resources and water quality	The applicant stated that manufacturing the new products would lead to the same or similar wastewater discharges as manufacturing the corresponding predicate products 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 search of the U.S. Fish and Wildlife Services' (U.S. FWS) critical habitat and endangered species list shows twelve endangered species (six clams, four flowering plants, a cray fish and a bat species) and two threatened species (a flowering plant and a bat species) are listed in Davidson County. ^{3,4} The applicant also reviewed the U.S. FWS maps and stated that the manufacturing facility is not within or near a critical habitat or endangered animal and plant species.
Geological features and soils	The applicant stated that there would be no facility expansion due to manufacturing the new products. Therefore, no effects on geological features or soils would occur as a direct impact from manufacturing the new products.
Solid waste and hazardous materials	The Agency does not anticipate that manufacturing the new products would lead to the presence of new chemicals in the manufacturing waste stream. The applicant stated that the waste generated from manufacturing the new products would be handled in the same manner as the waste generated from any other smokeless tobacco products manufactured at the facility and in accordance with the environmental permit. The applicant also stated that there would be no changes in solid waste generation from manufacturing the new products and no additional environmental controls would be needed.
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 would occur as a direct impact manufacturing the new products.
Socioeconomics and environmental	No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment revenue,

³ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=47037> Accessed December 20, 2018.

⁴ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed, December 20, 2018.

justice	<p>or taxes because the new products are intended to replace similar tobacco products currently manufactured at the facility.</p> <p>No disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new products because the facility is not located within an Indian reservation. Although a high percentage minority (60%) and low-income population (48% below poverty level) reside within 3 miles of the manufacturing facility of the new product, per 2010 U.S. Census and American Community Survey data,⁵ no new exposure would be anticipated.</p>
Regulatory compliance	<p>The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant provided information for the following air emission and wastewater permits:</p> <ol style="list-style-type: none"> (1) Air permits: Synthetic Minor Air Pollutant Source Operating Permits (permit numbers 81-2 through 81-4, 81-6, 81-8, 81-9 through 81-10) issued by the Metropolitan Government of Nashville and Davidson County, Public Health Department. These air permits place limits on air emissions and production capacities, and require submittal of compliance data to the local agency. (2) Wastewater permit: Industrial User Wastewater Discharge Permit, issued in accordance with applicable Metropolitan Government of Nashville and Davidson County regulations, which will expire in November 2021. The permit requires compliance with the relevant effluent limitations (40 CFR 400-699) to ensure the wastewater is of a certain quality for effective treatment at the POTW facility. The applicant stated that the facility submits regular discharge monitoring reports to the County. <p>The Agency's search of EPA's Enforcement and Compliance History Online (ECHO) did not reveal any violations of the federal environmental laws and regulations.⁶ 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.</p>

5.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with manufacturing under the proposed actions, would lead to cumulative impacts. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017, the U.S. Smokeless Tobacco's manufacturing facility in Nashville, Tennessee released 17,153 pounds of ammonia and 235 pounds of nicotine and nicotine salts to air (totaling 17,388 pounds) and transferred 40,409 pounds of ammonia and nicotine and nicotine salts to Central

⁵ EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000370820>. Accessed January 9, 2019.

⁶ EPA ECHO Detailed Facility Report: U S Smokeless Tobacco Manufacturing Co LLC. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000370820>. Accessed January 9, 2019.

Wastewater Treatment Plant (Table 1),⁷ constituting 14% of TRI releases in Davidson County.⁸ No other hazardous air pollutants were reported. Ammonia adversely affects ocular and respiratory systems; nicotine and nicotine salts have known adverse developmental effects.⁹ The TRI database search did not show that the U.S. Smokeless Tobacco manufacturing facility disposed of, treated, or released into the environment any other toxicants associated with manufacturing tobacco products. In addition, EPA’s ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at U.S. Smokeless Tobacco Facility in 2017

Production-Related Waste Managed or Released		Chemical Mass (Pounds)	
Recycled		17,970	
Energy Recovery		0	
Treated		102,420	
<i>Subtotal Waste Managed</i>		<i>120,390</i>	
On-site Release	Air	Ammonia	17,153
		Nicotine and Salts	235
	Water	Ammonia	0
		Nicotine and Salts	0
	Land	Ammonia	0
		Nicotine and Salts	0
Off-site Disposal/Release		40,409	
<i>Subtotal Waste Released</i>		<i>57,797</i>	
Total Production-Related Waste		178,187	

5.4 Impacts of No-Action Alternative

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

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products

The Agency evaluated potential environmental impacts that may be caused by use of the new products and found no significant impacts.

⁷ U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched December 20, 2018.

⁸ U.S. EPA. <https://myrtk.epa.gov/info/report.jsp?IDT=TRI&ID=37203STBCC800HA>. The site allows for searching the industrial facilities that manage toxic waste chemicals. Accessed January 9, 2019.

⁹ Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

6.1 Affected Environment

The affected environment includes human and natural environments in the United States; the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

6.2 Analysis of Potential Environmental Justice Impacts

The Agency evaluated the proposed actions for potential environmental impacts from use of the new products based on Agency-gathered information and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new products are likely 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 would be expected.

6.3 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with the use of the new products under the proposed actions.

6.4 Impacts of No-Action Alternative

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

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency evaluated potential environmental impacts that may be caused by disposal of the new products and found no significant impacts.

7.1 Affected Environment

The affected environment includes human and natural environments in the United States; the marketing orders would allow the new tobacco products to be sold to consumers nationwide who would dispose of the used products 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
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Biological resources	Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect biological resources. Improper disposal (littering) of the used new products could lead to terrestrial wildlife having direct exposure and hazardous substances leaching to aquatic environments and soils. However, no net increases in littering would be expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products (Confidential Appendix 2); 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 products and packaging waste.
Water resources and water quality	Proper disposal of the used new products and packaging in the municipal solid waste stream would not affect water resources. Improper disposal (littering) of the used new products could result in hazardous substances leaching into water systems. However, no net increase in littering would be expected because the new products would compete for the same market share occupied by currently marketed smokeless tobacco products; therefore, these impacts are not considered significant.
Solid waste and hazardous materials	The distribution of waste generated due to disposal of the new products and packaging is anticipated to correspond to the pattern of products use in the United States. However, introducing the new products into the U.S. market is not expected to increase the nationwide use and thereof disposal of smokeless tobacco products based on the Agency’s assessment; therefore, no net increase in littering would be expected.
Regulatory compliance	The new products have no features that would lead to a different rate of used products 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 existing smokeless tobacco products; therefore, these impacts are considered insignificant.

7.3 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with the disposal of the new products under the proposed actions.

7.4 Impacts of No-Action Alternative

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

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

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

Reviewer:

Hoshing W. Chang, Center for Tobacco Products

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

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

Comparison of the New Products to the Corresponding Predicate Products

STN	Component	Change from Corresponding Predicate Product
SE0015017 SE0015020 SE0015022	Tobacco in fermented tobacco	<ul style="list-style-type: none"> • Decrease in (b) (4) [REDACTED] • Addition of (b) (4) [REDACTED]
SE0015017 SE0015020 SE0015022	Ingredients in fermented tobacco	<ul style="list-style-type: none"> • Addition of (b) (4) [REDACTED] • Replacement of (b) (4) [REDACTED] (non-GRAS) with slightly higher amount of (b) (4) ¹⁰ [REDACTED] • Slight decrease in [REDACTED] • Slight increase in (b) (4) [REDACTED]

¹⁰ Generally Recognized as Safe (GRAS) is not applicable to tobacco products.

Confidential Appendix 2

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

STN	Unit	Projected Market Volumes New Product	
		First Year	Fifth Year
SE0015017	Cans	(b)	(4)
	Metric tons		
SE0015020	Cans		
	Metric tons		
SE0015022	Cans		
	Metric tons		
Total	Cans		
	Metric tons		

The applicant stated that the corresponding predicate products for the new products are currently on the market. The applicant also stated that the new and the corresponding predicate products would not be marketed simultaneously after the new products receive the marketing orders.