

**Programmatic Environmental Assessment for Marketing
Orders for Smokeless Tobacco Products Manufactured by
U.S. Smokeless Tobacco Company LLC**

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

May 17, 2019

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1. Applicant and Manufacturer Information

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

2. Product Information

New and Predicate Products

New Product STN	New Product Name	Predicate Product Name	Predicate Product STN
SE0015123	Husky Long Cut Wintergreen	Husky Long Cut Wintergreen	GF1200201
SE0015124	Skoal Bandits Mint	Skoal Bandits Mint	GF1200069
SE0015125	Skoal Pouches Apple Tobacco Blend	Skoal Pouches Apple Blend	GF1200226

Product Identification

New Product Name	Product Category	Sub Category	Retail Unit g/Can	Product Package
Husky Long Cut Wintergreen	Smokeless	Non-Portioned	34.02 grams/can	Plastic Can/Plastic Lid
Skoal Bandits Mint	Smokeless	Portioned	18.25 grams/can	Plastic Can/Metal Lid
Skoal Pouches Apple Tobacco Blend	Smokeless		23.25 grams/can	Plastic Can/Metal Lid

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 after finding the new tobacco products substantially equivalent to the corresponding predicate products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The predicate products are grandfathered products that were on the market as of February 15, 2007.

The Agency shall issue marketing orders if, after considering the substantial equivalence (SE) reports and amendments submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products.

The new and corresponding predicate products are different only in an ingredient (Confidential Appendix 1). The applicant provided first- and fifth-year marketing projections for the new products (Confidential Appendix 2).

4. Alternatives to the Proposed Actions

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

5.1. Affected Environment

The new products would be manufactured at the U.S. Smokeless Tobacco Company LLC facility at 800 Harrison St., Nashville, TN 37203 (Figure 1). The facility is within an industrial park in downtown Nashville, with a rail road spur along its southern perimeter, an iron fabricator and Goodwill Industries headquarters to the west and north, offices and parking lots to the north, and a five-lane road to the east with the Nashville Farmers Market building on the other side of the road.

Figure 1. Location of the Manufacturing Facility



5.2. Analysis of Potential Environmental Impacts

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

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing of the new products would lead to the same or similar air emissions as those associated with current smokeless product production at the facility and would not require a new or revised permit.
Water resources	The applicant stated that manufacturing the new products would lead to the same or similar wastewater discharges as those associated with current smokeless tobacco product production at the 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 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 of 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.
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 there would be no facility expansion or increase in the net production volume at the facility. Therefore, no socioeconomic effects (beneficial or adverse) would occur as a direct impact from manufacturing the new products.
Solid waste and hazardous materials	The applicant stated that manufacturing the new products would have no expected changes on manufacturing waste. The product modification includes a change to one ingredient. 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 the new products. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact from manufacturing the new products.
Environmental Justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations that live near the manufacturing facility.
Regulatory compliance	The applicant stated that the manufacturing facility complies with the Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act; the applicant stated that manufacturing the new products would not change the facility's compliance with relevant federal, state, and local environmental regulations. The applicant provided detailed information for the following wastewater discharge permit: Industrial User Waste Water Discharge Permit (CP-0286), issued in accordance with applicable Metropolitan Government of Nashville and Davidson County regulations, would be expired November 1, 2021. The Agency's search for the manufacturing facility in the U.S. Environmental Protection Agency's Enforcement and Compliance History Online database did not reveal any violations of environmental laws and regulations.

5.3. Cumulative Impacts

The Agency does not anticipate the proposed actions to incrementally increase or change the chemicals released to the environment from the facility's tobacco. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2017 the USSTC facility in Nashville, TN (1) recycled 17,970 pounds of ammonia and nicotine and nicotine salts, (2) treated 102,420 pounds both chemicals, and (3) released 57,367 pounds of both chemicals to the air and to Metro Central Wastewater Treatment Plant. Out of the amount released, 1,395 pounds of both chemicals transferred to the wastewater treatment plant (Table 1).¹ No other hazardous air pollutants were reported. Nicotine and nicotine salts have known adverse developmental effects and ammonia has been proven to adversely affect the respiratory system. 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 reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database² 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 the U.S. Smokeless Tobacco facility in 2017

Production-Related Waste Managed	Chemical Mass (Pounds)
Recycled	17,970
Treated	102,420
Released	57,367

5.4. Impacts from No-Action Alternative

The no-action alternative would not change the existing manufacturing of other smokeless tobacco at the U.S. Smokeless Tobacco Company facility, as many similar tobacco products would continue to be manufactured at the facility.

6. Potential Environmental Impacts of the Proposed Actions and the 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.

¹ U.S. Environmental Protection Agency (EPA). TRI Available at: <https://www3.epa.gov/enviro/facts/tri/efacilities/#/Facility/37203STBCC800HA>
Searched January 14, 2019.

² 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 14, 2018.

6.1. Affected Environment

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

6.2 Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from use 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 is expected.

6.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the use of the new products.

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 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 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 is the entire United States because the marketing orders would allow the new tobacco products to be sold to consumers in the United States 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 proposed actions were evaluated for potential environmental impacts from disposal based on Agency-gathered information and the applicant’s submitted information.

Environmental Resource	Analysis of Potential Impacts
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 soil. However, no net increase in littering is 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.
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	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 is 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.
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 not considered significant.

7.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the disposal of the new tobacco products.

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 tobacco products would continue to be marketed and therefore disposed of.

8. List of Preparers

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

Preparer:

Thomas Creaven, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biology/Neuroscience

Experience: Three years in NEPA document review, ten years in chemistry/physics education

Expertise: NEPA document review, chemistry/physics education

Reviewer:

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

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

Experience: Nine 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: Difference between the New and Predicate Products

The differences between the new and corresponding predicate products would be limited to the replacement of (b) (4) in the (b) (4) of the predicate products with an identical amount (b) (4). Additionally, a small amount of (b) (4) (b) (4) would be added to the (b) (4) component of the new products.

³ Generally recognized as safe, GRAS, is a designation for food additives and is not applicable to tobacco products.

Confidential Appendix 2: Marketing Projections for the New Products

STN	Name	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0015123	Husky Long Cut Wintergreen	Cans	(b) (4)	
		Metric tons		
SE0015124	Skoal Bandits Mint	Cans		
		Metric tons		
SE0015125	Skoal Pouches Apple Tobacco Blend	Cans		
		Metric tons		