

**Programmatic Environmental Assessment for Five Loose Moist
Snuff Products by U.S. Smokeless Tobacco Company LLC**

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

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Table of Contents

1.	Applicant and Manufacturer Information.....	3
2.	Product Information.....	3
3.	The Need for the Proposed Actions	3
4.	Alternative to the Proposed Actions.....	4
5.	Potential Environmental Impacts of the Proposed Actions and the Alternative - Manufacturing the New Products.....	4
5.1	Affected Environment.....	4
5.2	Analysis of Potential Environmental Impacts	5
5.3	Cumulative Impacts	5
5.4	Impacts from No-Action Alternative.....	6
6.	Potential Environmental Impact of the Proposed Actions and the Alternative - Use of the New Products	6
6.1	Affected Environment.....	6
6.2	Analysis of Potential Environmental Impacts	6
6.3	Cumulative Impacts	6
6.4	Impacts from No-Action Alternative.....	6
7.	Potential Environmental Impact of the Proposed Actions and the Alternative - Disposal of the New Products	6
7.1	Affected Environment.....	7
7.2	Analysis of Potential Environmental Impacts	7
7.3	Cumulative Impacts	7
7.4	Impacts from No-Action Alternative.....	7
8.	List of Preparers	8
9.	List of Agencies and Persons Consulted.....	8
	Confidential Appendix 1: Difference Between the New and Predicate Products	9
	Confidential Appendix 2: Marketing Projections for the New Products	10

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 St. Nashville, TN 37203

2. Product Information

New and Predicate Products

New Products	STN	Predicate Products	STN
Husky Fine Cut Wintergreen	SE0014544	Husky Fine Cut Wintergreen	GF1200197
Husky Long Cut Straight	SE0014545	Husky Long Cut Straight	GF1200200
Husky Long Cut Mint	SE0014546	Husky Fine Cut Mint	GF1200198
Husky Long Cut Natural	SE0014547	Husky Fine Cut Natural	GF1200199
Husky Fine Cut Natural	SE0014548	Husky Fine Cut Natural	GF1200196

Product Identification

Product Category	Smokeless
Product Subcategory	Loose Moist Snuff
Product Package	34.02 g loose moist snuff per can

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, is 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 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 predicate products are grandfathered products that were on the market as of February 15, 2007.

The new products differ from the corresponding predicate products in a change in an ingredient (Confidential Appendix 1). The applicant provided first- and fifth-year marketing projections for the new products (Confidential Appendix 2).

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not authorize marketing of the new tobacco products in the United States.

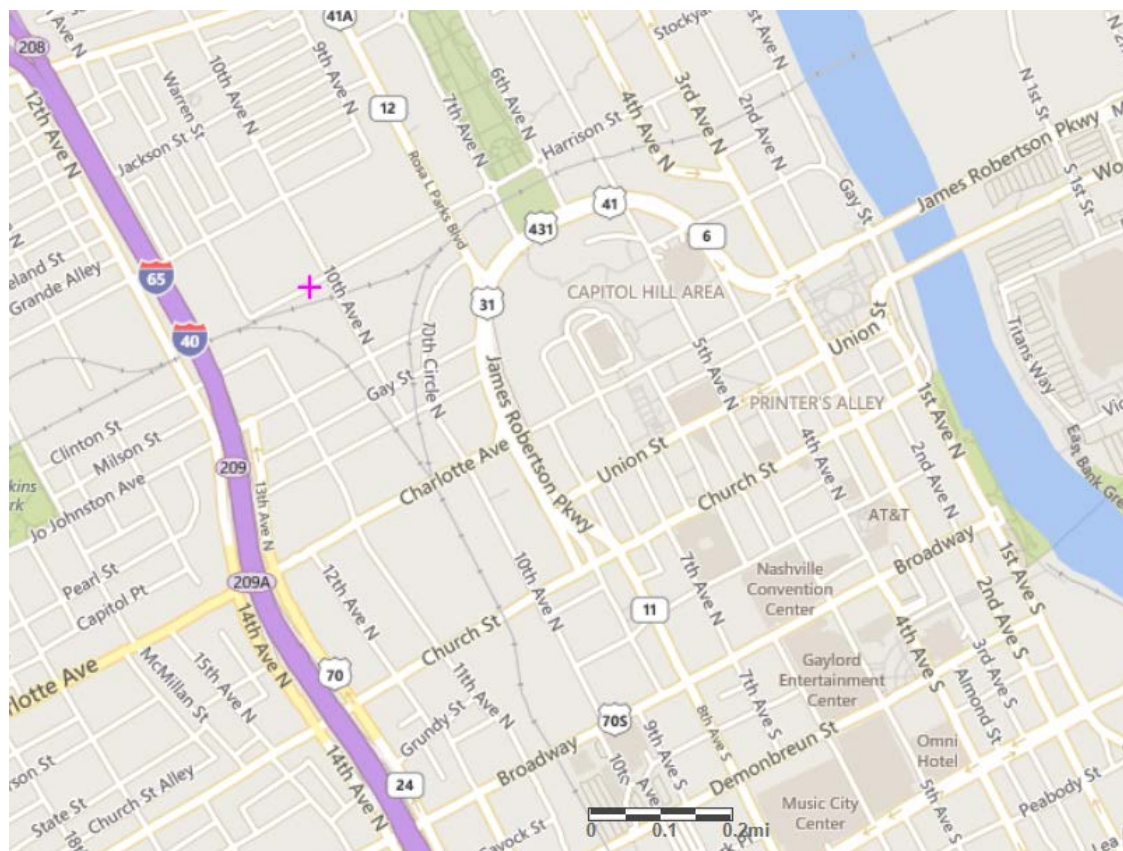
5. Potential Environmental Impacts of the Proposed Actions and the Alternative - Manufacturing the New Products

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 are manufactured at the U.S. Smokeless Tobacco Company LLC facility at 800 Harrison St., Nashville, TN 37203 (Figure 1).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.

Figure 1. Location of the manufacturing facility (crosshairs)



¹ NEPAassist. (2018). *Map of 800 Harrison St., Nashville, TN 37203*. Retrieved June 29, 2018, from nepassist.epa.gov/nepassist/nepamap.aspx.

5.2 Analysis of Potential Environmental Impacts

The proposed actions were evaluated 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 the new products would lead to the same or similar air emissions as manufacturing the corresponding predicate products 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 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 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; manufacturing 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 due to the new products. 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 minimal or no impact on total manufacturing waste. The new products differ from the corresponding predicate products due to a change in 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 manufacturing the new products.
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 relevant federal, state, and local environmental regulations.

5.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions.

5.4 Impacts from No-Action Alternative

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

6. Potential Environmental Impact of the Proposed Actions and the Alternative - 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.

6.1 Affected Environment

The affected environment is the entire United States because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

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 proposed actions.

6.4 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 smokeless tobacco products would continue to be marketed and therefore used.

7. Potential Environmental Impact of the Proposed Actions and the Alternative - 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 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 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 increases in littering are 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 increases in littering are 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 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 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 proposed actions.

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 smokeless 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 environmental assessment:

Preparer:

Shannon K. Hanna, Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Four years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment, and water quality

Reviewer:

Hoshing W. Chang, 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 new products contain (b) (4) that is generally recognized as safe (GRAS)² while the predicate products contain non-GRAS (b) (4)

² The generally recognized as safe (GRAS) designation does not apply to tobacco products.

Confidential Appendix 2: Marketing Projections for the New Products

STN	Name	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0014544	Husky Fine Cut Wintergreen	Cans	(b) (4)	
		Metric tons		
SE0014545	Husky Long Cut Straight	Cans		
		Metric tons		
SE0014546	Husky Long Cut Mint	Cans		
		Metric tons		
SE0014547	Husky Long Cut Natural	Cans		
		Metric tons		
SE0014548	Husky Fine Cut Natural	Cans		
		Metric tons		

The applicant stated that the predicate products are not currently marketed and that they do not intend to market the predicate products simultaneously with the new products.