

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

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

September 5, 2018

Table of Contents

1. Applicant and Manufacturer Information..... 3

3. The Need for the Proposed Actions 4

4. Alternatives to the Proposed Action 4

5. Potential Environmental Impacts of the Proposed Action and the Alternatives – Manufacturing the New Products..... 4

5.2 Analysis of Potential Environmental Impacts..... 5

5.3 Regulatory Compliance 7

5.4 Cumulative Impacts..... 7

5.5 Impacts from No Action Alternative 8

6. Potential Environmental Impact of the Proposed Actions and the Alternative - Use of the New Products 8

6.1 Affected Environment 8

6.2 Analysis of Potential Environmental Justice Impacts..... 8

6.3 Cumulative Impacts..... 8

6.4 Impacts from No-Action Alternative 8

7. Potential Environmental Impact of the Proposed Actions and the Alternative - Disposal of the New Products 8

7.1 Affected Environment 9

7.2 Analysis of Potential Environmental Impacts..... 9

7.3 Cumulative Impacts..... 9

7.4 Impacts from No-Action Alternative 10

8. List of Preparers 10

9. List of Agencies and Persons Consulted..... 10

Confidential Appendix 1: Difference Between the New and Predicate Products 11

1. Applicant and Manufacturer Information

Applicant Name:	U.S. Smokeless Tobacco
Applicant Address:	C LLC 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

Product Name	New Product STN	Predicate Product Name	Predicate Product STN
Copenhagen Pouches	SE0014494	Copenhagen Pouches	GF1200193
Copenhagen Snuff Fine Cut	SE0014495	Copenhagen Snuff Fine Cut	GF1200194
Copenhagen Long Cut Black	SE0014496	Copenhagen Long Cut Black	GF1200191
Copenhagen Long Cut Straight	SE0014497	Copenhagen Long Cut Straight	GF1200192
Copenhagen Long Cut	SE0014498	Copenhagen Long Cut	GF1200190

Product Identification

New Product Name	Product Category	Sub Category	Retail Unit g/Can	Product Package
Copenhagen Pouches	Smokeless	Portioned	23.25 (15 pouches)	Fiberboard base with metal lid
Copenhagen Snuff Fine Cut	Smokeless	Loose non-portioned	34.02	Fiberboard base with metal lid
Copenhagen Long Cut Black	Smokeless			Polypropylene base with metal lid
Copenhagen Long Cut Straight	Smokeless			Fiberboard base with metal lid
Copenhagen Long Cut	Smokeless			Fiberboard base with metal lid

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for 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) report and its 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 FDA does not issue marketing orders for the new tobacco products in the United States.

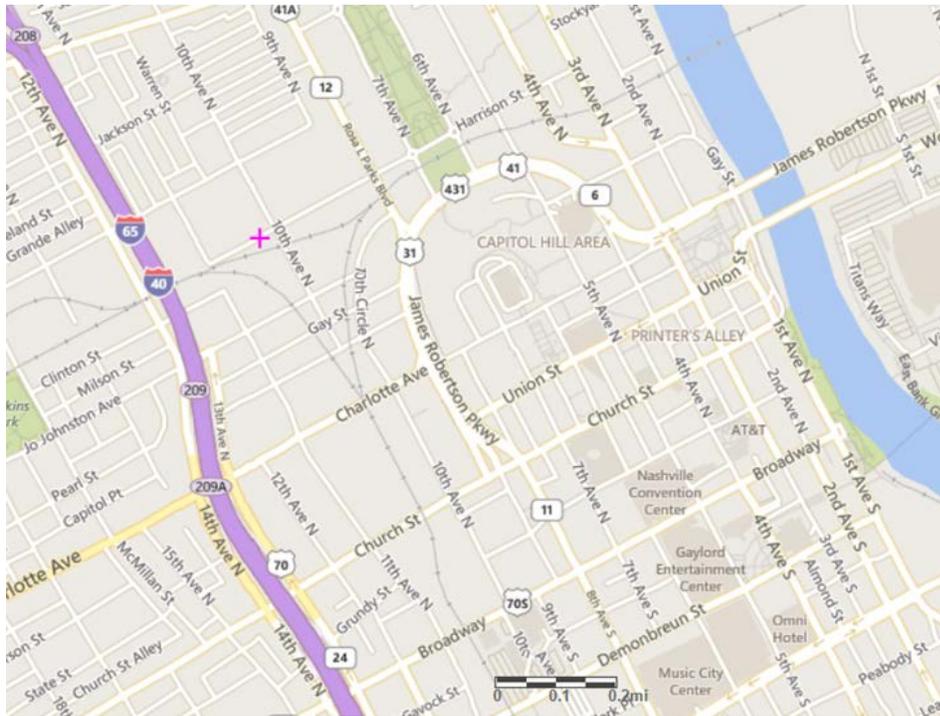
5. Potential Environmental Impacts of the Proposed Actions and the Alternatives – Manufacturing the New Products

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 are manufactured at the U.S. Smokeless Tobacco Company LLC facility at 800 Harrison St., 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 Lower Cumberland-Sycamore watershed.

Figure 1. Location of the Manufacturing Facility (crosshairs)



5.2 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
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.

5.3 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant provided detailed information for the following air permit:

Synthetic Minor Air Pollutant Source Operating Permit, issued in accordance with applicable Metropolitan Government of Nashville and Davidson County regulations, will be expired December 2018.

5.4 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 2016, the U.S. Smokeless Tobacco's manufacturing facility in Nashville, Tennessee released 154 pounds nicotine and nicotine salts to the air and transferred 622 pounds of nicotine and nicotine salts to Metro Central Wastewater Treatment Plant (Table 1).¹ No other hazardous air pollutants were reported. Nicotine and nicotine salts have known adverse developmental effects. 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 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 2016

Production-Related Nicotine and Salts Managed or Released		Chemical Mass (Pounds)
Recycled		4,834
Energy Recovery		0
Treated		403
Subtotal Waste Managed		5,237
On-site Release	Air	154
	Water	0
	Land	0
Off-site Disposal/Release		63,622
Subtotal Waste Released		63,776
Total Production-Related Waste		69,013

¹ U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched July 6, 2018.

² EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed July 6, 2018.

5.5 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 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 Justice 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 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 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:

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: 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: Difference Between the New and Predicate Products

The new products contain rose oil that is generally recognized as safe (GRAS)³ while the predicate products contain non-GRAS (b) (4)

³ 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
SE0014494	Copenhagen Pouches	Cans	(b)	(4)
		Metric tons		
SE0014495	Copenhagen Snuff Fine Cut	Cans		
		Metric tons		
SE0014496	Copenhagen Long Cut Black	Cans		
		Metric tons		
SE0014497	Copenhagen Long Cut Straight	Cans		
		Metric tons		
SE0014498	Copenhagen Long Cut	Cans		
		Metric tons		