

**Environmental Assessment for a Marketing Order for a New
Smokeless Tobacco Product Manufactured by
U.S. Smokeless Tobacco Company LLC**

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

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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 Bay 10, 2303 Bells Road Richmond, VA 23234

2. Product Information

New Product	STN	Predicate Product
Copenhagen Long Cut Special Mint	SE0015280	Skoal Long Cut Mint

Product Category	Smokeless
Product Subcategory	Loose Moist Snuff
Product Quantity per Retail Unit	34.02 g loose moist snuff per can
Product Package	Polypropylene can capped with metal lid, paper side label, polyethylene shrink film per 5 can log roll, 18 log rolls per corrugated board shipping case.

3. The Need for the Proposed Actions

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. 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. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new product differs from the predicate product in moisture content, tobacco, and ingredients added (Confidential Appendix 1).

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 Alternatives - Manufacturing the New Product

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

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the two manufacturing facilities. The new product would be manufactured at the U.S. Smokeless Tobacco Company LLC (USSTC) facilities located at 800 Harrison St., Nashville, TN, 37203 and Bay 10, 2303 Bells Road, Richmond, VA, 23234 (Figure 1).

The Tennessee 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} Bay 10, located in Richmond VA, is in a mixed use industrial, commercial, and residential area, west to an interstate freeway (I-95). The facility is located in the James River watershed, which occupies the central portion of Virginia and covers 24% of total land area of the state of Virginia.³ Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.⁴

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>.

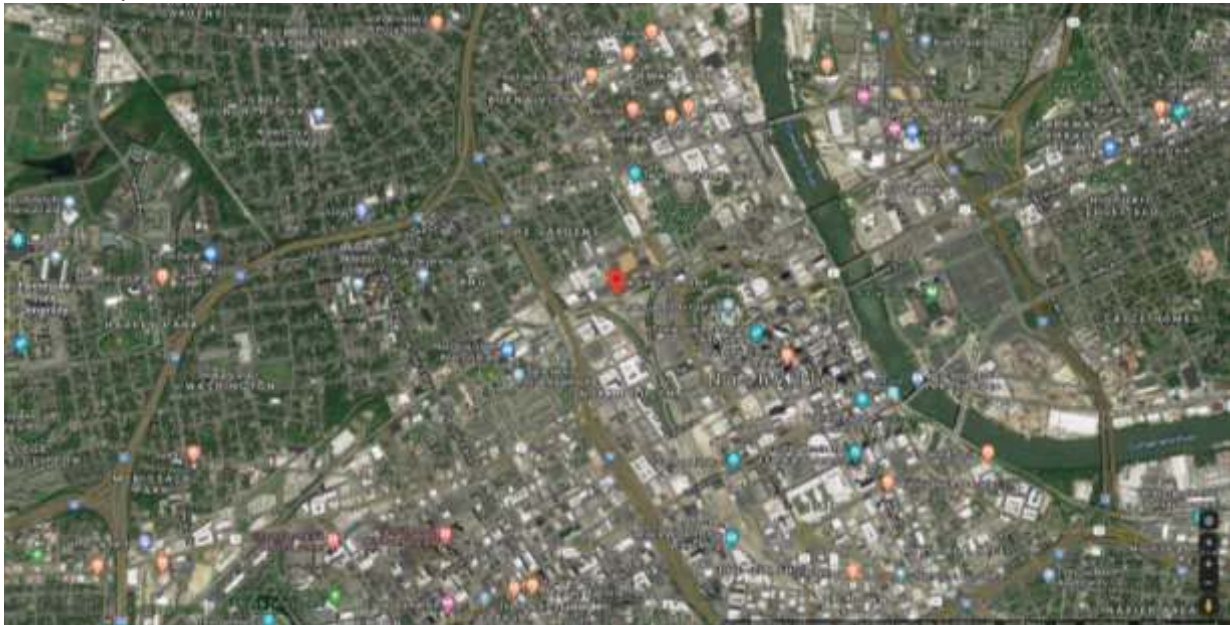
² USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed March 11, 2020.

³ Virginia Department of Environmental Quality. Available at: <http://deq.state.va.us/Portals/0/DEQ/Water/SWRP/App%20B%20James%20River%20Basin%20Summary.pdf>. Accessed March 11, 2020

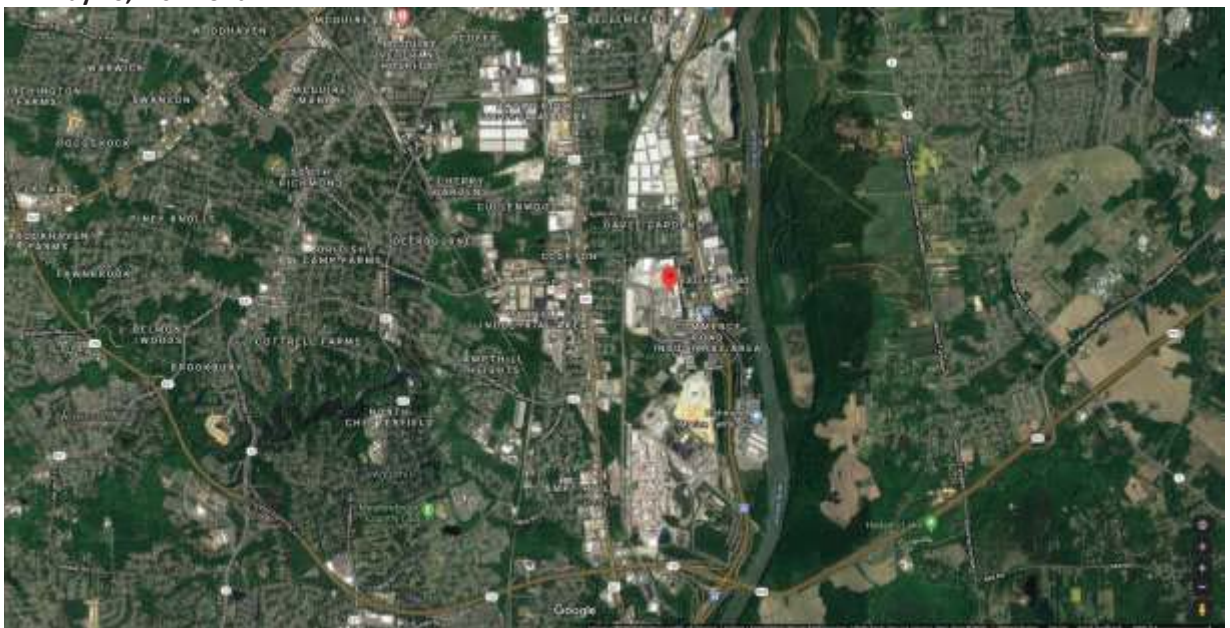
⁴ Ibid.

Figure 1. Location of the Manufacturing Facility

A. USSTC, Nashville TN⁵



B. Bay 10, Richmond VA⁶



⁵ Google. 2020. Map of 800 Harrison St., Nashville, TN, 37203. Retrieved from Google Maps: www.google.com/maps. March 11, 2020.

⁶ Ibid.

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from manufacturing the new product 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 product is not expected to result in changes in the types of air emissions from the manufacturing facilities and would not require new or revised permits.
Water resources	The applicant stated that manufacturing the new product is not expected to result in changes in the types of water discharges from the manufacturing facilities and would not require new or revised permits.
Soil, land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, no changes in soil, land use or zoning would occur as a direct impact from the proposed action.
Biological resources	The applicant stated that there would be no facility expansion due to manufacturing the new product and that manufacturing the new product would not result in changes in types of air emissions or water discharges. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new product.
Socioeconomic conditions	The applicant stated that there would be no facility expansion or changes in types of air emissions or water discharges at the facility. Therefore, no socioeconomic effects (beneficial or adverse) would occur as a direct impact from manufacturing the new product.
Environmental justice	Because no significant environmental impacts were identified, there would be no disproportionate impacts to environmental justice populations that live near the manufacturing facilities.
Solid waste and hazardous materials	The applicant stated that manufacturing the new product is not expected to result in emissions of new or additional compounds from the manufacturing facilities. Additionally, the applicant stated that no material changes in solid waste generation are expected to result from manufacturing the new product. Therefore, the Agency does not anticipate that manufacturing the new product 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 manufacturing the new product. Therefore, no effects to floodplains, wetlands, or coastal zones would occur as a direct impact of manufacturing the new product.

Environmental Resource	Analysis of Potential Impacts
Regulatory compliance	<p>The applicant stated that the manufacturing facilities are in compliance with the Clean Air Act, Clean Water Act and the Resource Conservation and Recovery Act along with relevant federal, state, and local environmental regulations. The applicant provided information for the following air emission and wastewater permits:</p> <p>(1) Air permits:</p> <ul style="list-style-type: none"> a) Nashville TN facility – 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. b) Bay 10 facility, Richmond VA – Stationary Source Permit to Construct and Operate issued by the Virginia Department of Environmental Quality (VA DEQ) under Registration No.: 52609. The air permit was issued in accordance with applicable USEPA and VA DEQ regulations, and places limits on air emissions and production capacities or annual smokeless tobacco throughputs. <p>(2) Wastewater permits:</p> <ul style="list-style-type: none"> a) Nashville TN facility – 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. b) Bay 10 facility, Richmond VA – covered under the existing regulatory permit for the PM USA Manufacturing Center Complex. Industrial user wastewater pretreatment permit (permit number 2149) from the City of Richmond POTW facility. The permit requires compliance with effluent limitations (40 CFR 400-699) and requires monitoring 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 VA DEQ. <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 at the listed facilities.^{7,8} The applicant also stated that each 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 does not anticipate the proposed action would incrementally increase or change the chemicals released to the environment from the facilities' tobacco manufacturing. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2018, the U.S. Smokeless Tobacco's manufacturing facility in Nashville, Tennessee released 231 pounds of nicotine and nicotine salts to air (Table 1).⁹ No other hazardous air pollutants were reported. The Richmond facility was not found in the ECHO database under the address provided, however, the Philip Morris USA facility occupies the same space but has a different address, 3601 Commerce Road, Richmond, VA 23234. Philip Morris and USSTC are corporate entities under the parent company, Altria.

A search in the EPA's TRI database showed that in 2018, the Philip Morris USA manufacturing facility in Richmond, Virginia released 10,313 pounds of nicotine and nicotine salts to air, but released no other hazardous air pollutants at reportable levels (Table 2).¹⁰ Nicotine and nicotine salts have known adverse developmental effects.¹¹ The TRI database search did not show that the U.S. Smokeless Tobacco manufacturing facilities 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 facilities 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 Facilities in 2018

Production-Related Waste Managed or Released			Chemical Mass (Pounds)	
			USSTC Nashville TN	Bay 10 Richmond VA
Recycled			18,345	122,530
Energy Recovery			0	0
Treated			671	94,266
<i>Subtotal Waste Managed</i>			<i>19,016</i>	<i>216,796</i>
On-Site Release	Air	Ammonia	0	0
		Nicotine and Nicotine Salts	231	10,313
Off-Site Disposal/Release			32,382	35,528
<i>Subtotal Waste Released</i>			<i>32,613</i>	<i>45,841</i>
Total Production-Related Waste			51,398	262,637

⁷ 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 15, 2020.

⁸ EPA ECHO Detailed Facility Report: Philip Morris USA Tobacco Co. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed January 15, 2020

⁹ U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched January 15, 2020.

¹⁰ U.S. Environmental Protection Agency (EPA). TRI Data Form R & A Download. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched on January 15, 2020.

¹¹ Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

5.4 Impacts from 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 at the listed facilities.

6. Potential Environmental Impacts of the Proposed Action and Alternatives - Use of the New Product

The Agency evaluated potential environmental impacts that 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 Agency-gathered information and the applicant's submitted information.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new product is 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

The Agency did not identify any actions that, when considered with the new product's use under the proposed action, would lead to cumulative impacts.

6.4 Impacts from No-Action Alternative

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

7. Potential Environmental Impacts of the Proposed Action and Alternative - Disposal of the New Product

The Agency evaluated 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 the new tobacco product to be sold to consumers nationwide who would dispose of the used new product and packaging as municipal solid waste, recycled material, or litter.

7.2 Analysis of Potential Environmental Impacts

The proposed action was 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 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 to the used product and hazardous substances leaching to aquatic environments and soil. However, no net increase in littering is 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 net increase in littering is 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.
Solid Waste	The distribution of waste generated due to disposal of the new product and packaging is expected to correspond to the pattern of product use in the United States. However, no net increase in solid waste is 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.
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 the new product disposal under the proposed action, would lead to cumulative impacts.

7.4 Impacts from No-Action Alternative

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

8. List of Preparers

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

Preparers:

Ronald Edwards, MS, Center for Tobacco Products

Education: MS in Biology

Experience: Twenty-six years in environmental regulation and laboratory toxicology

Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

Reviewer:

Gregory G. Gagliano, M.S., Center for Tobacco Products

Education: MS in Environmental Science

Experience: Thirty-seven years in environmental compliance and analysis

Expertise: Environmental toxicology, risk assessment, regulatory compliance, NEPA analysis

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1: Comparison of the New Product to the Predicate Product

SE Report	Characteristic	Change
SE0015280	Tobacco moisture content	Increased moisture content.
	Tobacco type	Decrease in (b) (4)
	Ingredients	<p>Addition of (b) (4)</p> <p>Decrease in (b) (4)</p> <p>Replace (b) (4)</p>

Confidential Appendix 2: First- and Fifth-Year Market Volume Projections for New Product

STN	New Product	Unit	Market Volume	
			First-Year Projection	Fifth-Year Projection
SE0015280	Copenhagen Long Cut Special Mint	Cans	(b) (4)	
		Metric Tons		

The applicant stated that the predicate product is not currently on the market, but that they reserve the right to market the predicate product in the future.