

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

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

August 7, 2020

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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 Addresses:	800 Harrison Street Nashville, TN 37203 ----- 2303 Bells Road, Bay 10 Richmond, VA 23234

2. Product Information

New Product Name, Submission Tracking Number (STN), and Predicate Product Name

New Product Name	STN	Predicate Product Name
Copenhagen Long Cut Reserve	SE0015412	Copenhagen Long Cut Smooth Wintergreen

Product Identification

Product Category	Smokeless
Product Subcategory	Loose Moist Snuff
Product Quantity per Retail Unit	34.02 grams loose moist snuff per can
Product Package	Polypropylene can bottom with a metal lid, paper side-label, polyethylene overwrap, and cardboard shipping case.

3. The Need for the Proposed Action

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 the marketing order. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product. The predicate product was found substantially equivalent (SE0014987) by FDA and received a marketing order on February 26, 2019.

The new product differs from the predicate product due to changes in ingredients (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 the Alternative – Manufacturing the New Product

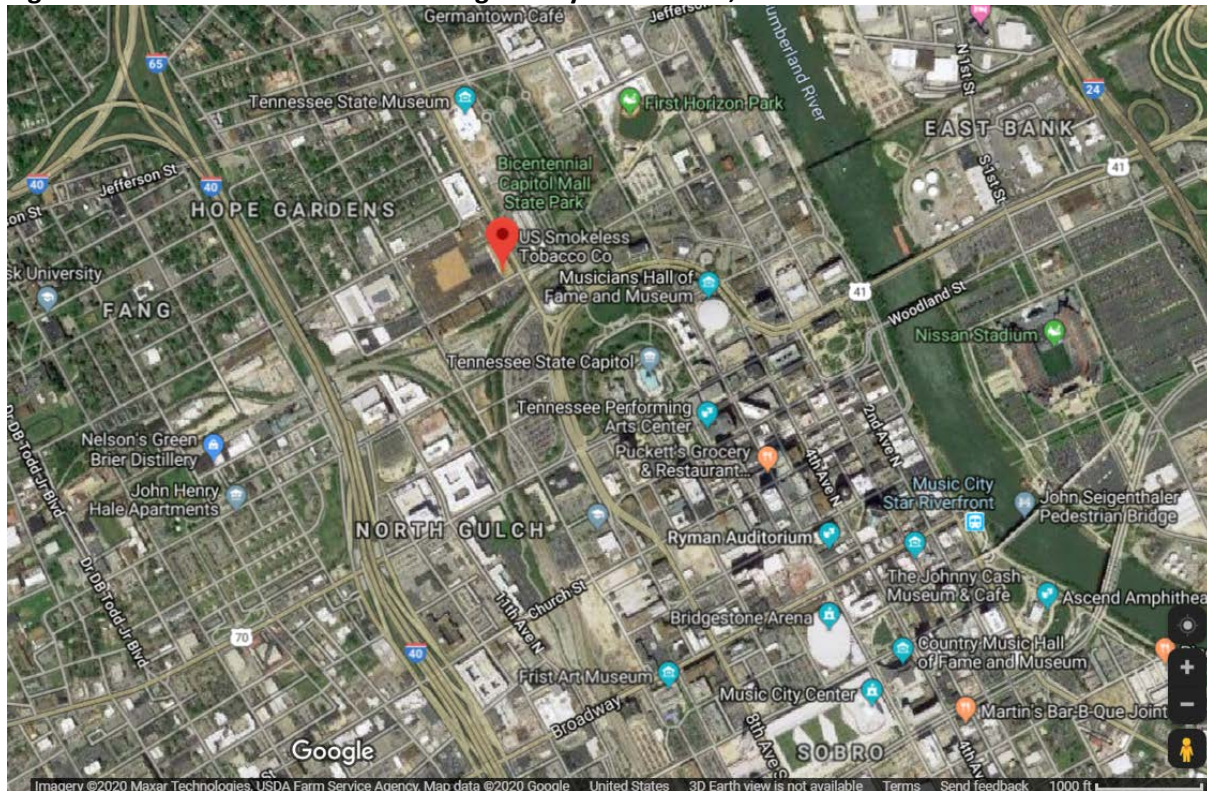
The Agency evaluated potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facilities. The new product would be manufactured by two U.S. Smokeless Tobacco Company LLC (USSTC) facilities located at 800 Harrison St., Nashville, TN, 37203 (Figure 1) and 2303 Bells Rd., Bay 10, Richmond, VA, 23234 (Figure 2).

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 65.¹ The facility is located in the Lower Cumberland-Sycamore watershed.^{2,3}

Figure 1. Location of the Manufacturing Facility in Nashville, TN



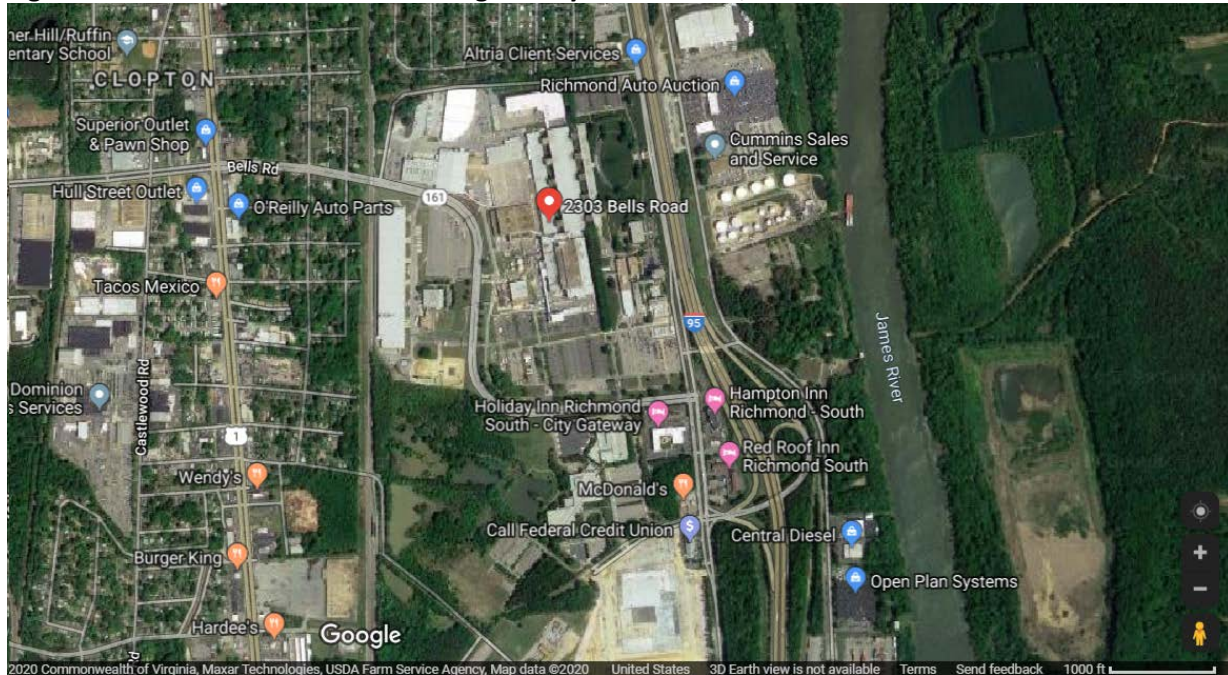
¹ Google. 2020. Map of 800 Harrison Street, Nashville, TN 37203. Retrieved from Google Maps: www.google.com/maps. July 27, 2020.

² 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>.

³ USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed July 27, 2020.

The Bay 10 facility in Richmond, VA is in a mixed use industrial, commercial, and residential area west of interstate I-95.⁴ 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.⁵ Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.⁶

Figure 2. Location of the Manufacturing Facility in Richmond, VA



5.2 Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from manufacturing the new product based on Agency-gathered information and the applicant-submitted information, including projected market volumes for the new and predicate products (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new product would have the same or similar air emissions as those associated with current smokeless tobacco products manufactured at the facilities and would not require a new or revised air emission permit.

⁴ Google. 2020. Map of 2303 Bells Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. July 27, 2020

⁵ 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 July 27, 2020.

⁶ Ibid.

Water resources and water quality	The applicant stated that manufacturing the new product would not lead to changes in wastewater discharges from the manufacturing facilities and would not require a new or revised wastewater discharge permit.
Land use and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, no changes in 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. The applicant reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps. According to the maps, 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, TN. ^{7,8} The U.S. FWS maps also showed three threatened species (two plants, and one northern long-eared bat), and one endangered freshwater mussel species are listed in the city of Richmond and the bordering counties (Henrico and Chesterfield Counties). ⁹ However, the applicant stated that none of these species are found near the manufacturing facilities. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new product.
Geological features and soils	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, no effects on geological features or soils would occur as a direct impact from manufacturing the new product.
Socioeconomic conditions	No facility expansion is anticipated; therefore, no impacts would be expected on employment, state or municipal revenue and taxes, or on police force and fire department resources.
Solid waste and hazardous materials	The applicant stated that the waste generated from manufacturing the new product would be handled in the same manner as the waste generated from any other smokeless tobacco products manufactured at the facilities and in accordance with the environmental permits. The applicant also stated that no material changes in solid waste generation are expected from manufacturing the new product and no additional environmental controls would be required. 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.

⁷ 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 July 27, 2020.

⁸ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed, July 27, 2020.

⁹ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=51087>. Accessed July 27, 2020.

Environmental justice	No significant environmental impacts associated with the proposed action were identified. Therefore, no disproportionate impacts to environmental justice populations near the manufacturing facilities are anticipated
Regulatory compliance	The applicant stated that the manufacturing facilities comply with all federal, state, and local environmental regulations and provided detailed information for the facilities' air emission and wastewater permits. The applicant also stated that the facilities comply with the Endangered Species Act and the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Furthermore, 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 for the Nashville facility. ¹⁰

5.3 Cumulative Impacts

The Agency did not identify any actions that, when considered with manufacturing under the proposed action, would lead to cumulative impacts. A search in the EPA's Toxic Release Inventory (TRI) database showed that in 2018, the manufacturing facility in Nashville, TN released 235 pounds of nicotine and nicotine salts to air and transferred 32,151 pounds of nicotine and nicotine salts to Central Wastewater Treatment Plant (Table 1).¹¹ Nicotine and nicotine salts have known adverse developmental effects.¹²

Table 1. Management of Chemical Waste Associated with Manufacturing Tobacco Products at Nashville U.S. Smokeless Tobacco Facility in 2018

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			18,345
Energy Recovery			0
Treated			671
<i>Subtotal Waste Managed</i>			<i>19,016</i>
On-Site Release	Air	Nicotine and Salts	231
Off-Site Disposal/Release			32,151
<i>Subtotal Waste Released</i>			<i>32,382</i>
Total Production-Related Waste			51,398

The Richmond facility was not found in the ECHO database under the address provided; however, the facility building is located in the Philip Morris USA's (PMUSA) manufacturing center at 3601 Commerce Road, Richmond, VA 23234. Therefore, production-related releases from the USSTC manufacturing facility are included in PMUSA's toxic release data reported in the EPA's TRI database. In 2018, PMUSA

¹⁰ EPA ECHO Detailed Facility Report: U S Smokeless Tobacco Manufacturing Co LLC. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000370820>. Accessed July 27, 2020.

¹¹ U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched July 27, 2020.

¹² Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

manufacturing facility in Richmond, VA released 10,313 pounds of nicotine and nicotine salts to air (Table 2).¹³

Table 2 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Richmond Philip Morris USA Facility in 2018

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			122,530
Energy Recovery			0
Treated			94,266
<i>Subtotal Waste Managed</i>			<i>216,796</i>
On-Site Release	Air	Nicotine and Salts	10,313
Off-Site Disposal/Release			35,528
<i>Subtotal Waste Released</i>			<i>45,841</i>
Total Production-Related Waste			262,637

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.

5.4 Impacts of the No-Action Alternative

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

6. Potential Environmental Impacts of the Proposed Action and the Alternative – 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 includes human and natural environments in the United States because the marketing order would allow for the new tobacco product to be sold to consumers in the United States.

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.

¹³ See footnote # 11.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new product is expected to be used by 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 would lead to cumulative impacts when considered with the new product use under the proposed action.

6.4 Impacts of the 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 the 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 includes human and natural environments in the United States because the marketing order would allow the new tobacco product to be sold to consumers nationwide who would dispose of the used product and packaging as municipal solid waste (MSW), recycled material, or litter.

7.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from disposal of the new product 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 MSW 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 soils. However, no net increases in littering would be expected because the new product would be disposed of by consumers who use other currently marketed smokeless tobacco products. Therefore, these impacts are not considered significant.
Environmental justice	No significant environmental impacts associated with the disposal of the new product and packaging were identified. Therefore, no disproportionate impacts to environmental justice populations are anticipated.

Water resources and water quality	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 into water systems. However, no net increase in littering would be 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 and hazardous materials	The distribution of waste generated due to disposal of the new product and packaging is anticipated to correspond to the pattern of the product use in the United States. However, introducing the new product into the U.S. market is not expected to increase the nationwide use and disposal of smokeless tobacco products based on the Agency's assessment. Therefore, no net increase in littering would be expected.
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 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 product under the proposed action.

7.4 Impacts of the No-Action Alternative

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

8. List of Preparers

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

Preparers:

Susana Addo Ntim, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science

Experience: Eight years in various scientific activities

Expertise: NEPA Analysis; fate, transport and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-two years in various scientific activities including eight years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Reviewers:

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

Experience: Forty-two years in various scientific activities including eight years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

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

Education: M.S. in Environmental Science

Experience: Thirty-seven years in environmental compliance and analysis

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

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1: Changes in the New Product as Compared with the Predicate Product

STN	Component	Change from Predicate Product
SE0015412	Tobacco components	<ul style="list-style-type: none"> • Reduction in total tobacco. • Reduction in (b) (4) tobacco, (b) (4) tobacco, (b) (4) tobacco, and (b) (4) tobacco.
	Ingredients	<ul style="list-style-type: none"> • Addition of (b) (4) (b) (4), and (b) (4) • Increase in (b) (4) and (b) (4). • Reduction in the levels of 16 other ingredients added to tobacco, including (b) (4) (approximately >70%) and in (b) (4) (approximately > 50%).

Confidential Appendix 2: Market Volumes for the New and Predicate Products

STN	Unit	Market Volumes				
		Current Market Volume ¹⁴	Projected Market Volumes			
			First Year		Fifth Year	
		Predicate Product	New product	Predicate Product	New product	Predicate Product
SE0015412	Cans Metric tons	(b) (4)				

The applicant stated that they intend to continue marketing the predicate product after the marketing order for the new product is issued.

¹⁴ The applicant provided the current market volume for the predicate product for April 22, 2019 through July 20, 2019.