

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

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

February 3, 2020

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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 and 2303 Bells Rd (Bay 10) Richmond, VA, 23234

2. Product information

New and Predicate Product

New Product		Predicate Product	
STN	Name	STN	Name
SE0015402	Copenhagen Long Cut Special Wintergreen	SE0014987	Copenhagen Long Cut Smooth Wintergreen

Product Identification

Product Type	Smokeless
Product Sub-Category	Loose Moist Snuff
Product Quantity Per Unit of Sale	34.02 grams/can
Product Package	Plastic can with metal lid

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 finding the new tobacco product substantially equivalent to the predicate product 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. The predicate product was previously found substantially equivalent to a grandfathered product. FDA issued a marketing order for the predicate product on February 26, 2019. The new and predicate products would be marketed simultaneously if the agency issues a marketing order for the new product.

The Agency shall issue a marketing order if, after considering the substantial equivalence report and amendments submitted by the applicant, the new product is found substantially equivalent to the predicate product.

The new product differs from the predicate product in tobacco quantity, cut size, nicotine content, curing parameters and the ingredients added to the tobacco (Appendix 1.).

4. Alternatives 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 Alternatives – Manufacturing the New Product

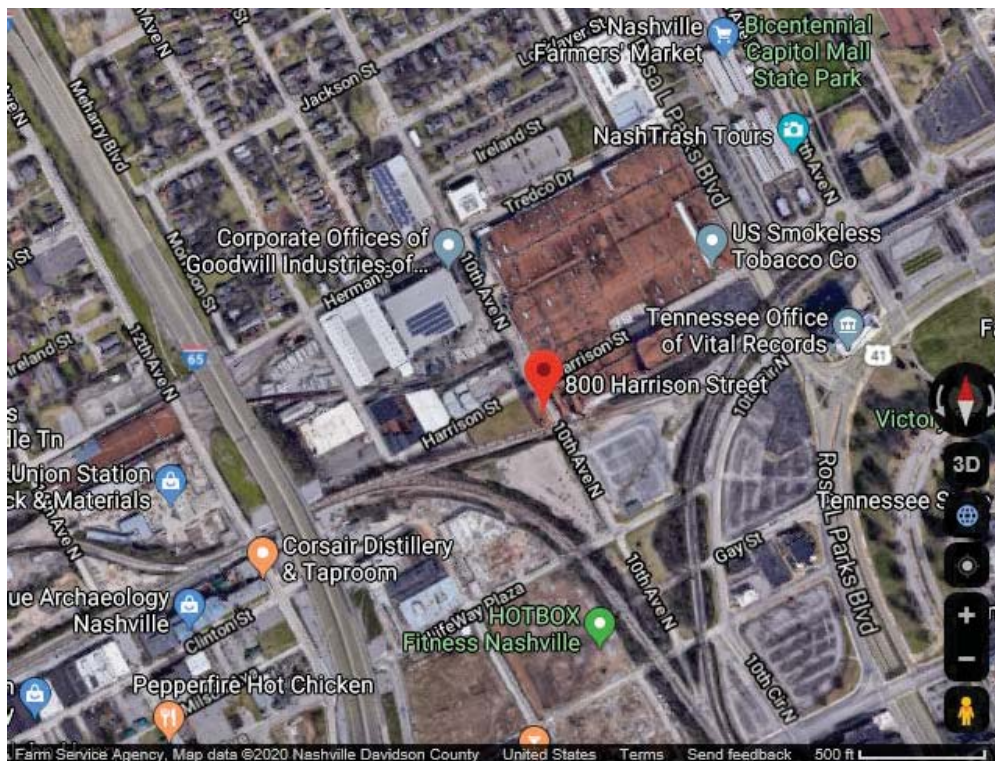
The Agency evaluated potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts.

5.1. Affected Environment

The new product would be manufactured at two USSTC operated production facilities located at 800 Harrison St., Nashville, TN, 37203 and at 2303 Bells Rd (Bay 10) Richmond, VA, 23234.

The Nashville facility is 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 Watershed¹.

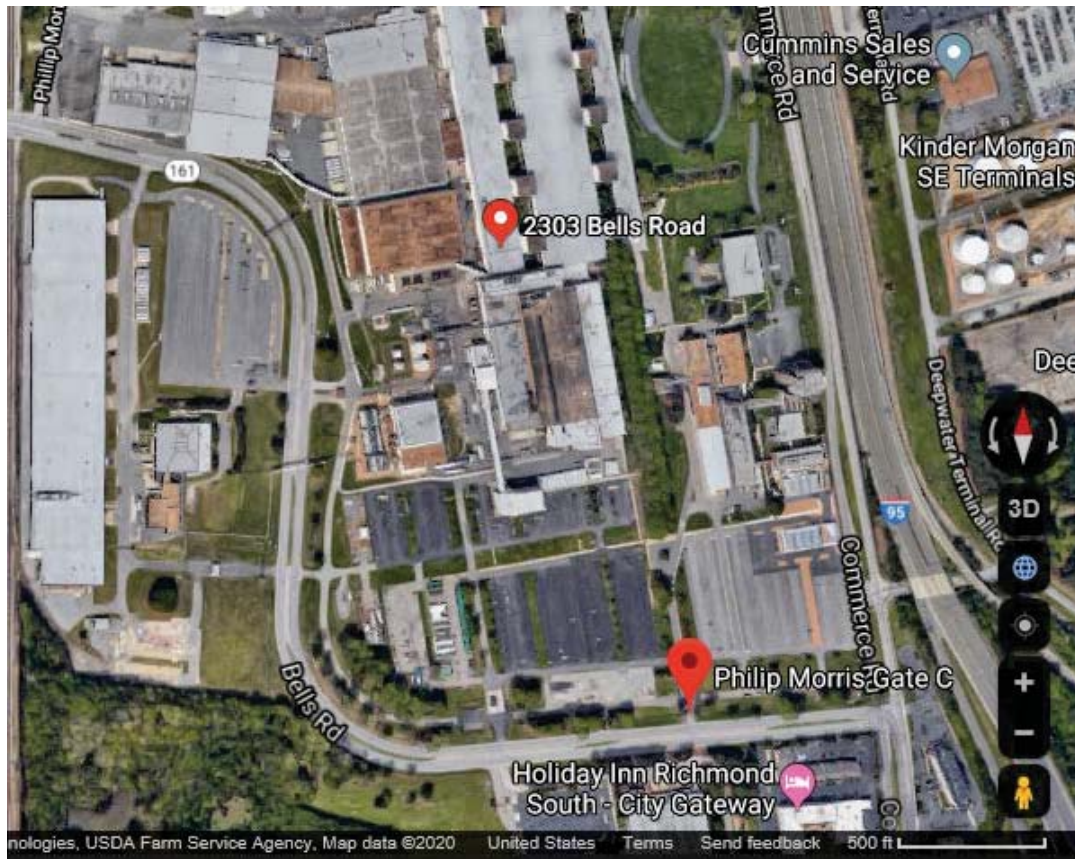
Figure 1. Location of the Nashville, TN Manufacturing Facility



¹ A watershed is an area of land where all bodies of water drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. Such bodies of water include the following: surface water from lakes, streams, reservoirs and wetlands; the underlying ground water; and rainfall, See <https://water.usgs.gov/edu/watershed.html> and <http://www.dcr.virginia.gov/soil-and-water/document/wshedguideb2b.pdf>.

The Richmond facility 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.² Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.³

Figure 2. Location of the Bay 10 facility in Richmond, VA.



5.2. Analysis of Potential Environmental Impacts

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

² 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 December 19, 2019

³ Ibid.

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 each facility and would not require a new or revised permit.
Water resources	The applicant stated that manufacturing the new product would have the same or similar wastewater discharges as products currently manufactured at each 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 product. 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 product and manufacturing the new product would not change emissions or discharges. Therefore, no effects to biological resources would occur as a direct impact from manufacturing the new product.
Soils	The applicant stated that there would be no facility expansion due to the new product. Therefore, no effects on soils would occur as a direct impact from manufacturing the new product.
Socioeconomic conditions	The applicant stated that there would be no facility expansion due to the new product. Therefore, no socioeconomic effects (beneficial or adverse) would occur as a direct impact from manufacturing the new product.
Solid waste and hazardous materials	The applicant stated that the new product would not change solid waste generation at the manufacturing facilities and waste would be disposed of in the same manner as waste generated by other smokeless tobacco products manufactured at the same facility. None of the new ingredients are hazardous materials. Therefore, no effects to solid waste or hazardous materials would occur as a direct impact from manufacturing the new product.
Floodplains, wetlands, and coastal zones	The applicant stated that there would be no facility expansion due to the new product. Therefore, no effects to floodplains, wetlands, or coastal zones 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 near the manufacturing facility.
Regulatory compliance	<p>The applicant stated that the manufacturing facilities comply with all 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> <p>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.</p> <p>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> <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.^{4,5} 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>
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5.3. Cumulative Impacts

The Agency does not anticipate the proposed action to 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).⁶ 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).⁷ Ammonia adversely affects ocular and respiratory systems; nicotine and nicotine salts have

⁴ 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.

⁵ 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

⁶ U.S. Environmental Protection Agency (EPA). TRI Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched January 15, 2020.

⁷ 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.

known adverse developmental effects.⁸ 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 Product at the U.S. Smokeless Tobacco facility 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
Subtotal Waste Managed			19,016	216,796
On-Site Release	Air	Ammonia	0	0
		Nicotine and Salts	231	10,313
Off-site Disposal/Release			32,151	35,528
Subtotal Waste Released			32,382	45,841
Total Production-Related Waste			50,582	262,637

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 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 Product

The Agency evaluated potential environmental impacts that may be caused by use of the new product and found no significant impacts based on Agency-gathered information and the applicant's submitted information.

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 Justice Impacts

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

⁸ Chemical health effects information comes from the OSHA Carcinogen List and the TRI-CHIP datasets.

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

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 conditions of smokeless tobacco products, as similar tobacco products would continue to be used in the United State.

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

The Agency evaluated the 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 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 and hazardous substances leaching to aquatic environments and soil. However, no net increases in littering are 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 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 increases in littering are expected because the new product would compete for the same market share occupied by currently marketed smokeless tobacco product; 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 existing smokeless tobacco product; 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 product.

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 E. Creaven, Center for Tobacco Products

Education: Ph.D., in Biology/Neuroscience

Experience: Ten years in science education and three years in NEPA document review

Expertise: NEPA document review and science education

Reviewer:

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

Education: MS in Environmental Science and PhD in Biochemistry

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatments

9. List of Agencies and Persons Consulted

Not applicable.

Appendix 1: Difference Between the New and Predicate Product

Component	Change from Predicate Product
Tobacco	<ul style="list-style-type: none">• Reduction in tobacco cuts per inch (b) (4)• Reduction in (b) (4) (mg/g)• Reduction in all (b) (4)• Reduction in nicotine content
Ingredients	<ul style="list-style-type: none">• Addition of (b) (4)• Addition of (b) (4)• Addition of (b) (4)• Addition of (b) (4)• Reduction in (b) (4)• Increased (b) (4) content

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

STN	New Product	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0015402	Copenhagen Long Cut Special Wintergreen	Cans	(b) (4)	
		Metric tons		

Appendix 3: In-Market Volume and the First- and Fifth-Year Market Volume Projections for the Predicate Product

STN	Predicate Product	Unit	In-Market Volume	Projected Market Volume	
			April-July 2019	First Year	Fifth Year
SE0014987	Copenhagen Long Cut Smooth Wintergreen	Cans	(b) (4)		
		Metric tons			