

**Environmental Assessment for Marketing Order for a
New Portioned Moist Snuff 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: | 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 3601 Commerce Rd (Bay 10) Richmond, VA, 23234 |

2. Product Information

New and Predicate Product

| New Product | | Predicate Product | |
|-------------|--|-------------------|------------------------------|
| STN | Name | STN | Name |
| SE0015523 | Copenhagen Premium Pouches Wintergreen | GF1200229 | Skoal Pouches Wintergreen |

Product Identification

| | |
|--|----------------------------|
| Product Type | Smokeless |
| Product Sub-Category | Portioned Moist Snuff |
| Product Quantity Per Unit of Sale | 24.00 grams/can |
| Product Package | Plastic can with metal lid |

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for U.S. 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 one new portioned moist snuff product into interstate commerce and submitted to the Agency a substantial equivalence (SE) report. The Agency shall issue a marketing order if the new product is found substantially equivalent to the predicate product. The predicate product, a grandfathered product, was marketed as of February 15, 2007. The predicate product is not currently being marketed and the applicant stated the new and predicate products would not be manufactured simultaneously after the new product receives a marketing order.

The new and predicate products differ by total tobacco weight (g), portion weight (g), pouch material, cut size and milling parameters. The fermented tobacco of the new product contains a change in rose oil and minute amounts of sodium chlorate and bright stem tobacco.

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 Impact of the Proposed Action and the Alternatives – Manufacturing the New Product

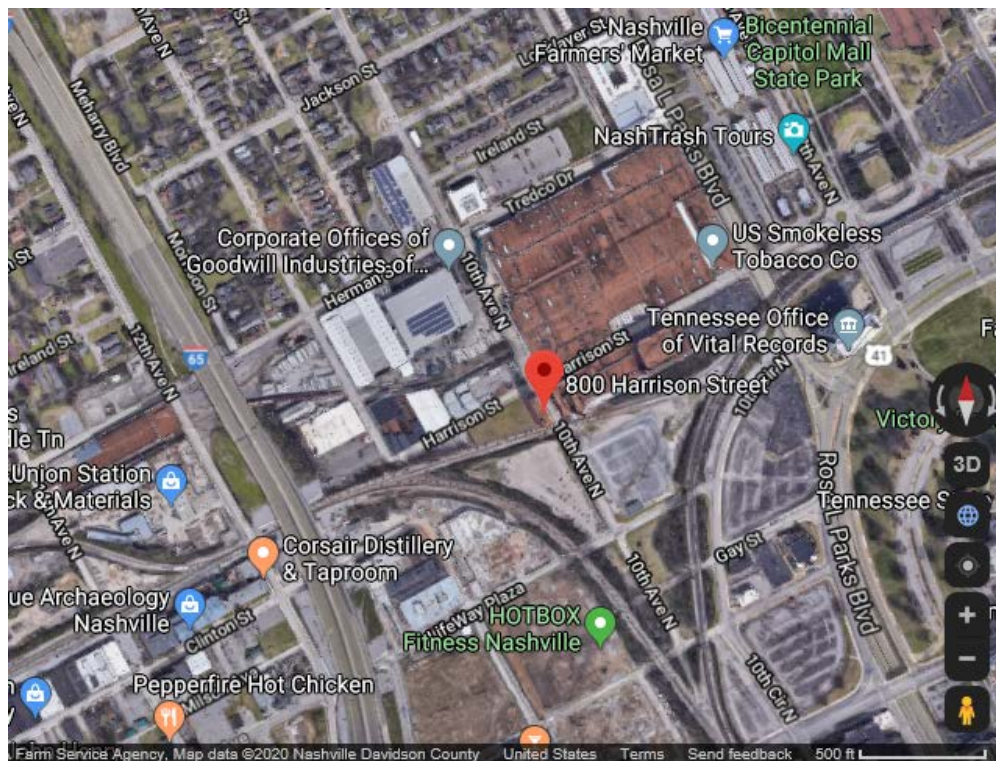
The Agency evaluated potential environmental impact that may be caused by manufacturing the new product and found no significant impact.

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.

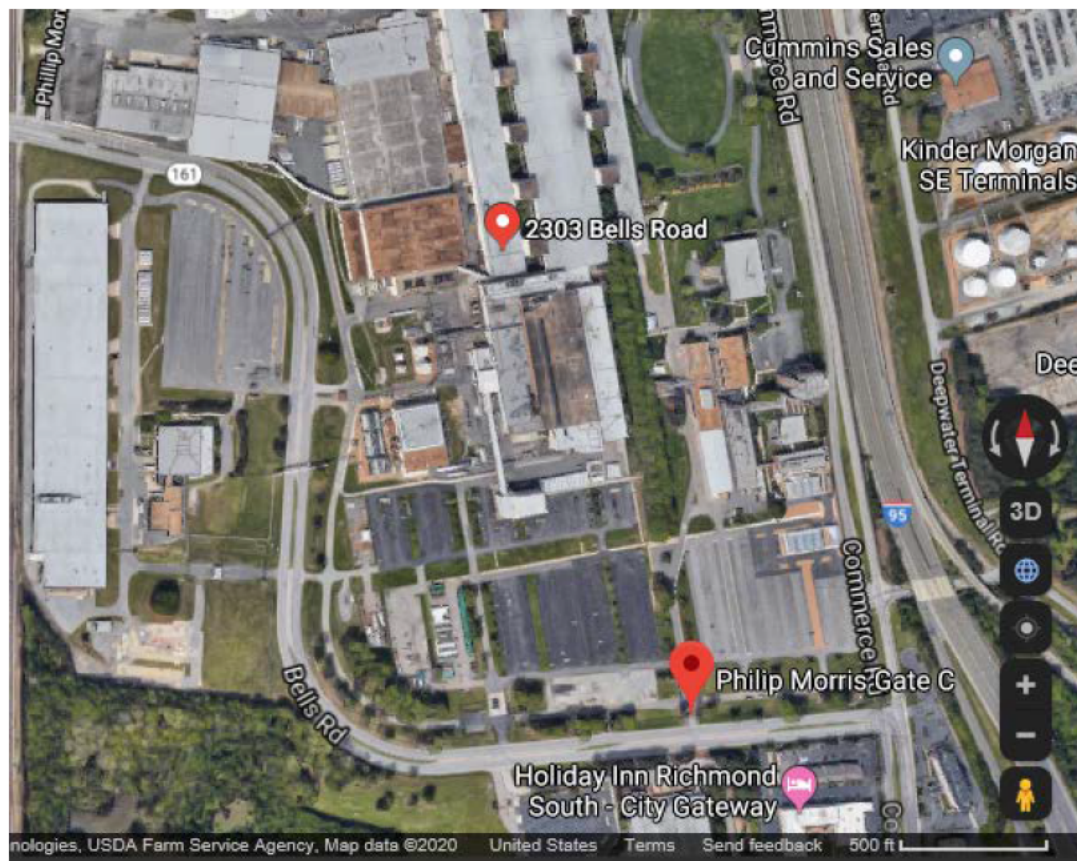
Figure 1. Location of the Nashville, TN Manufacturing Facility



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 Impact

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

| Environmental Resource | Analysis of Potential Impact |
|------------------------|--|
| 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 permit. |

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 August 29, 2019

³ Ibid

| | |
|--|--|
| Water resources | The applicant stated that manufacturing the new product would have the same or similar wastewater discharges as products currently manufactured at the facilities 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 action. |
| 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 impact was identified, there would be no disproportionate impact to environmental justice populations near the manufacturing facilities. |
| 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 at the manufacturing facilities.^{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> |
|--|---|

5.3. Cumulative Impact

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)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 Richmond manufacturing facility released 10,313 pounds of nicotine and nicotine salts to air. No other hazardous air pollutants at were reported (Table 1).⁷ 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

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 March 25, 2020.

⁵ EPA ECHO Detailed Facility Report: Philip Morris USA Tobacco Co. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed March 25, 2020

⁶ https://enviro.epa.gov/enviro/P2_EF_Query.p2_report?FacilityId=372035TBCC800HA&pReport=2 Accessed March 25, 2020

⁷ https://enviro.epa.gov/enviro/P2_EF_Query.p2_report?FacilityID=23234PHLLP3601C&pReport=2 Accessed March 25, 2020

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 Waste Associated with Manufacturing the Tobacco Product at the U.S. Smokeless Tobacco Company Operated 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 |
| Subtotal Waste Managed | | | 19,016 | 216,796 |
| On-Site Release | Air | Ammonia | 0 | 0 |
| | | Nicotine and Nicotine 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. Impact 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 facilities, as many similar tobacco products would continue to be marketed and therefore manufactured.

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

The Agency evaluated potential environmental impact that may be caused by use of the new product and found no significant impact 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 Impact

The Agency evaluated the proposed action for potential environmental impact from use of the new product based on Agency-gathered information and the applicant's submitted information.

| Environmental Resource | Analysis of Potential Impact |
|------------------------|--|
| 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 Impact to environmental justice populations is expected. |

6.3. Cumulative Impact

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

6.4. Impact 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 used in the United States.

7. Potential Environmental Impact of the Proposed Action and the Alternatives - Disposal of the New Product

The Agency evaluated the potential environmental impact that may be caused by disposal of the new product and found no significant impact.

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 Impact

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

| Environmental Resource | Analysis of Potential Impact |
|-----------------------------------|---|
| 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, this impact is not considered significant. |
| Environmental justice | Because no significant environmental impacts were identified, there would be no disproportionate impact 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, this impact 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 Impact

No actions were identified that would lead to cumulative Impact due to the disposal of the new tobacco product.

7.4. Impact 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: PhD 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, PhD, Center for Tobacco Products

Education: MS in Environmental Science and PhD in Biochemistry

Experience: 11 years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Appendix 1: Difference Between the New and Predicate Product

| Component | Change from Predicate Product |
|---------------------|--|
| Pouch material | <ul style="list-style-type: none"> Replaced the polypropylene pouch with a Texin resin pouch |
| Tobacco | <ul style="list-style-type: none"> Increased tobacco cuts per inch (b) (4) cpi to (b) (4) cpi) Increased portion weight Reduced total tobacco (mg/g) Reduced all tobacco blend constituents (mg/g) (b) (4) |
| Tobacco Ingredients | <ul style="list-style-type: none"> Increased nicotine content per portion Increased (b) (4) Added (b) (4) and (b) (4) Reduced (b) (4) content Increased (b) (4) content |
| (b) (4) Ingredients | <ul style="list-style-type: none"> Replaced non-GRAS (b) (4) extract with (b) (4) that is GRAS⁸ Added miniscule amounts of (b) (4) |

⁸ Generally recognized as safe (GRAS) is a designation that does not apply to ingredients in tobacco products

Appendix 2: Marketing Projections for the New Product

| STN | Name | Unit | Projected Market Volume | |
|-----------|--|-------------|-------------------------|------------|
| | | | First Year | Fifth Year |
| SE0015523 | Copenhagen Premium Pouches Wintergreen | Cans | (b) (4) | |
| | | Metric tons | | |