Environmental Assessment for a Modified Risk Order for a Loose Moist Snuff Product

Manufactured by U.S. Smokeless Tobacco Company LLC

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

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1. Introduction

1.1 Background

On March 20, 2018, U.S. Smokeless Tobacco Company LLC (USSTC) submitted to the Food and Drug Administration (FDA) a modified risk tobacco product application (MRTPA) seeking marketing authorization for a loose moist snuff product under the provisions of Section 911(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). On March 26, 2021, FDA completed its review of the MRTPA. FDA determined that the application in its current form did not provide sufficient evidence to meet the standards of 911(g)(1), but they could be amended in a way that would support the issuance of a modified risk order. Accordingly, FDA issued a Response Letter, which included eight deficiencies. On September 29, 2021, USSTC submitted an amendment to address the FDA Response Letter. The applicant amended their applications by proposing a product name change to the revised MRTPA.

FDA prepared this environmental assessment (EA) to evaluate the potential environmental impacts from marketing a "loose moist snuff with a modified risk claim" (referred to as the "new product") in the United States and from the no-action alternative of not issuing marketing orders for the product. This EA is prepared in accordance with the Council on Environmental Quality's (CEQ's) regulations (40 CFR 1500 - 1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR Part 25.40).

1.2 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 Locations:	800 Harrison Street Nashville, TN 37203

1.3 Product Information

Submission Tracking Number (STN) and Name of the New Product

New Product STN	New Product
MR0000108	Copenhagen Classic Snuff

1.4 Product Identification

Product Category	Smokeless
Product Subcategory	Loose Moist Snuff
Product Quantity per Retail Unit	1.2 oz.(34.02 grams) of loose moist snuff per can.
Product Package	The packaging materials consist of a fiberboard can with a metal lid, a Coated one-Side (C1S) paper label on the side and bottom, and a polypropylene shrink wrap.

2. The Purpose and Need for the Proposed Action

Purpose: USSTC submitted to the FDA a MRTPA for a loose, moist snuff product to obtain a modified risk order under Section 911(g) of the FD&C Act to change the statutory mandated health warnings on the package labels and advertisements of a previously found grandfathered product [GF1200194]. USSTC wishes to introduce the tobacco product with the proposed modified risk claim (the new product) into interstate commerce for commercial distribution in the United States with the following proposed claim to the product's advertising label: "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."Upon receipt of an MRTPA, FDA considers the submission, using criteria detailed in section 911(g) of the FD&C Act, and issues a risk modification order that either allows or denies the proposed risk modification claim for a commercially marketed tobacco product. The purpose of FDA's MRTPA review is to determine whether an applicant has shown that the tobacco product sold or distributed with the proposed modified risk information will (A) significantly reduce harm and the risk of tobacco related disease to individual tobacco users and (B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Need: FDA is responsible for reviewing an MRTPA, making a finding as described in the previous paragraph, and subsequently determining whether or not to issue a marketing order for the proposed new product.

3. Proposed Action and the Alternative

Proposed action: The proposed action is for the FDA to issue a modified risk granted order under the provisions of 911(g)(1) authorizing the marketing of Copenhagen Classic Snuff tobacco with the following claim to the advertising label: "IF YOU SMOKE, CONSIDER THIS: Switching completely to this product from cigarettes reduces risk of lung cancer."

Alternative: The no-action alternative is the FDA does not issue a modified risk order for marketing the new product in the United States.

4. Potential Environmental Impacts of the Proposed Action and Alternative – Manufacturing the New Product

The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new product and found no significant impacts based on Agency-gathered information and the following applicant-submitted information:

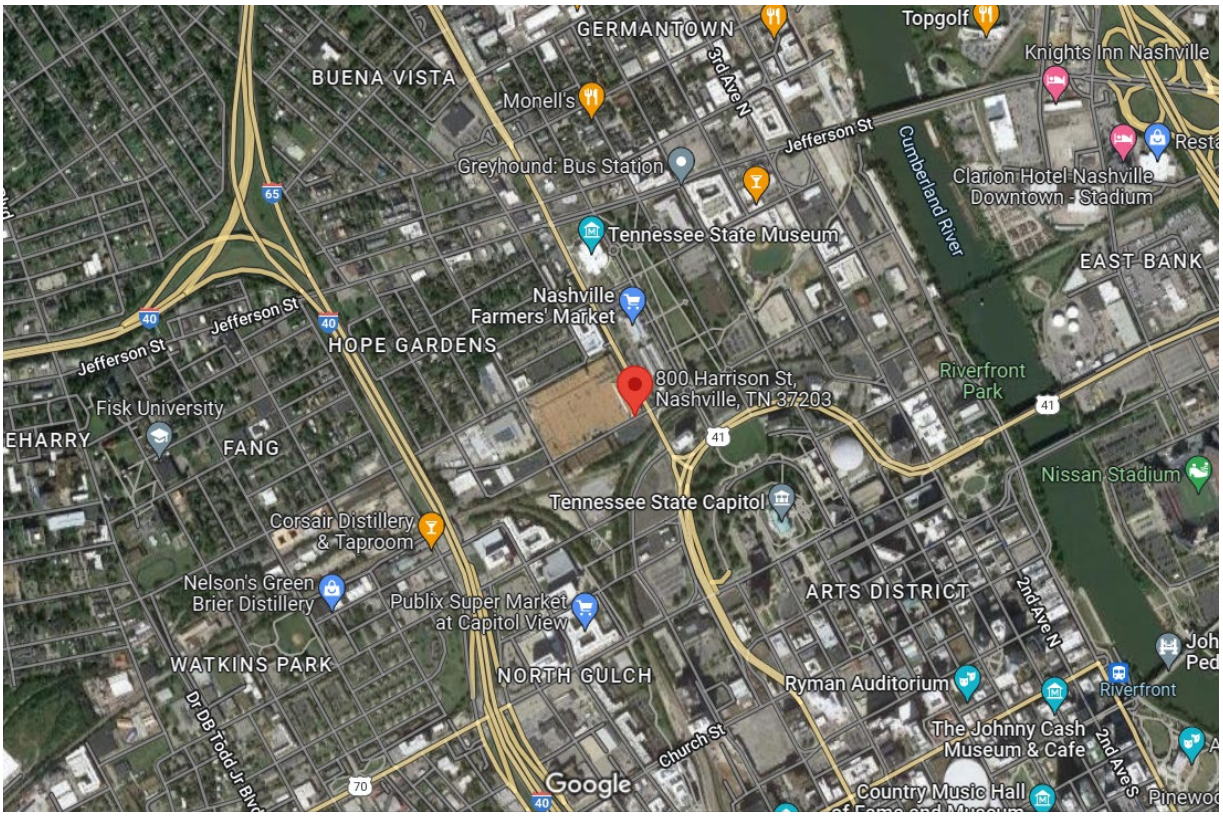
- Ingredients in the new product are commonly used in other smokeless tobacco products.
- The new product would not require additional resources or equipment to produce.
- No facility expansion or new construction is expected due to manufacture of the new product.
- Based on the applicant's submitted information, the new product will replace the currently marketed grandfathered product.

4.1 Affected Environment

The new product would be manufactured at the address listed in section 1.2 (Figure 1).

The manufacturing facility is in a mixed-use industrial, commercial and residential area just west of the the Cumberland River and east of interstates 40 and 65. The facility is located in the Lower Cumberland-Sycamore Watershed (U.S. EPA Waters GeoViewer, 2022).

Figure 1. Location of the Manufacturing Facility[1]



4.2 Analysis of Potential Environmental Impacts

The Agency does not anticipate that the proposed action will significantly increase or change chemicals released to the environment from tobacco manufacturing at the USSTC facility.

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 facility and would not require a new or revised permit. A search in the U.S. Environmental Protection Agency (EPA)'s Toxic Release Inventory (TRI) database showed that in 2021, USSTC manufacturing facility in Nashville, TN released 439.6 pounds of nicotine and nicotine salts to air and

[1] Google Maps. (2022). Map for 800 Harrison Street, Nashville, TN 37203. Retrieved from www.google.com/maps. Accessed May 19, 2022.

Environmental Resource	Analysis of Potential Impacts
	transferred 57,686 pounds of nicotine and nicotine salts offsite. The TRI database search did not show that the USSTC manufacturing facility released into the environment any other reportable toxicants associated with manufacturing. No other hazardous air pollutants were reported. (U.S. EPA TRI, 2022) The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals into the environment.
Water resources	The applicant stated that manufacturing the new product would have the same or similar wastewater discharges as products currently manufactured at the facility and would not require a new or revised permit. The Agency verified that no TRI-reportable chemicals were released to water from the manufacturing facility. (U.S. EPA TRI, 2022)
Land use and zoning	The applicant stated that manufacturing the new product would not involve manufacturing facility expansion. Therefore, no changes in land use or zoning would occur as a direct impact of the proposed action. The Agency verified that no TRI-reportable chemicals were released to the land from the manufacturing facility. (U.S. EPA TRI, 2022)
Biological resources	No effects to biological resources would occur as a direct impact of manufacturing the new product because no facility expansion or change in chemical emissions are expected. The applicant reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps. The U.S. FWS's list of species by county shows that the Nashville area (Davidson County) may have eleven endangered species (six types of clams, one crayfish , two flowering plants, and two ian bat species) and two threatened species (one flowering plant and one bat species) (U.S. FWS ECOS, 2022a; 2022b). However, the applicant stated that none of these species are found near the manufacturing facility. The Agency searched the U.S. FWS maps and verified the accuracy of the listed species.
Geological features and soils	No facility expansion would be expected due to manufacturing the new product . Therefore, no effects to geological features or soils would occur as a direct impact of manufacturing the new product manufacture.
Socioeconomic conditions	No impacts would be expected on employment, state or municipal revenue and taxes, or on police force and fire department resources because there would be no facility expansion due to manufacturing the new product.
Environmental justice	No new chemicals would be released from manufacturing the new product. Therefore, no disproportionate impacts to minority and low-income populations near the manufacturing facilities are anticipated.
Solid waste and hazardous materials	The applicant stated that the new product would not change solid waste generation at the manufacturing facility and waste would be disposed of in the same manner as waste generated by other smokeless tobacco products manufactured at the same facility. 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 no facility expansion would be expected due to manufacturing the new product. Therefore, no effects to floodplains, wetlands, or coastal zones are anticipated.

Environmental Resource	Analysis of Potential Impacts
Regulatory compliance	The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The applicant provided information for the following air emission and wastewater permits: (1) Air permits: 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. (2) Wastewater permits: Industrial User Wastewater Discharge Permit (permit number CP-0286), issued in accordance with applicable Metropolitan Government of Nashville and Davidson County regulations. 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. The Agency's search of U.S. EPA's Enforcement and Compliance History Online did not reveal any violations of the federal environmental laws and regulations (U.S. EPA ECHO, 2022). The applicant also stated that the facility complies with the Endangered Species Act.

4.3 Impacts from the No-Action Alternative

The no-action alternative would not change existing manufacturing of other smokeless tobacco products at USSTC manufacturing facility because manufacture of similar smokeless tobacco products would continue at this facility.

5. Potential Environmental Impacts of the Proposed Action and Alternative – Use of the New Product

The Agency evaluated potential environmental impacts that may be caused by use of the new product with the modified risk claim and found no significant impacts.

5.1 Affected Environment

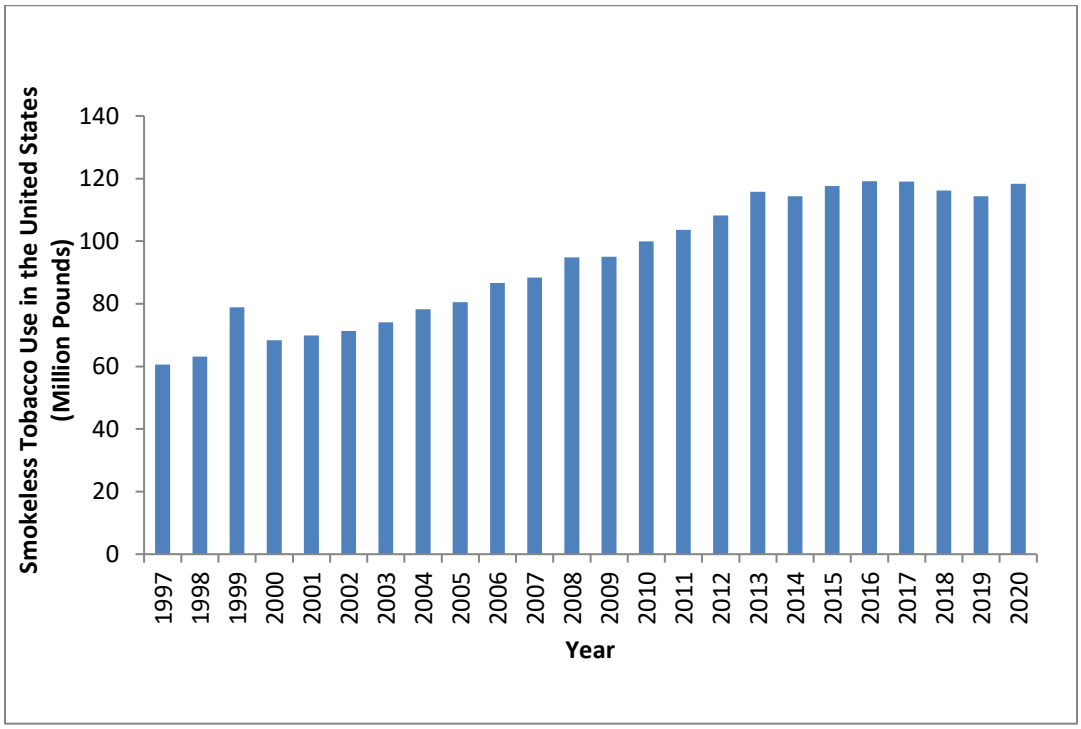
The affected environment includes human and natural environments in the United States because the marketing order would allow for the new modified risk product to be sold to consumers in the United States with the advertising claim nationwide.

5.2 Analysis of Potential Environmental Impacts

The proposed action was evaluated for potential environmental impacts from use of the new product based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new products as proxy for use (Confidential Appendix 1).

Data from the tobacco products monthly statistical release reports from U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) show that since 1997, snuff tobacco sale as a proxy for consumption in the United States has increased overall but leveled off in recent years (Figure 2; U.S. TTB, 2022).[2]

Figure 2. Use of Smokeless Tobacco in the United States, 1997 – 2020



The applicant stated that the new product will replace the currently marketed grandfathered product. The Agency does not expect the new product to significantly increase snuff use in the United States because (1) the new tobacco products are expected to compete with, or replace, other currently marketed snuff, and (2) the ingredients in the new tobacco products are used in other currently marketed tobacco products.

Environmental Resource	Analysis of Potential Impacts
Environmental justice	The new product is likely to be used by consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no change in impacts to minority and low-income populations would be expected.

[2] Sales data reported by TTB are used as a proxy for consumption.

5.3 Impacts from the No-Action Alternative

The no-action alternative would not change existing use of other smokeless tobacco products because use of many similar smokeless tobacco products would continue in the United States.

6. 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 based on Agency-gathered information and the applicant's submitted information.

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 product to be sold to consumers nationwide who would dispose of used new product and packaging as municipal solid waste (MSW), recycled material, or litter.

6.2 Analysis of Potential Environmental Impacts

Environmental Resource	Analysis of Potential Impacts
Biological resources	Proper disposal of the used new product and packaging in the MSW stream would not adversely affect biological resources. Improper disposal (littering) could lead to direct terrestrial wildlife exposure and hazardous substances leaching to aquatic environments and soil. However, no net litter increases 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	No significant environmental impacts associated with disposal of the used new product and packaging were identified. The new product is likely to be used, and thereof disposed, by consumers that use existing smokeless tobacco products, competing for the same market share. Therefore, no disproportionate impacts to minority and low-income populations are anticipated.
Water resources	Proper disposal of the used new product and packaging in the MSW stream would not affect water resources. Improper disposal (littering) could result in hazardous substances leaching to water systems. However, no net litter increases 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.
Solid waste and hazardous materials	Distribution of waste generated from disposal of the used new product and packaging is anticipated to correspond to U.S. product use patterns. However, introducing the new product into the U.S. market is not expected to increase nationwide use and disposal. Therefore, no net increase in littering would be expected.

Environmental Resource	Analysis of Potential Impacts
Regulatory compliance	The new product has no features that would lead to a different used product litter rate 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 and currently marketed smokeless products. Therefore, these impacts are not considered significant.

6.3 Impacts from the No-Action Alternative

The no-action alternative would not change existing smokeless tobacco product and packaging material disposal because disposal of similar products would continue in the United States.

7. List of Preparers

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

Preparers:

William E. Brenner, B.S., Center for Tobacco Products
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- Experience: Eight years in various scientific activities
- Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

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- Education: Ph.D. in Plant Molecular Biology and Virology
- Experience: Forty-three years in various scientific activities including ten years in NEPA practice
- Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

8. List of Agencies and Persons Consulted

None.

9. References

U.S. EPA Enforcement and Compliance History Online (ECHO). (2022). Facility Search. Available at: https://echo.epa.gov/. Accessed September 8, 2022.

U.S. EPA Toxic Release Inventory Database (TRI). (2022). TRI Facility Release Reports. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched September 9, 2022.

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U.S. Fish and Wildlife Services (U.S. FWS) Environmental Conservation Online System (ECOS). (2022a). Endangered Species Online Mapper: Listed species believed to or known to occur in Davidson, Tennessee. Available at: https://ecos.fws.gov/ecp/report/species-listings-by-current-range-county?fips=47037. Accessed September 8, 2022.

U.S. FWS ECOS. (2022b). Critical Habitat for Threatened & Endangered Species Online Mapper. Available at: https://fws.maps.arcgis.com/home/webmap/viewer.html?webmap=9d8de5e265ad4fe09893cf75b8dbfb77. Search for Davidson County, TN. Accessed September 8, 2022.

U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB). (2022). Tobacco statistics. U.S. Department of the Treasury.statistical data aAvailable at: https://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed April 22, 2021.

Confidential Appendix 1: First- and Fifth-Year Market Volume Projections for the New Product

First- and fifth-year market volume projections of the new product were compared to the total forecasted use of snuff tobacco in the United States.[3] The projected use of the new product in the first and fifth year of marketing after a modified risk order is issued account for about (b) (4) % and (b) (4) % respectively of the forecasted snuff tobacco use in the United States.[4]

STN	Unit	Market Volume			
		First-Year (Projected) New Product	% Of Total Snuff Tobacco Used[5]	Fifth-Year (Projected) New Product	% Of Total Snuff Tobacco Used[6]
MR0000108	Cans	(b) (4)		(b) (4)	
	Metric Tons	(b) (4)	(b) (4)	(b) (4)	(b) (4)

[3] The Agency used historical data regarding total use of snuff from 1997 to 2020 to mathematically estimate the total number of snuff tobacco used in the United States. Using the best-fit trend line with an R^2 value of 0.9459, the forecasted amount of snuff tobacco that will be used in the United States is estimated at 126,903,000 pounds in the first year and 133,705,000 pounds in the fifth year of marketing the new product.

[4] Market volumes are used as proxy for use, assuming that all produced products will be consumed or used in the United States.

[5] Projected Market Occupation of the New Product in the United States (%)=

$$\frac{\text{Projected Market Volume of the New Product (Metric } Tons) \; x \; 2204.62 \frac{Pounds}{Metric\ Ton}}{\text{Projected Use of snuff tobacco in United States (pounds)}} x \; 100$$

[6] ibid