

**Environmental Assessment for a Marketing Order for a Loose
Moist Snuff Product by American Snuff Company, LLC**

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

July 12, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	RAI Services Company
Applicant Address:	401 North Main Street Winston-Salem, NC 27101
Manufacturer Name:	American Snuff Company, LLC
Product Manufacturing Locations:	ASC Clarksville 4583 Guthrie Highway, Clarksville, TN 37040
	ASC Memphis 5106 Tradeport Drive Memphis, TN 38141
	ASC Taylor Brothers 2415 South Stratford Road Winston-Salem, NC 27103

2. Product Information

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

New Product	STN	Predicate Product
Grizzly Premium Natural Fine Cut	SE0015250	Grizzly Premium Natural Fine Cut

Product Identification

Product Category	Smokeless
Product Subcategory	Loose Moist Snuff
Product Quantity per Retail Unit	34.02 g loose moist snuff per can
Product Package	The packaging materials consist of polypropylene can with tin steel lid, with pressure sensitive paper labels on the side and bottom, and polypropylene shrink film overwrap.

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 after finding the new tobacco product substantially equivalent to the predicate product. 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 a marketing order if the new product is found substantially equivalent to the predicate product.

The new product differs from the predicate product in the material used for the can lid, moisture content, inclusion level of tobacco blend, and product pH (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 considered potential impacts to resources in the environment that may be affected by manufacturing the new product and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Components of the new product are similar to other smokeless tobacco products manufactured at the facilities.
- The new product would not be commercially marketed simultaneously with the predicate product if a marketing order is granted for the new product.
- The new product is intended to compete with and eventually replace similar tobacco products currently manufactured at the facilities.
- No facility expansion or new construction is expected due to manufacturing the new product.

5.1. Affected Environment

American Snuff Company, LLC (ASC) operates one manufacturing facility in North Carolina; ASC Taylor Brothers (Winston-Salem, NC) and two facilities in Tennessee; ASC Clarksville and ASC Memphis. The new products would be manufactured at these facilities with addresses listed in section 1 of this document (Figure 1).

Figure 1. Land Use Surrounding the Manufacturing Facilities:

a) ASC Clarksville¹



b) ASC Memphis²



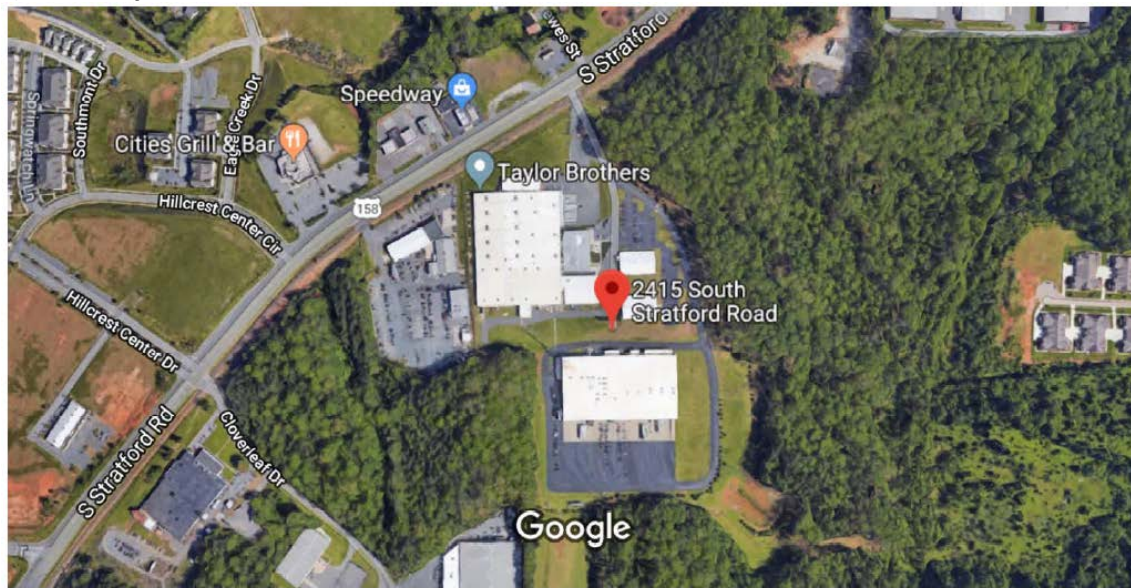
¹ Land use surrounding ASC Clarksville manufacturing facility via Google Maps

<https://www.google.com/maps/place/American+Snuff+Co./@36.6210499,-87.2237863,908m/data=!3m1!1e3!4m5!3m4!1s0x0:0x76c1b4e6faf494de!8m2!3d36.6210499!4d-87.2237863>

² Land use surrounding ASC Memphis manufacturing facility via Google Maps.

<https://www.google.com/maps/place/American+Snuff+Co+LLC/@35.009457,-89.8540979,963m/data=!3m1!1e3!4m5!3m4!1s0x0:0x10a8b67f930060d4!8m2!3d35.009457!4d-89.8540979>

c) ASC Taylor Brothers³



Imagery ©2018 Google, Map data ©2018 Google 500 ft

The affected environment includes human and natural environments surrounding these facilities. ASC Clarksville is located in an industrial area in Montgomery County, TN in the Red River watershed, hydrologic unit code (HUC) 05130206. The facility is bounded to the north west by US highway 79, and to the north east by an industrial metal fabricator and installer (Figure 1a).

ASC Memphis is located in Shelby county, TN in the Middle Nonconnah Creek watershed, HUC 08010211. The facility is surrounded by industries; bounded to the east by Johns Creek, to the west by a logistics company, to the north by a hardware distribution center, and to the south by an HVAC distribution center (Figure 1b).

ASC Taylor Brothers is located in Forsyth County, NC; surrounded by woodlands, bounded to the north by US highway 158, and to the west by a flow paint and body center (Figure 1c).

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's submitted information, including projected market volumes for the new product (Confidential Appendix 2).

³ Land use surrounding ASC Taylor Brothers manufacturing facility via Google Maps. <https://www.google.com/maps/place/2415+S+Stratford+Rd+Winston-Salem+NC+27103/@36.0517151,-80.3205278,156m/data=!3m1!1e3!4m5!3m4!1s0x8853b07d83b14ebf:0xfa982007a4da1f4!8m2!3d36.0516295!4d-80.319404>. Accessed September 19, 2018

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that there would be no changes in the manufacturing process. Therefore, manufacturing the new product would not lead to changes in air emissions and would not require additional controls for air emissions.
Water resources	Manufacturing the new product would have the same or similar wastewater discharges as products currently manufactured at the ASC facilities and would not require additional controls for wastewater discharge.
Land use and zoning	The applicant stated that there would be no expansion at any of the manufacturing facilities 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	No effects to biological resources would occur as a direct impact from manufacturing the new product because no facility expansion is expected.
Geological features and soils	The applicant stated that there would be no expansion at any of the manufacturing facilities 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 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 anticipated.
Solid waste and hazardous materials	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 ASC facilities. 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 expansion at any of the manufacturing facilities due to manufacturing the new product. Therefore, no effects to floodplains, wetlands, or coastal zones are anticipated.
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	<p>The applicant stated that the three American Snuff Company, LLC manufacturing facilities comply with all federal, state, and local environmental regulations. The Agency's search for the manufacturing facilities in the EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations.⁴</p> <p>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. The applicant reviewed the U.S. Fish and Wildlife Service maps⁵ and stated that the</p>

⁴ U.S. EPA ECHO Detailed Facility Report: American Snuff Company, Clarksville TN. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110043670514>; American Snuff Company, Memphis, TN Available at: <https://echo.epa.gov/detailed-facility-report?fid=110045562315>. American Snuff Company, Winston Salem, NC. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110001477526>. Accessed January 2, 2019.

⁵ U.S. Fish and Wildlife Service (U.S. FWS), available at: <https://www.fws.gov/> Accessed January 11, 2018

manufacturing facilities in Clarksville TN, Memphis, TN, and Winston-Salem, NC are not within or near a critical habitat, ⁶ or endangered animal and plant species.
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5.3. Cumulative Impacts

The Agency does not anticipate the proposed actions would significantly increase or change the chemicals released to the environment from tobacco manufacturing at the ASC facilities. A search in EPA's Toxic Release Inventory (TRI) database showed that in 2017, ASC's manufacturing facilities in Tennessee released 7,783 pounds of ammonia and 1,254 pounds of nicotine and nicotine salts to air and released 1,099 pounds of ammonia and 6,727 pounds of nicotine and nicotine salts offsite. The manufacturing facility in Winston Salem, North Carolina released 2,455 pounds of ammonia and 13,614 pounds of nicotine and nicotine salts to air and released 3,060 pounds of ammonia and 11,028 pounds of nicotine and nicotine salts offsite. None of the manufacturing facilities released TRI-reportable chemicals to land or water (Table 2).⁷ No other hazardous air pollutants were reported. Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts have known adverse developmental effects.⁸ The TRI database search did not show that any of the American Snuff Company manufacturing facilities disposed of, treated, or released into the environment any other reportable 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.

⁶ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed January 11, 2019.

⁷ U.S. EPA. TRI Data: Available at:

ASC Clarksville https://oaspub.epa.gov/enviro/P2_EF_Query.p2_report?FacilityId=3704WMRCNS4483G&pReport=2,

ASC Memphis https://oaspub.epa.gov/enviro/P2_EF_Query.p2_report?FacilityId=3814WMRCNS516TR&pReport=2,

ASC Taylor Brothers <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/27103TYLRB2415S>.

Accessed January 11, 2019.

⁸ U.S. EPA. myRight-to-Know, available at: <https://myrtk.epa.gov/info/>. The site allows for searching the industrial facilities that manage toxic waste chemicals by entering the facility address and clicking on the facility location on the map. Accessed September 19, 2018.

Table 2 Management of Chemical Waste Associated with Manufacturing at the American Snuff Company, LLC Facilities

Production-Related Waste Managed or Released	Chemical Mass (pounds)		
	ASC Clarksville, TN	ASC Memphis, TN	ASC Taylor Brothers, NC
Recycled	0	0	0
Energy Recovery	0	0	0
Treated	0	0	0
<i>Subtotal Waste Managed</i>	<i>0</i>	<i>0</i>	<i>0</i>
On-Site Release	Ammonia	7,506	277
	Nicotine and Nicotine Salts	1,017	237
Off-Site Release	Ammonia	0	1,210
	Nicotine and Nicotine Salts	0	7,678
<i>Subtotal Waste Released</i>	<i>8,523</i>	<i>9,403</i>	<i>30,157</i>
Total Production-Related Waste	8,523	9,403	30,157

5.4. Impacts from the No-Action Alternative

The no-action alternative would not change the existing manufacturing of other smokeless tobacco products at the American Snuff Company, LLC manufacturing facilities as many similar smokeless tobacco products would continue to be manufactured at these facilities.

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 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.

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 environmental justice populations would be expected.

6.3. Cumulative Impacts

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

6.4. Impacts from the No-Action Alternative

The no-action alternative would not change the existing use of other smokeless tobacco products, as many similar smokeless 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 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 nationwide who would dispose of the used new product and packaging as municipal solid waste (MSW), recycled material, or litter.

7.2. Analysis of Potential Environmental Impacts

The proposed action was evaluated 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 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	No significant environmental impacts associated with the disposal of the used product and packaging were identified; therefore, no disproportionate impacts to environmental justice 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) of the used new product could result in hazardous substances leaching to 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 products. Therefore, these impacts are not considered significant.

Environmental Resource	Analysis of Potential Impacts
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 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 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 currently marketed smokeless tobacco products. Therefore, these impacts are not considered significant.

7.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts when considered with disposal of the new product under the proposed action.

7.4. Impacts from the No-Action Alternative

The no-action alternative would not change the existing condition of the disposal of smokeless tobacco products and packaging material, as many 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 programmatic environmental assessment:

Preparer:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Five years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

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

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
SE0015250	Can lid	Replacement of plastic lid with a tin steel lid
	Moisture	1.8% decrease in moisture
	Tobacco Inclusion	A ^{(b) (4)} mg/g increase in (b) (4), a ^{(b) (4)} mg/g increase in (b) (4), a ^{(b) (4)} mg/g increase in (b) (4), and a ^{(b) (4)} mg/g increase in (b) (4) tobacco
	Product pH	Change to ^{(b) (4)} from ^{(b) (4)} in the predicate product

Confidential Appendix 2: Marketing Projections for the New Product

STN	Product Name	Unit	Projected Market Volume	
			First Year	Fifth Year
SE0015250	Grizzly Premium Natural Fine Cut	Cans	(b) (4)	(b) (4)
		Pounds	(b) (4)	(b) (4)

The applicant stated that they would not simultaneously market the new and predicate products after receiving the marketing order for the new product.