

**Environmental Assessment for a Marketing Order for
New Pipe Tobacco
Manufactured by Sutliff Tobacco Company**

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

February 18, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	Sutliff Tobacco Company
Applicant Address:	600 Perdue Ave. Richmond, VA 23224
Manufacturer Name:	Sutliff Tobacco Company
Product Manufacturing Location:	600 Perdue Ave. Richmond, VA 23224

2. Product information

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

New Product	STN	Predicate Product
#208 Apple Flavor	SE0015635	#208 Apple Flavor

Product Identification

Product Category	Pipe Tobacco
Product Subcategory	Pipe Tobacco Filler
Product Quantity per Retail Unit	1.5 oz per pouch
Product Package	Plastic pouch

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 one 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 corresponding predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new product differs from the predicate product in product quantity (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.

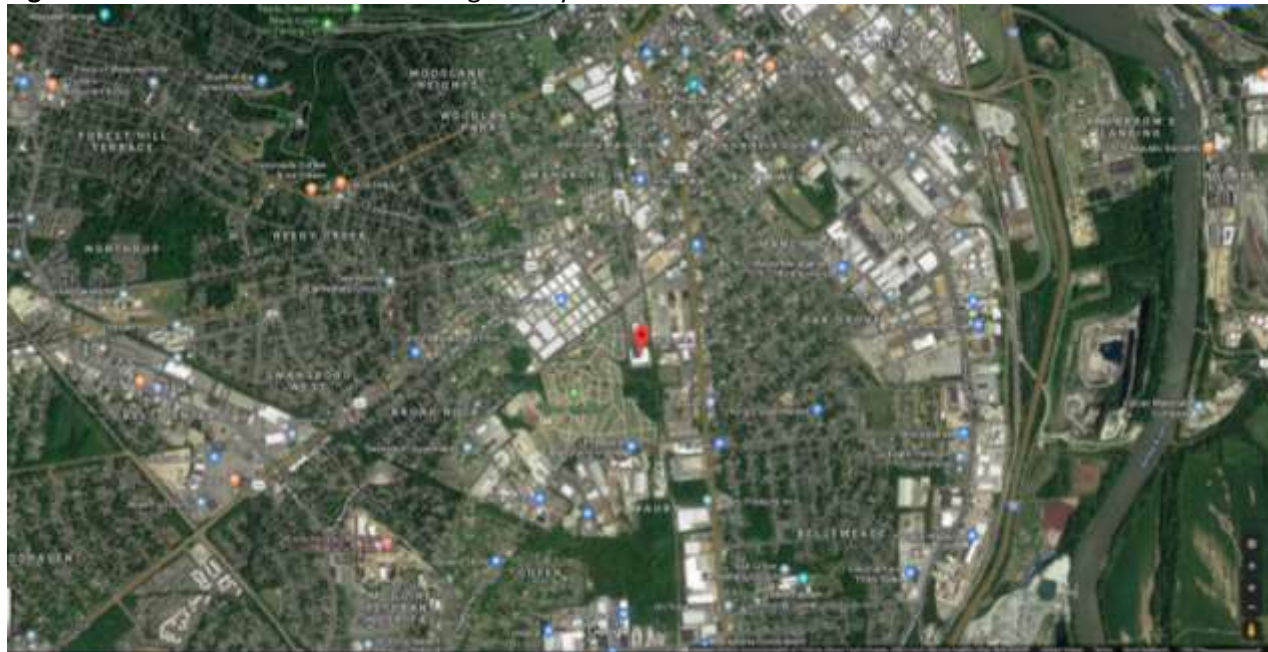
5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

The Agency considered 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 facility. The new product is manufactured by the Sutliff Tobacco Company, 600 Perdue Ave., Richmond, VA 23224 (Figure 1). The manufacturing facility is located west of I-95 and southwest of downtown Richmond, VA and the James River.

Figure 1. Location of the Manufacturing Facility¹



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.^{2,3} Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.⁴

5.2 Analysis of Potential Environmental Impacts

The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new product based on Agency-gathered information and the applicant's submitted

¹ Land use surrounding manufacturing facility via Google Map. GoogleMaps. 2020. Map of 600 Perdue Ave., Richmond, VA 23224. www.google.com/maps. Accessed January 9, 2020.

² 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>.

³ 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 January 9, 2020.

⁴ Ibid

information. Included in the information the Agency considered were the projected market volumes for the new and predicate products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that the new and predicate product contain the same or similar ingredients. The applicant also stated that manufacturing the new product would not lead to changes in air emissions to the environment from the manufacturing facility and would not require a new or revised air emission permit.
Water resources	The applicant stated that manufacturing the new product would not lead to changes in wastewater discharges from the manufacturing facility 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 actions.
Biological resources	The applicant stated that the manufacturing process for the new product would not jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The applicant stated that there are no plans of expanding the facility production beyond its current permitted level. The applicant reviewed the U.S. Fish and Wildlife Service’s (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species (two flowering plants – sensitive joint-vetch and swamp pink, and one mammal - northern long-eared bat), and two endangered freshwater mussel species - James spinymussel and Atlantic Pigtoe are listed in the city of Richmond and the bordering counties (Henrico and Chesterfield Counties). ^{5,6} 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 effects on geological features or soils are expected because no facility expansion is anticipated.
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 applicant stated that no additional capacity for disposal of manufacturing waste and no additional environmental controls would be required. There would be no material composition changes in the new product. 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	There would be no expected facility expansion due to manufacturing the new product. Therefore, no effects on floodplains, wetlands, or coastal zones are anticipated.

⁵ U.S. Fish and Wildlife Service (U.S. FWS), available at: <https://www.fws.gov/endangered/>. Accessed January 23, 2019.

⁶ Critical habitat maps available at: <https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449>

Regulatory compliance	The applicant stated that the manufacturing facility complies with all local, state and federal environmental laws.
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5.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with manufacturing the new product under the proposed action.

5.4 Impacts of the No-Action Alternative

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

6. Potential Environmental Impacts of the Proposed Action and Alternatives – 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 SE Report.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate that using the new product would lead to the release of new chemicals into the air, as compared to the predicate product or other currently marketed pipe tobacco products because the only change is in product quantity. The new and predicate product ingredients are anticipated to remain unchanged.
Environmental justice	No new emissions are expected due to use of the new product. Therefore, there would be no new disproportionate impacts on minority or low-income populations.

6.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with use of the new product under the proposed action.

6.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of pipe tobacco products, as many similar tobacco products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Action and Alternatives – 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 applicant to distribute and sell the new tobacco product to consumers in the United States.

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 information in the SE Report, including market volume information for the new and predicate products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new product into the U.S. market would not be expected to increase the nationwide use of pipe tobacco products. Therefore, disposal of the used product and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the used new product and packaging materials in the MSW would not affect biological resources. Although the used product and packaging materials may be littered in undeveloped areas and wildlife habitat, littering levels are not expected to change from the current levels due to existing tobacco products. Introducing the new product into the U.S. market would not be expected to increase the nationwide use of pipe tobacco products based on the projected market volumes reported by the applicant.
Water resources	Proper disposal of the used new product and packaging materials in the MSW would not affect water resources. Improper disposal (littering) of used new product could result in hazardous substances leaching to water systems. However, no net increase in littering would be expected; introducing the new product into the U.S. market would not be expected to increase the nationwide use and disposal of pipe tobacco products, because the new product would compete for the same market share with other currently marketed pipe tobacco products.
Environmental justice	No significant environmental impacts associated with the disposal of the used new product and packaging were identified, therefore no change in impacts to environmental justice populations are anticipated.
Regulatory compliance	The new product has no features that would lead to a different rate of littering for the used product and packaging compared to currently marketed pipe

	tobacco products. Despite state and local littering ordinances, it is assumed that noncompliance (littering) would occur at the same rate for the new product as for the currently marketed pipe tobacco products.
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7.3. Cumulative Impacts

No actions were identified that would lead to cumulative impacts when considered with the new product disposal under the proposed action.

7.4. Impacts of the No-Action Alternative

The no-action alternative would not change the existing condition of the disposal of pipe tobacco products and packaging materials, as many other pipe 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:

Preparer:

Ronald Edwards, MS, Center for Tobacco Products

Education: MS in Biology

Experience: Twenty-five years in environmental regulation and laboratory toxicology

Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

Reviewer:

Gregory G. 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.

Appendix 1. The New Product Compared to the Predicate Product

STN	Product Quantity	
	Tobacco Filler per Bag	
	New Product	Predicate Product
SE0015635	1.5 oz.	1 lb.

Confidential Appendix 1. Market Volume Information for the New and Predicate Products

The applicant intends to simultaneously market the new and predicate products if a marketing order is issued. The applicant also stated that manufacturing both the new and predicate products is within the total facility's current capacity.

STN	Market Volume Projections (Pounds)			
	First Year		Fifth Year	
	New Product	Predicate Product	New Product	Predicate Product
SE0015635	(b) (4)			