

**Programmatic Environmental Assessment for Marketing
Orders for New Pipe Tobacco Fillers
Manufactured by Top Tobacco, LP**

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

September 19, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	Top Tobacco, LP
Applicant Address:	2301 Ravine Way Glenview, IL 60025
Manufacturer Name:	Top Tobacco LP
Product Manufacturing Location:	204 Top Tobacco Road Lake Waccamaw, NC 28450

2. Product information

New Product Names, Submission Tracking Numbers (STN), and Predicate Product Names

New Product	STN	Predicate Product
SMOKER FRIENDLY Regular 0.75 Pouch	SE0015380	Gambler Regular Pouch (0.65 oz)
SMOKER FRIENDLY Green 0.75 Pouch	SE0015381	Gambler Menthol Pouch (0.65 oz)

Product Identification

Product Category	Pipe Tobacco
Product Subcategory	Pipe Tobacco Filler
Product Quantity per Retail Unit	0.75 oz per pouch, 144 pouches per shipping case
Product Package	The packaging materials consist of a polyethylene-based bag and zipper, a rubber-based adhesive, and a paperboard shipping case.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce two new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency substantial equivalence (SE) reports to obtain the marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the corresponding predicate products. The predicate products are grandfathered products commercially marketed in the United States as of February 15, 2007.

The new products differ from the corresponding predicate products in product quantity (Appendix 1).

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new tobacco products in the United States.

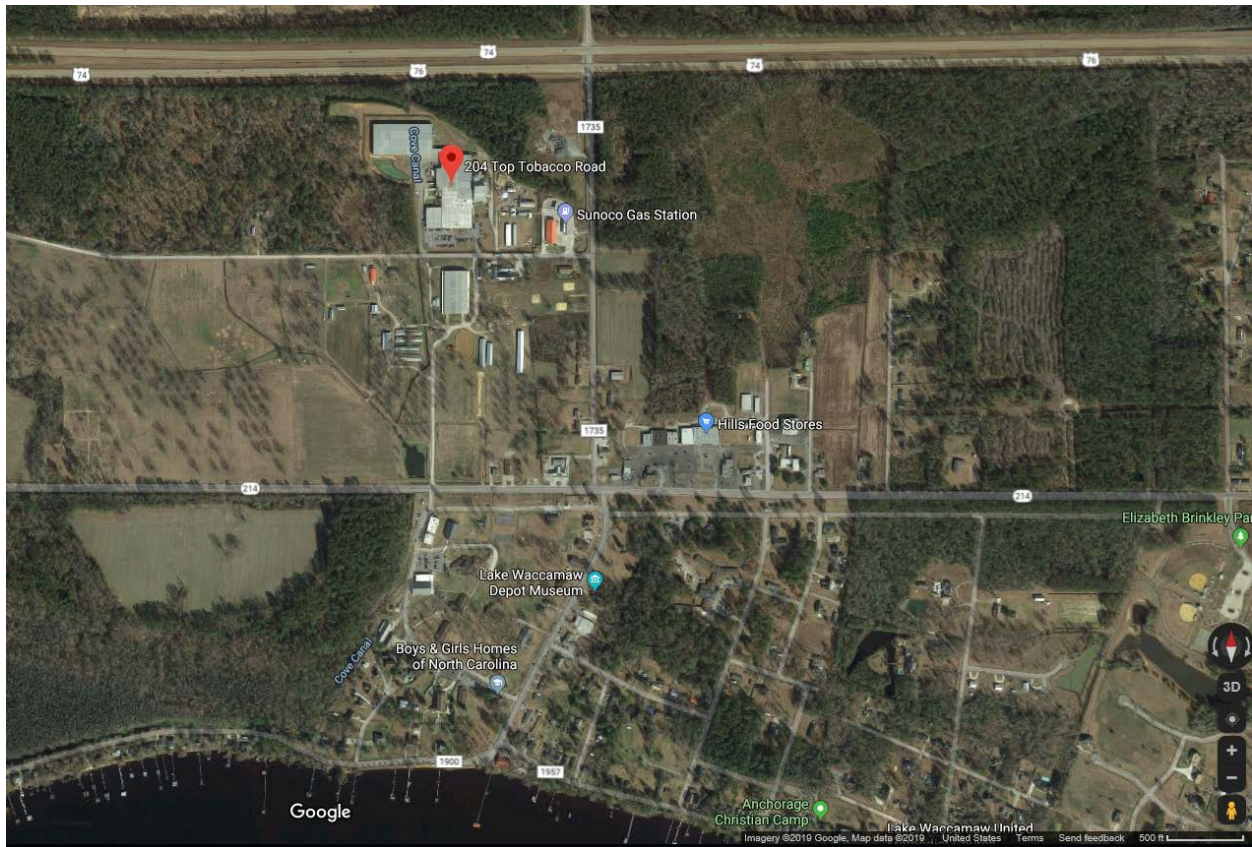
5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

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

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products are manufactured by the Top Tobacco, LP at 204 Top Tobacco Road, Lake Waccamaw, NC 28450 (Figure 1). The manufacturing facility is located in rural Columbus County, NC, bounded by Andrew Jackson Highway (I-74 and I-76) to the north, Chauncey Town Road (SR-1735) to the east, and Lake Waccamaw state park to the south.

Figure 1. Location of the Manufacturing Facility¹



¹ Land use surrounding manufacturing facility via Google Map. GoogleMaps. 2019. Map of 4775 Northwest 132nd Street, Miami, FL 33054. www.google.com/maps. Accessed August 22, 2019.

The facility is surrounded by undeveloped forested land and wetland in Lake Waccamaw sub-basin watershed (hydrologic unit code 03040206), the largest Carolina bay lake and the second largest natural lake in the state.^{2,3,4}

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 products 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 and predicate products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that the new products and the corresponding predicate products contain same or similar ingredients. The applicant also stated that manufacturing the new products 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 products 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 products. 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 is carried out under controls and standards that protect the environment, including species and habitats addressed under the Endangered Species Act (ESA). No effects on listed species or their habitat and biological resources are anticipated because no facility expansion is expected.
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 products. Therefore,

² U.S. Fish and Wildlife Service. National Wetland Inventory Mapper: surface waters and wetlands. Available at: <https://www.fws.gov/wetlands/data/Mapper.html>. Accessed August 22, 2019.

³ 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>. Accessed August 22, 2019.

⁴ North Carolina Department of Environmental Quality. Chapter 4: Waccamaw Sub-basin. Available at: <https://files.nc.gov/ncdeg/Water%20Quality/Planning/BPU/BPU/Lumber/Lumber%20Plan/2010%20Plan/Chapter%204%20-%20Waccamaw%20River%20Subbasin.pdf>. Accessed August 22, 2019.

	the Agency does not anticipate that manufacturing the new products 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 products. Therefore, no effects on floodplains, wetlands, or coastal zones are anticipated.
Regulatory compliance	The applicant stated that the manufacturing facility complies with all local, state and federal environmental laws, including the ESA.

5.3 Cumulative Impacts

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

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 Actions and Alternatives – Use of the New Products

The Agency evaluated potential environmental impacts that may be caused by use of the new products and found no significant impacts.

6.1. Affected Environment

The affected environment includes, within the limits of the law, human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

6.2. Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from use of the new products based on Agency-gathered information and the applicant’s submitted SE Reports.

Environmental Resource	Analysis of Potential Impacts
Air quality	The Agency does not anticipate that using the new products would lead to the release of new chemicals into the air, as compared to the predicate products or other currently marketed pipe tobacco products because the only change is in product quantity. The new products and their ingredients are anticipated to remain unchanged.
Environmental justice	No new emissions would be expected due to the use of the new products. 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 products under the proposed actions.

6.4. Impacts of the No-Action Alternative

The no-action alternative would not change the existing conditions of use of pipe tobacco products, as similar pipe tobacco products would continue to be used in the United States.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

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

7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow the new tobacco products to be sold to consumers nationwide who would dispose of the used products and packaging as municipal solid waste (MSW), recycled material, or litter.

7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed actions for potential environmental impacts from disposal of the new products based on information in the SE Reports, including market volume information for the new and predicate products (Confidential Appendix 1).

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new products into the U.S. market would not be expected to increase the nationwide use of pipe tobacco products. Therefore, disposal of the used products and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the used new products and packaging materials in the MSW stream would not affect biological resources. Although the used products 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 products 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 products and packaging materials in the MSW stream would not affect water resources. Improper disposal (littering) of used new products could result in hazardous substances leaching to water systems. However, no net increase in littering would be expected; introducing the new products into the U.S. market would not be expected to increase the nationwide use and disposal of pipe tobacco products, because the new products 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 products and packaging were identified, therefore no change in impacts to environmental justice populations are anticipated.
Regulatory compliance	The new products have no features that would lead to a different rate of littering for the used products 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 products as for the currently marketed pipe tobacco products.

7.3. Cumulative Impacts

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

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 programmatic environmental assessment:

Preparer:

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

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. Product Quantity: The New Products Compared to the Corresponding Predicate Products

STN	Product Quantity	
	Tobacco Filler per Bag (oz)	
	New Product	Predicate Product
SE0015380	0.75 oz.	0.65 oz.
SE0015381	0.75 oz.	0.65 oz.

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

The applicant intends to continue marketing the new products and the corresponding products after the marketing orders are issued. The applicant stated that the new products are intended to compete or replace same or similar products currently on the market. The applicant also stated that manufacturing the new and predicate products comprise a small fraction of the total facility's current production.⁵

STN	Current-Year Market Volume (Pounds)		Market Volume Projections (Pounds)			
			First Year		Fifth Year	
	New Product	Predicate Product	New Product	Predicate Product	New Product	Predicate Product
SE0015380	(b) (4)					
SE0015381	(b) (4)					
Total	(b) (4)					

⁵ Total facility's current-year production is (b) (4) pounds.