

**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**

April 26, 2021

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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 and Predicate Tobacco Product Names and Submission Tracking Numbers (STN)

Tobacco Product	New	Predicate (Previously Found SE)	Predicate (Grandfathered)
STN	SE0017388	Not applicable	GF1804248
Name	4 ACES Turkish 6 oz Medium Bag	Not applicable	Gambler Regular Medium Bag (6 oz)
Eligibility status	Not applicable		Grandfathered
Relevant amendments	None		
STN	SE0017425	Not applicable	GF1804247
Name	LARGO Bold 16 oz. Large Bag	Not applicable	Gambler Regular Large Bag (16 oz)
Eligibility status	Not applicable		Grandfathered
Relevant amendments	None		
STN	SE0017626	Not applicable	GF1804247
Name	GAMBLER Turkish 16 oz. Large Bag	Not applicable	Gambler Regular Large Bag (16 oz)
Eligibility status	Not applicable		Grandfathered
Relevant amendments	None		
STN	SE0017648	Not applicable	GF1804248
Name	LARGO Sun Grown 6 oz. Medium Bag	Not applicable	Gambler Regular Medium Bag (6 oz)
Eligibility status	Not applicable		Grandfathered
Relevant amendments	None		

Product Identification as Amount of Pipe Tobacco Filler per Bag

Product Category	Pipe Tobacco	
Product Subcategory	Pipe Tobacco Filler	
Product Quantity per Retail Unit	SE0017388 SE0017648	6 oz/bag
	SE0017425 SE0017626	16 oz/bag
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 four new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency four 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 new products are intended to compete with or replace existing pipe tobacco products currently on the market in the United States.

The new products differ from the corresponding predicate products in quantity of pipe tobacco and in the ingredients (Confidential 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.

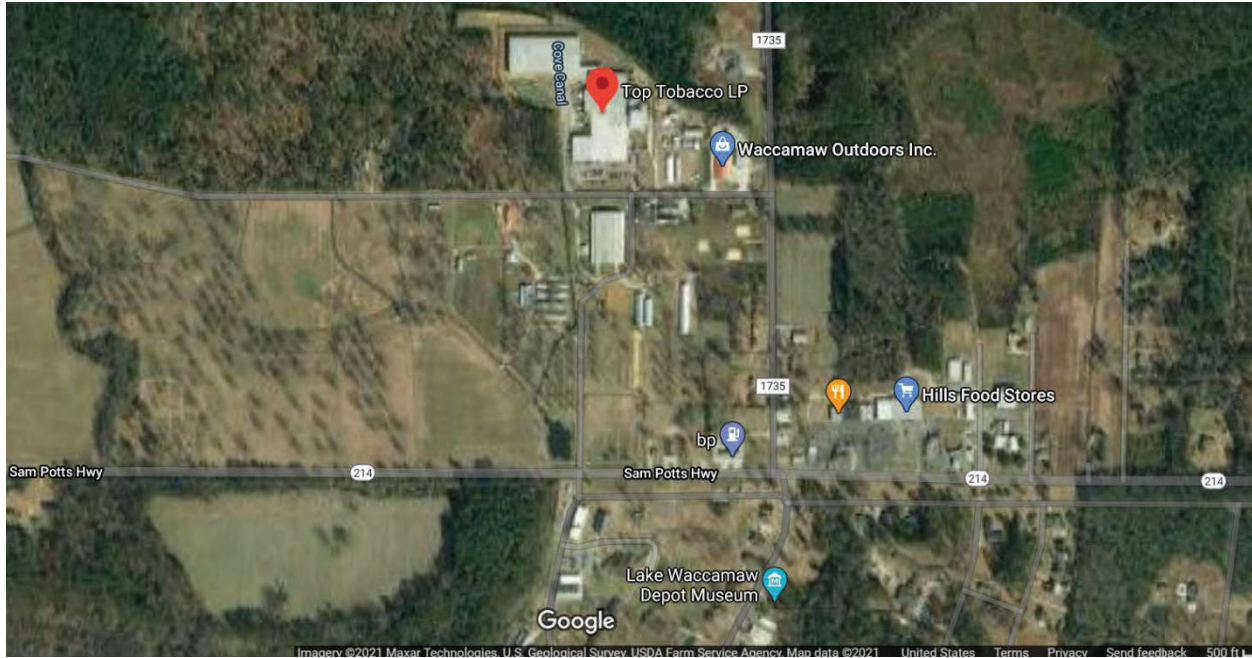
5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

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 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



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 information submitted by the applicant that included the projected market volumes and market projections for the new and predicate products (Confidential Appendix 2).

¹Land use surrounding manufacturing facility (Google Map of 204 Top Tobacco Road, Lake Waccamaw, NC 28450; www.google.com/maps. Accessed March 22, 2021).

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 March 12, 2021.

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 March 20, 2021.

⁴ North Carolina Department of Environmental Quality. Chapter 4: Waccamaw Sub-basin. Available at: <https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Lumber/Lumber%20Plan/2010%20Plan/Chapter%204%20-%20Waccamaw%20River%20Subbasin.pdf>. Accessed March 20, 2021.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that the new products and the corresponding predicate products contain the 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, 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 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. 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 and market information for the new and predicate products (Confidential Appendix 2).

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. 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:

Vyomesh Patel, Ph.D., Center for Tobacco Products

Education: PhD in Head and Neck Cancer

Experience: Twenty-four years in pharmaceutical toxicology and experimental carcinogenesis

Expertise: Preclinical drug evaluation, regulatory toxicology, animal models of human cancers

Reviewer:

Shannon K Hanna, PhD., Center for Tobacco Products

Education: Ph.D. in Environmental Science and Management

Experience: Five years in environmental science, three years in toxicology

Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1. Ingredient Changes in the New Products Compared to the Corresponding Predicate Products.

The applicant provided lists of all ingredients for the new and predicate products. Ingredient changes were noted in all four SE Reports. Changes included increases (b) (4)) and additions (b) (4)) in the new products, while the remaining ingredients were either removed or decreased in the new products compared to the corresponding predicate products.

SE Report	Ingredient	New Product (mg/g)	Predicate Product (mg/g)
SE0017388 (6 oz/Bag)	(b) (4)	(4)	(4)
SE0017425 (16 oz/Bag)	(b) (4)	(4)	(4)

<p>SE0017626 (16 oz/Bag)</p>	<p>(b) (4)</p> <p>Total Weight (b) (4)</p>
<p>SE0017648 (6 oz/Bag)</p>	<p>(b) (4)</p> <p>Total Weight (b) (4)</p>

¹NE: Not employed; NA: Not applicable.

Confidential Appendix 2. Current, First-, and Fifth Year Market Volume Information for the New and Predicate Products.

The applicant intends to continue marketing the new products and the corresponding predicate products after the marketing orders are issued. The applicant stated that the new products are intended to compete with similar products currently on the market. Manufacturing the new and predicate products (total (b) (4)) will comprise ~26% of the total facility's current production and <1% of the total U.S. tobacco market.⁵

STN	Current-Year Market Volume (Pounds)		Market Volume Projections (Pounds)			
			First Year		Fifth Year	
	New Product	Predicate Product ^a	New Product	Predicate Product	New Product	Predicate Product
SE0017388	(b) (4)					
SE0017425						
SE0017626						
SE0017648						
Total						

^aGrey box indicate duplicate predicate products.

⁵Total facility's current-year production is (b) (4) pounds and the total U.S. tobacco market of (b) (4) pounds for 2019.