

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

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

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Table of Contents

- 1. Applicant and Manufacturer Information..... 3
- 2. Product information..... 3
- 3. The Need for the Proposed Actions 3
- 4. Alternatives to the Proposed Actions 3
- 5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products..... 4
 - 5.1 Affected Environment..... 4
 - 5.2 Analysis of Potential Environmental Impacts 4
 - 5.3 Cumulative Impacts 5
 - 5.4 Impacts of the No-Action Alternative 5
- 6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Products 6
 - 6.1. Affected Environment..... 6
 - 6.2. Analysis of Potential Environmental Impacts 6
 - 6.3. Cumulative Impacts 6
 - 6.4. Impacts of the No-Action Alternative 6
- 7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products 6
 - 7.1. Affected Environment..... 7
 - 7.2. Analysis of Potential Environmental Impacts 7
 - 7.3. Cumulative Impacts 7
 - 7.4. Impacts of the No-Action Alternative 8
- 8. List of Preparers 8
- 9. List of Agencies and Persons Consulted..... 8
- Appendix 1. Product Quantity: The New Products Compared to the Predicate Products 9
- Confidential Appendix 1. Market Volume information for the New and Predicate Products..... 10

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

STN	New Product	Predicate Product
SE0015347	LARGO Regular 0.75 oz. Pouch	Gambler Regular Pouch (0.65 oz)
SE0015348	HIGH CARD Regular 5 oz. Medium Bag	Gambler Regular Medium Bag (6 oz)

Product Identification

Product Category	Pipe Tobacco
Product Subcategory	Pipe Tobacco Filler
Product Quantity per Retail Unit	0.75 oz and 5.0 oz loose tobacco per bag
Product Package	The filler is packed in a bag made of a polyethylene-based film and zipper and a rubber-based adhesive

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 the 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 in Lake Waccamaw, NC (Figure 1). The manufacturing facility is located in rural Columbus County, NC, surrounded by undeveloped forested land. The facility is 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



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).

¹ Land use surrounding manufacturing facility via Google Map.

<https://www.google.com/maps/place/Top+Tobacco+LP/@34.327006,-78.5256456,635m/data=!3m1!1e3!4m13!1m7!3m6!1s0x89aa5d83e3e5ef67:0x13fee42fa3dd47fa!2s204+Top+Tobacco+Rd,+Lake+Waccamaw,+NC+28450!3b1!8m2!3d34.327545!4d-78.525306!3m4!1s0x89aa5d83e3e5ef67:0x16970666d9ca190f!8m2!3d34.327545!4d-78.525306>. Accessed August 8, 2019.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant 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 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. The product modifications do not include any changes to material composition. 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 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 are 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 is not 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 is not 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 is expected; introducing the new products into the U.S. market is not 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:

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:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. List of Agencies and Persons Consulted

Not applicable.

Appendix 1. Product Quantity: The New Products Compared to the Predicate Products

STN	Product Quantity	
	Tobacco Filler per Bag (oz)	
	New Product	Predicate Product
SE0015347	0.75 oz.	0.65 oz.
SE0015348	5 oz.	6 oz.

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

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
SE0015347	(b) (4)					
SE0015348	(b) (4)					
<i>Total</i>	(b) (4)					