

**Programmatic Environmental Assessment for
Marketing Orders for Pipe Tobacco Filler
Manufactured by Top Tobacco LP**

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

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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 Name | New Product STN | Predicate ProductName |
|---------------------------------|------------------------|----------------------------------|
| GAMBLER Gold Mini Bag (1 oz) | SE0015374 | Gambler Light Medium Bag (6 oz) |
| GAMBLER Menthol Mini Bag (1 oz) | SE0015375 | Gambler Menthol Medium Bag (6oz) |

Product Identification

| | |
|---|--|
| Product Category | Pipe Tobacco Filler |
| Product Sub-Category | Combusted, Solid (cut leaf) |
| New Product Quantity Per Retail Unit | Sold individually, mini bags (1 oz) of pipe tobacco filler. 144 mini bags per shipping case. |
| Package | The packaging materials consist of individual polypropylene bags 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 the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency two substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue marketing orders if the new products are found substantially equivalent to the predicate products.

The new products differ from the corresponding predicate products in product quantity and package size. Specifically, the new products are 1.0 oz bags, meaning that each contains 5.0 oz less tobacco per bag compared to the corresponding predicate product.

On November 30, 2018 the agency determined the predicate products to SE0015374 and SE0015375 are grandfathered products as they were marketed in the United States as of February 15, 2007. The predicate

products are currently being marketed. The applicant stated that Top Tobacco LP will continue to market the new and predicate products if the new products are authorized for marketing.

4. Alternatives to the Proposed Actions

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

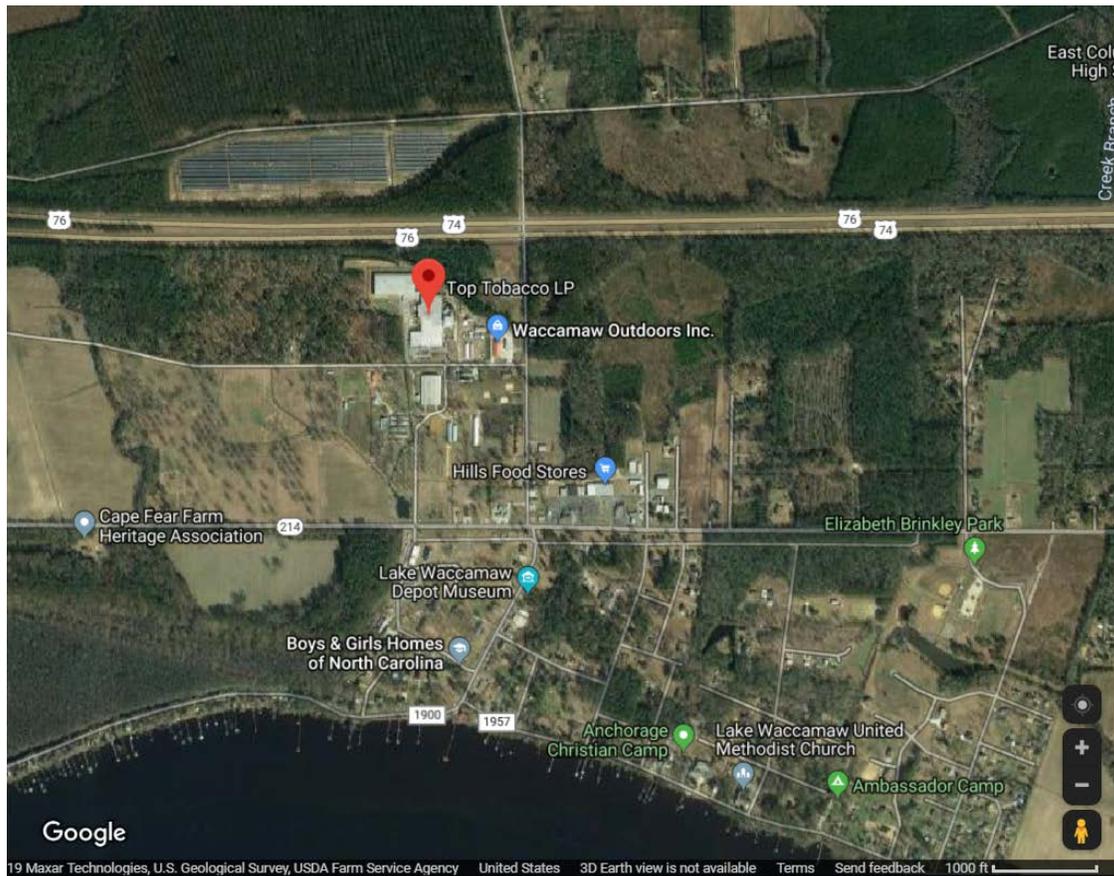
5. Potential Environmental Impacts of the Proposed Actions and the Alternatives – Manufacturing the New Products

The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts.

5.1 Affected Environment

The new products are manufactured by the Top Tobacco Company in Lake Waccamaw, NC (Figure 1). The Top Tobacco property is in rural Columbus County, NC where it is surrounded by undeveloped forested land. The production 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 Manufacturing Facility



5.2 Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from manufacturing based on Agency-gathered information and the applicant's submitted information, including the projected market volumes for the new and predicate products (Confidential Appendix 1).

| Environmental Resource | Analysis of Potential Impacts |
|--|--|
| Air quality | No air quality changes due to manufacturing would be expected because the new products differ only in package quantity compared to the predicate products. Additionally, the applicant stated that production of the new products would occupy a small portion of the total production at the facility. Lastly, the applicant stated that no new or revised air permits would be required due to manufacturing the new products. |
| Water resources | No impacts on water quality due to manufacturing would be expected because the new products differ only in package quantity compared to the predicate products. The applicant stated that production of the new products would occupy a small portion of the total production at the facility. Lastly, the applicant stated that no new or revised water permits would be required due to manufacturing the new products. |
| Land use and zoning | No conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use is expected because the applicant states that no facility expansion is anticipated. No zoning changes are anticipated because no construction would occur that would require land use. |
| Biological resources | The applicant stated the manufacture of the new product is carried out under controls and standards that protect the environment. The manufacturing materials and manufacturing processes will not have any adverse effects on any endangered species or the critical habitat of the species identified under the ESA. As required for compliance with the ESA, the manufacture of the new product is neither expected to jeopardize the continued existence of any endangered species, nor result in the destruction or adverse modification of the habitat of any such species, as prohibited under the ESA. |
| Geological features and soils | No effects on geological features or soils are expected because no facility expansion is anticipated. |
| Socioeconomic conditions | No facility expansion is anticipated; therefore, no impacts on employment; state or municipal revenue; or police and fire department resources are expected. Expansion of the manufacturing facility would not be necessary. |
| Solid waste and hazardous materials | The applicant stated that no additional capacity for disposal of manufacturing waste or any additional environmental controls would be required because manufacturing the new products would occupy less than 0.4 % of the total production at the facility. Additionally, proper disposal of any waste related to manufacturing the new products would be handled in compliance with applicable laws and regulations. |
| Floodplains, wetlands, and coastal zones | No effects to floodplains, wetlands, or coastal zones are expected because no facility expansion is anticipated. |
| Regulatory compliance | The applicant stated that the manufacturing facility would comply with all applicable federal, regional, and local regulations and requirements; this includes those related to emissions, solid waste, and liquid waste. |

5.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions.

5.4 Impacts of the No-Action Alternative

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

6. Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New Products

The Agency considered potential impacts to resources in the environment that may be affected by use of the new products and found no significant impacts.

6.1 Affected Environment

The affected environment includes human and natural environments in the United States because 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.

| Environmental Resource | Analysis of Potential Impacts |
|------------------------|---|
| Air quality | The applicant stated that no new compounds would be emitted from use of the new products. Therefore, 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. |
| Environmental justice | The new products are expected to be used by the same consumers that use the predicate products. Therefore, no change in impacts to environmental justice populations is expected. |

6.3 Cumulative Impacts

No actions were identified that, when considered with the proposed actions, would lead to cumulative impacts.

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 filler, as many similar products would continue to be marketed in the United States.

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

The Agency has considered the potential impacts to resources in the environment that may be affected by disposal of the new products and found no significant impacts.

7.1 Affected Environment

The affected environment is the entire United States because the marketing orders would allow for the new tobacco products to be sold to consumers nationwide who would dispose of the used products and packaging. The disposal would be via municipal solid waste (MSW) landfills, recycling centers, or as litter.

7.2 Analysis of Potential Environmental Impacts

The proposed actions were evaluated for potential environmental impacts from disposal of the new products.

| 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. Thus, disposal of the used products and packaging would not affect air quality. |
| Biological resources | Proper disposal of used products and packaging materials from the new products in MSW would not affect biological resources. Used products and packaging materials from the new products may be littered in undeveloped areas and wildlife habitat. However, 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 Agency’s assessment and the projected market volume for the new products. |
| Environmental justice | No significant environmental impacts associated with the disposal of the used products and packaging from the new products were identified, therefore no disproportionate impacts to environmental justice populations are anticipated. |
| Water resources | Proper disposal of used new products and packaging materials from the new products in the MSW would not affect water resources. Improper disposal (littering) could occur in or near surface water. However, 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 other similar products based on the projected market volumes reported by the applicant (Confidential Appendix 1). |
| Regulatory compliance | It is assumed that the portion of products and packaging waste that is disposed of by users as litter, despite littering ordinances, would be no greater than the current tobacco product littering rates. |

7.3 Cumulative Impacts

No actions were identified that would lead to cumulative impacts due to the proposed actions.

7.4 Impacts of the No-Action Alternative

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

8. List of Preparers

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this programmatic environmental assessment.

Preparer:

Thomas Creaven, Ph.D., Center for Tobacco Products
Education: B.S. in Chemistry/Biology and Ph.D. in Neuroscience
Experience: Ten years in science education, 3 years in NEPA review.
Expertise: Science education, NEPA review

Reviewer:

Gregory G. Gagliano, M.S., Center for Tobacco Products
Education: M.S. in Environmental Science
Experience: Thirty-six years in environmental toxicology
Expertise: Ecotoxicology, risk assessment, regulatory compliance, NEPA analysis

9. List of Agencies and Persons Consulted

Not applicable.

Confidential Appendix 1: Market Volume Projections for the New and Predicate Products

| New Product Market Volume Projections | | | |
|---------------------------------------|------------------|-----------------------|-----------------------|
| STN | In-Market Pounds | First-Year Projection | Fifth-Year Projection |
| | | (b) (4) | |
| SE0015374 | (b) (4) | | |
| SE0015375 | | | |

| Predicate Product Market Volume Projections | | | |
|---|------------------|-----------------------|-----------------------|
| STN | In-Market Pounds | First-Year Projection | Fifth-Year Projection |
| | | (b) (4) | |
| SE0015374 | (b) (4) | | |
| SE0015375 | | | |