

**Programmatic Environmental Assessment for Marketing
Orders for New Pipe Tobacco
by Alliance One Specialty Products, LLC**

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

October 12, 2021

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1. Applicant and Manufacturer Information

Applicant Name:	Alliance One Specialty Products, LLC
Applicant Address:	2305 Baldree Road PO Box 1929 Wilson, NC 27893
Manufacturer Name:	Eastern Carolina Packaging, LLC, a Division of Alliance One Specialty Products, LLC
Product Manufacturing Location:	1900B Stantonsburg Road SE Wilson, NC 27893

2. Product information

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

Table 1: Identification of the New and Products

STN	New Product	Predicate Product
SE0016771	EC Pipe Gold (1oz.)	Pipe Tobacco Natural
SE0016772	EC Pipe Gold (2oz.)	Pipe Tobacco Natural
SE0016773	EC Pipe Gold (3oz.)	Pipe Tobacco Natural
SE0016774	EC Pipe Gold (8oz.)	Pipe Tobacco Natural
SE0016775	EC Pipe Gold (12oz.)	Pipe Tobacco Natural
SE0016776	EC Pipe Gold (16oz.)	Pipe Tobacco Natural

Product Identification

Product Category	Pipe Tobacco	
Product Subcategory	Pipe Tobacco Filler	
Product Quantity per Retail Unit	SE0016771	1 oz finished pipe tobacco per bag
	SE0016772	2 oz finished pipe tobacco per bag
	SE0016773	3 oz finished pipe tobacco per bag
	SE0016774	8 oz finished pipe tobacco per bag
	SE0016775	12 oz finished pipe tobacco per bag
	SE0016776	16 oz finished pipe tobacco per bag
Product Package	The tobacco pipe filler is packaged in polyphenylene ether bags. The bags are packed into a cardboard case. The number of bags per case is determined by the bag weight: (SE0016771) 144 bags, (SE0016772, SE0016773) 36 bags, (SE0016774, SE0016775, SE0016776) 24 bags per cardboard 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 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 differ from their 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 products in the United States.

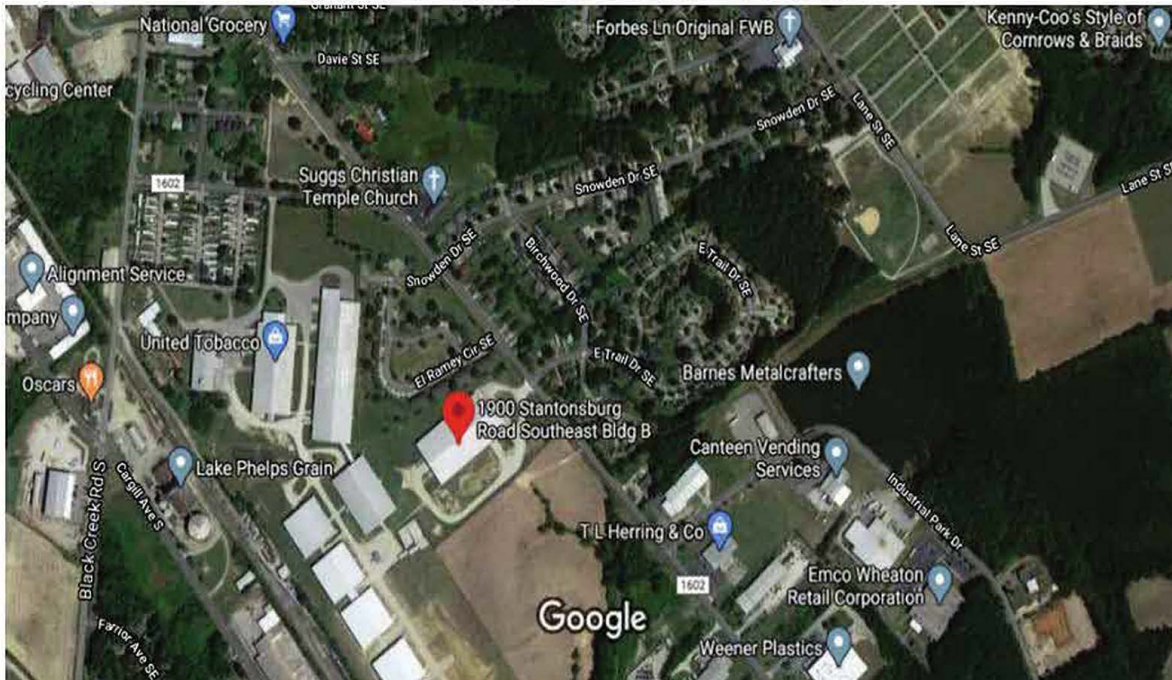
5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

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 packaged by Eastern Carolina Packaging, LLC in Wilson, NC (Figure 1). The packaging facility is located in a suburban light industrial tobacco processing area of Wilson, NC. The facility is bounded by State Route 1602 to the east and other tobacco processing facilities to the west.

Figure 1. Location of the Manufacturing Facility¹



¹ Land use surrounding manufacturing facility via Google Map. <https://www.google.com/maps>. Accessed September 8, 2021.

5.2 Analysis of Potential Environmental Impacts

The Agency considered potential impacts to resources in the environment that could be affected by packaging 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 packaging the new products will not lead to changes in air emissions to the environment from the manufacturing facility and will not require a new or revised permit.
Water resources	The applicant stated that packaging the new products will not lead to changes in wastewater discharges from the packaging facility and will not require a new or revised wastewater discharge permit.
Soil, land use and zoning	The applicant stated that there will be no facility expansion due to packaging the new products. Therefore, no changes in land use or zoning will occur as a direct impact from the proposed actions.
Biological resources	The applicant stated that the packaging facility does not exist in a US Fish and Wildlife Service Critical Habitat area for threatened and endangered species. No effects on listed species or their habitat and biological resources are anticipated because no facility expansion is expected.
Socioeconomic conditions	No impacts will be expected on employment, state or municipal revenue and taxes, or on police force and fire department resources because there will be no facility expansion anticipated.
Solid waste and hazardous materials	The applicant stated that the packaging facility will require no new environmental controls for solid waste. Therefore, the Agency does not anticipate that manufacturing the new products will lead to the presence of new chemicals in the manufacturing waste stream.
Floodplains, wetlands, and coastal zones	There will be no expected facility expansion due to packaging the new products. Therefore, no effects on floodplains, wetlands, or coastal zones are anticipated.
Regulatory compliance	The applicant stated that the packaging facility complies with all local, state and federal environmental laws, including the ESA and CITES.

5.3 Cumulative Impacts

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

5.4 Impacts of the No-Action Alternative

The no-action alternative will not change the existing conditions of packaging pipe tobacco filler at the listed facility, as similar pipe tobacco products will 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 might be caused 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 will allow for the new 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 will 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 and packaging.
Environmental justice	No new emissions are expected due to the use of the new products. Therefore, there will be no new disproportionate impacts on minority or low-income populations.

6.3. Cumulative Impacts

No actions were identified that will 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 will not change the existing conditions of use of pipe tobacco products, as similar pipe tobacco products will 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 will allow the new products to be sold to consumers nationwide who will 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 (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 will not significantly affect air quality.
Biological resources	Proper disposal of the used new products and packaging materials in the MSW stream will 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 will not be expected to increase the nationwide use of pipe tobacco products based on the current and projected market volumes reported by the applicant.
Water resources	Proper disposal of the used new products and packaging materials in the MSW stream will 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 will 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.
Solid waste and hazardous materials	The distribution of waste generated due to disposal of the new products and packaging is anticipated to correspond to the pattern of product use and disposal in the United States. However, introducing the new products into the U.S. market is not expected to increase the nationwide use and disposal. Therefore, no net increase in littering will be expected.
Regulatory compliance	The new products have no features that will 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) will 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 will 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 will not change the existing condition of the disposal of pipe tobacco products and packaging materials, as many other pipe tobacco products will 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:

Chad Baisden, MS, Center for Tobacco Products

Education: MS in Natural Resources

Experience: Five years in various scientific activities

Expertise: Environmental risk assessment, regulatory compliance

Reviewer:

Gregory G. Gagliano, Center for Tobacco Products (product-specific analyses, primary author)

Education: M.S. in Environmental Science

Experience: Thirty-nine 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: Comparison of New Products with Predicate Products

STN	Product Quantity	
	Tobacco Filler per Bag (oz)	
	New Product	Predicate Product
SE0016771	1	6
SE0016772	2	
SE0016773	3	
SE0016774	8	
SE0016775	12	
SE0016776	16	

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

The applicant intends to continue marketing the predicate products after receiving marketing orders for the new products. The new products are expected to compete with or replace similar pipe tobacco products currently on the market. The First- and fifth-year market volume projections for the new products were compared to the total 2020 pipe tobacco use in the United States.² If the current stable trend of pipe tobacco use³ in the United States persists, the projected use of the new products in the first and fifth year of marketing will account for (b) (4) % and (b) (4) %, respectively.⁴

STN	Market Volume Projections ⁵ (number of pounds)			
	First Year		Fifth Year	
	New Product	Predicate Product	New Product	Predicate Product
SE0016771	(b) (4)			
SE0016772				
SE0016773				
SE0016774				
SE0016775				
SE0016776				
Total				

² The Agency used historical data regarding total use of pipe tobacco from 1997 to 2020 to mathematically estimate the total number of pipe tobacco (pounds) used in the United States. Using the best-fit trend line with an R² value of 0.8144, the forecasted number of cigarettes that will be used in the United States is estimated at 30.226 million pounds in the first year and 15.107 million pounds in the fifth year of marketing the new products.

³ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Product (pounds)}}{\text{Projected Use of Pipe Tobacco in United States (pounds)}} \times 100$

⁴ Pipe tobacco use in the United States showed a stable trend from 1997 to 2008, increased from 2009 to 2012, and has since stabilized (2013 to date). Retrieved from <https://www.ttb.gov/tobacco/tobacco-statistics>. Accessed September 6, 2021.

⁵ Applicant states that there will be no "real" manufacturing at Eastern Carolina Packaging, LLC (ECP). ECP will purchase the finished tobacco and package it in different size bags at ECP.