

**Environmental Assessment for a Marketing Order for a New
Roll-Your-Own Tobacco Filler Manufactured
by Santa Fe Natural Tobacco Company, Inc.**

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

September 12, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	RAI Services Company
Applicant Address:	401 North Main Street Winston Salem, NC 27101
Manufacturer Name:	Santa Fe Natural Tobacco Company, Inc.
Product Manufacturing Address:	3220 Knotts Grove Road Oxford, NC 27565

2. Product Information

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

STN	New Product Name	Predicate Product Name
SE0015376	Natural American Spirit Perique Blend Pouch	Natural American Spirit Perique Blend Pouch

Product Identification

Product Category	Roll-Your-Own
Product Sub-Category	Roll-Your-Own Tobacco Filler
Number of Products per Retail Unit	40 grams per pouch
Product Package	The tobacco filler is packaged in a multi-layer polypropylene film, paper, and polyethylene polypropylene coextruded film pouch with tape and polypropylene film overwrap

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for U.S. Food and Drug Administration (FDA) to issue a marketing order 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 product into interstate commerce for commercial distribution in the United States.

The applicant submitted to the Agency one substantial equivalence (SE) report to obtain a marketing order for the new product. The Agency shall issue the marketing order, after considering the SE Report, if the new product is found substantially equivalent to the predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new product differs from the predicate product in the ratio of tobacco blend components and the packaging (Confidential Appendix 1).

4. Alternatives to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new tobacco product in the United States.

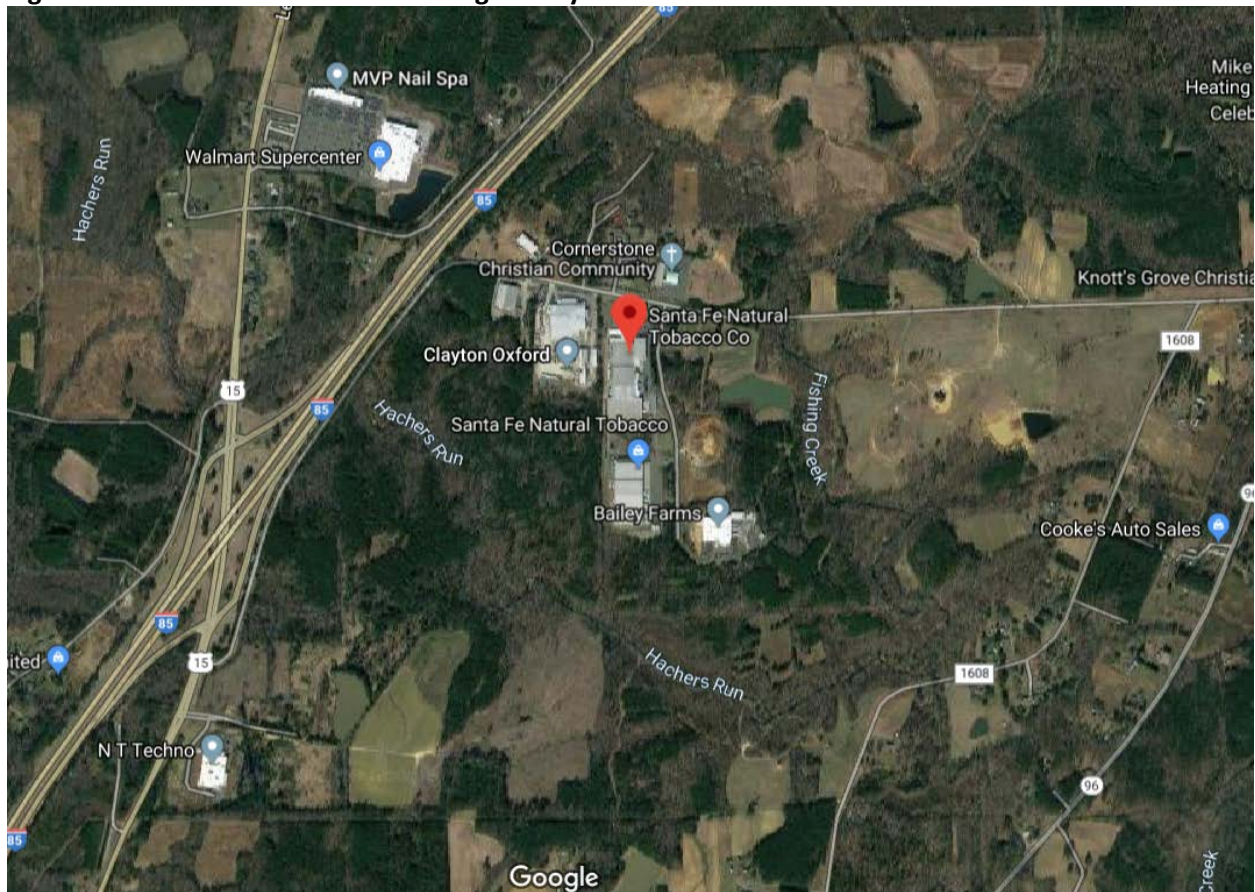
5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

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

5.1 Affected Environment

The new and predicate products are manufactured at Santa Fe Natural Tobacco Company, Inc. located at 3220 Knotts Grove Road, Oxford, NC (Figure 1). The manufacturing facility is located in an industrial and commercial area surrounded by forests and farmland. A metal fabrication facility is next door and a church is across the street. Interstate 85 is to the west. A small lake and creek are located to the east of the facility.¹

Figure 1. Location of the Manufacturing Facility



¹ Google. 2019. Map of 3220 Knotts Grove Road, Oxford, NC 27565. Retrieved from Google Maps: www.google.com/maps. September 3, 2019.

5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from manufacturing the new product based on information gathered by the Agency and the information in the SE Report, including projected market volumes for the new product (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	No air quality change surrounding the facility would be expected. The applicant stated that the only difference between the new product and the predicate product is the ratio of the different types of tobacco and a change in the packaging.
Water resources and water quality	The applicant stated that manufacturing the new product would not require additional environmental controls for water discharge. No impacts on water resources are expected because the liquid waste discharge is not anticipated to change at the manufacturing facility; little change in the ingredients being used in the facility is expected. The applicant stated that the only change between the new product and the predicate product is the ratio of the different types of tobacco and a change in the packaging.
Land use and zoning	No conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use is expected because no facility expansion or new construction is anticipated. Therefore, no changes in zoning or land use would be expected and no adverse effects on soils would occur from manufacturing the new product.
Biological resources	The applicant stated that the only change between the new product and the predicate product is the ratio of the different types of tobacco and a change in the packaging. Therefore, no changes to biological resources is expected. Additionally, the applicant stated that the manufacturing facility is not within or close proximity to critical habitat of a threatened or endangered species identified under the Endangered Species Act of the Convention on International Trade in Endangered Species of Wild Fauna and Flora and that the manufacture of the new product would not jeopardize the existence of any listed species or destroy or adversely impact any critical habitat.
Geological features and soils	No effects on geological features or soils are expected because no facility expansion is anticipated.
Socioeconomic conditions	No impacts on employment, revenue, taxes, or community resources, such as police force and fire department resources, are expected because no facility expansion is anticipated.
Solid waste and hazardous materials	No impacts on solid waste or hazardous materials are expected because the applicant stated that the only difference between the new product and the predicate product is the ratio of the different types of tobacco and a change in the packaging.
Floodplains, wetlands, and coastal zones	There would be no facility expansion and the applicant did not propose any land disturbance. Therefore, there would be no effects on floodplains, wetlands, or coastal zones.
Regulatory compliance	The applicant stated that the manufacturing facility is in compliance with all local, state, and federal environmental laws.

5.3 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts due to the manufacturing of the new product.

5.4 Impacts from No-Action Alternative

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

6. Potential Environmental Impact of the Proposed Action and Alternatives – Use of the New Product

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

6.1. Affected Environment

The affected environment is the entire United States because the marketing order would allow for the new tobacco product to be sold to consumers nationwide. The new RYO tobacco product is intended to be used with RYO paper and users may smoke them indoors or outdoors, as the law permits.

6.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from use of the new product based on information gathered by the Agency and the information submitted by the applicant.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that the only change between the new product and the predicate product is the ratio of the different types of tobacco and a change in the packaging. Therefore, the Agency does not anticipate that using the new product would lead to the release of new chemicals into the air, as compared to the predicate product or similar currently marketed products.
Environmental justice	The new product is expected to be used by the same consumers that use the predicate product. Therefore, no changes in impact to environmental justice populations are anticipated.

6.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts due to the use of the new product.

6.4. Impacts from No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of RYO tobacco products, as many similar tobacco products would continue to be marketed and therefore used in the United States.

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

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

7.1. Affected Environment

The affected environment is the entire United States because the marketing order would allow for the new tobacco product to be sold to consumers nationwide. The disposal would be via municipal solid waste (MSW) landfills, recycling centers, or as litter.

7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential impacts from disposal of the new product based on information submitted in the SE Report, including market volume information for the new and predicate products (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products; therefore, disposal of the used product and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the used new product and packaging materials from the new product in MSW would not affect biological resources. Used product and packaging materials from the new product may be littered in undeveloped areas and wildlife habitat. However, introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products based on the Agency’s assessment. Therefore, littering levels are not expected to change from the current levels due to existing tobacco products.
Environmental justice	No significant environmental impacts associated with the disposal of the used product and packaging materials were identified, therefore no disproportionate impacts to environmental justice populations are anticipated.
Water resources and water quality	Proper disposal of used new product and packaging materials in the MSW stream would not affect water resources. Improper disposal could occur in or near surface water. However, introducing the new product into the U.S. market is not expected to increase the nationwide use of RYO tobacco products, based on the projected market volumes reported by the applicant (Confidential Appendix 2). Therefore, littering levels are not expected to change from the current levels due to existing products

Regulatory compliance	It is assumed that littering of the new product and packaging waste, despite state and local ordinances, would be no greater than the littering rate of the currently marketed RYO tobacco products.
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7.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts due to the disposal of the new product.

7.4. Impacts from No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of RYO tobacco products, as many similar tobacco products would continue to be marketed and therefore disposed of in the United States.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this environmental assessment (EA):

Preparers:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
 Education: Ph.D. in Environmental Science and Management
 Experience: Four 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

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, regulatory compliance, NEPA analysis

9. List of Agencies and Persons Consulted

Not applicable.

CONFIDENTIAL APPENDIX 1

Comparison of the New Product to the Predicate Product

SE Report	Component	Change
SE0015376	Tobacco blend	The new product incorporates less (b) (4) (b) (6) and (b) (4) perique (b) (6) tobacco leaf than the predicate product.
	Packaging	The new product pouch is composed of paper inserted between polyethylene and polypropylene film while the predicate product pouch is composed of polyethylene

CONFIDENTIAL APPENDIX 2

Current-Year Market Volume for the Predicate Product and First- and Fifth-Year Market Volume Projections for the New Product

STN	Unit	Current-Year (2018) Market Volume Predicate Product	First-Year Market Volume Projections New Product	Fifth-Year Market Volume Projections New Product
SE0015376	Pouch	(b) (4)	(b) (4)	(b) (4)

The applicant stated that the new product would replace the predicate product.