

**Programmatic Environmental Assessment for Marketing
Orders for Combusted Filtered Cigarettes Manufactured by
Santa Fe Natural Tobacco Company**

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

December 2, 2019

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1. Applicant and Manufacturer Information

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

2. Product Information

New Product and Original Product Names and Submission Tracking Numbers (STNs)

New Product		Original Product	
Name	STN	Name	STN
Natural American Spirit Balanced Taste Box	EX0000826	Natural American Spirit Balanced Taste	SE0006275
Natural American Spirit Smooth Taste Box	EX0000827		

Product Identification

Product Category	Cigarette
Product Subcategory	Combusted filtered
Product Number per Retail Unit	Twenty cigarettes per pack with ten packs per paper board carton.
Product Package	The packaging materials consist of a solid bleached sulphate inner frame, box, and carton; foil inner liner; and polypropylene film overwrap.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the U.S. Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for two combusted, filtered cigarettes. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant

may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The new products are made by modifying the single original product. These modifications are to the cigarette seam adhesive and tipping paper (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.

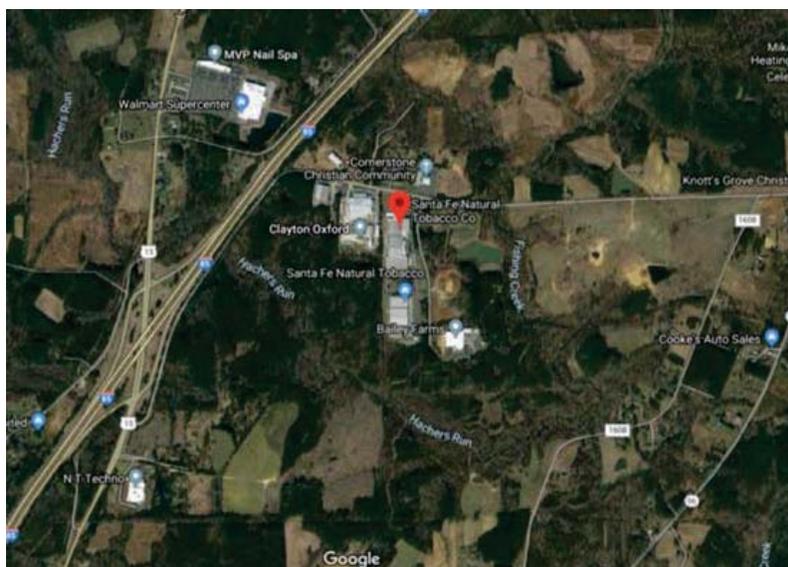
5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Products

The Agency considered potential impacts to resources in the environment that could be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Ingredients in the cigarette paper seam adhesive are commonly used in other products manufactured at the facility.
- The new products are intended to replace a percentage of the currently marketed original product without impacting the overall future projected market volumes. In other words, market volume projections for the new and original products do not exceed what would be projected for just the original product if the new products did not receive marketing orders.
- The new products would compete with similar tobacco products manufactured at the facility.
- No facility expansion is expected due to manufacturing the new products.

5.1 Affected Environment

Figure 1. Location of the Manufacturing Facility¹



¹ Google. 2019. Map of 3220 Knotts Grove Road, Oxford, NC 27565. Retrieved from Google Maps: www.google.com/maps. November 10, 2019.

The new and original 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.

5.2 Air Quality

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals into the environment. The applicant stated that manufacturing the new products is not expected to result in changes in air emissions; accordingly, the applicant concluded that manufacturing the new products would not require any additional environmental controls for air emissions.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The applicant stated that manufacturing the new products would not require any additional environmental controls for water discharge.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, or zoning. The applicant stated there would be no expected facility expansion. Therefore, there would be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

5.5 Biological Resources

The Agency does not anticipate manufacturing the new products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA). The search of the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps shows one threatened mussel (yellow lance), one endangered mussel (dwarf wedgemussel), two endangered plants (harperella and smooth coneflower), four at-risk invertebrates, and two at-risk vertebrates are listed in Granville County.^{2,3} The applicant also reviewed the U.S. FWS maps and stated that the manufacturing facility is not within or near a critical habitat, or endangered animal and plant species.

² U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/raleigh/species/cntylist/granville.html>. Accessed November 15, 2019.

³ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed November 15, 2019.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations. The agency verified the applicant's statement using information available on the Environmental Protection Agency (EPA)'s Enforcement and Compliance History Online (ECHO) database. ECHO shows that the facility is in compliance with air emission and storm water requirements under the following permits:

- (1) Air permit number 10622411 issued by the North Carolina Department of Environmental Quality.
- (2) Storm water permit number NCG060231 issued by the North Carolina Department of Environmental Quality.

Additionally, the facility submits release data to the EPA under the provisions of the Toxic Release Inventory (TRI) program (permit # 27565SNTFN322KN).

The applicant also stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

5.7 Socioeconomics and Environmental Justice

No changes in impacts on minority populations are expected due to manufacturing the new products because no new chemical releases to the environment from manufacturing the new products were identified.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no anticipated facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

5.10 Cumulative Impacts

The Agency does not anticipate that the proposed actions would incrementally increase or change the chemicals released to the environment from the tobacco manufacturing facility. A search in EPA's TRI database showed that in 2018, Santa Fe Natural Tobacco Company manufacturing facility in Oxford, North Carolina released 1,696 pounds of nicotine and nicotine salts to air onsite and 18,831 pounds of

nicotine and nicotine salts offsite.⁴ Nicotine and nicotine salts have known adverse developmental effects.⁵ No other hazardous air pollutants were reported. The TRI database search did not show that the Santa Fe Natural Tobacco Company manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA’s ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at the Oxford Manufacturing Facility of Santa Fe Natural Tobacco Company

Production-Related Waste Managed or Released		Chemical Mass (pounds)	
Recycled		0	
Energy Recovery		0	
Treated		0	
<i>Subtotal Waste Managed</i>		<i>0</i>	
On-Site Release	Air	Ammonia	0
		Nicotine and Nicotine Salts	1,696
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-Site Release		Ammonia	0
		Nicotine and Nicotine Salts	18,831
<i>Subtotal Waste Released</i>		<i>20,527</i>	
Total Production-Related Waste		20,527	

The applicant stated that manufacturing the new products would not require additional environmental controls for air emission, water discharge or solid waste disposal.

5.11 Impacts of the No-Action Alternative

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

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

The Agency considered potential impacts to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant’s submitted information. Included in the information the Agency considered were the

⁴ U.S. Environmental Protection Agency (EPA). TRI Data available at: <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Release/27565SNTFN322KN>. Accessed on November 15, 2019.

⁵ U.S. EPA. myRight-to-Know, available at: <https://myrtk.epa.gov/info>. The site allows for searching the industrial facilities that manage toxic waste chemicals by entering the facility address and clicking on the facility location on the map. Accessed November 15, 2019.

projected market volumes for the new products and the documented decline in cigarette use in the United States.

6.1. Affected Environment

The affected environment includes 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. Air Quality

The Agency does not anticipate new chemicals would be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other cigarettes already on the market because (1) the combustion products from the new products would be released in the same manner as the combustion products from the original product and any other marketed cigarettes; (2) the new products are expected to compete with, or replace, other currently marketed cigarettes, (3) the ingredients in the new products are used in other currently marketed tobacco products.

6.3. Environmental Justice

No new emissions are expected due to use of the new products. Therefore, there would be no disproportionate impacts on minority or low-income populations.

6.4. Cumulative Impacts

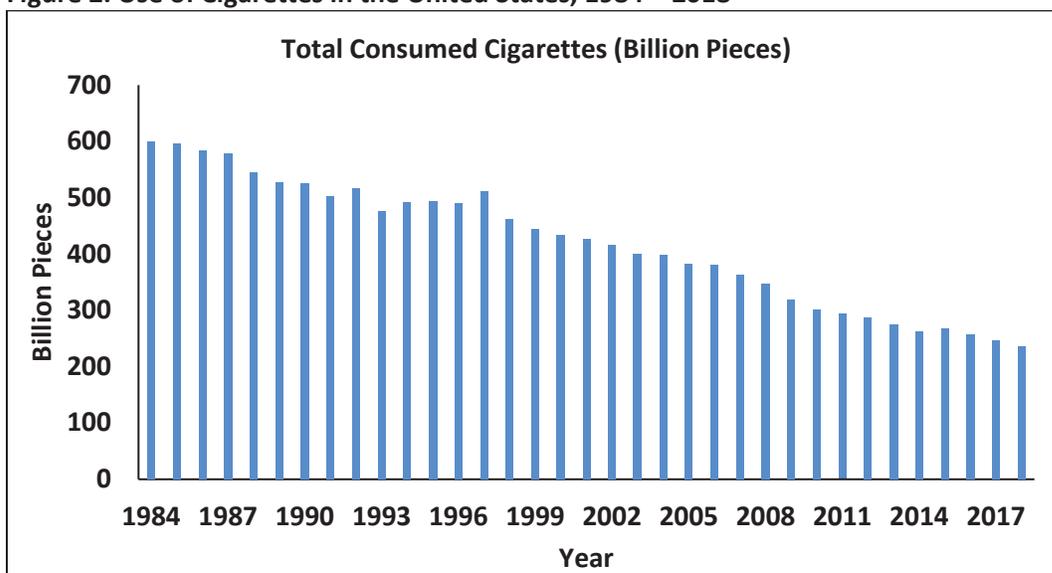
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in mixtures in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. It can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).
- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

However, the use of cigarettes in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).⁶ This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. SHS exposure declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

Figure 2. Use of Cigarettes in the United States, 1984 – 2018



As of March 2018, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2018). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

6.5. Impacts of the No-Action Alternative

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

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

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new products. The Agency found no significant impacts based on publicly available

⁶ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed July 1, 2019.

information such as the documented continuous decline in use of cigarettes in the United States, and the applicant's submitted information, including the projected market volumes for the new products.

7.1. Affected Environment

The affected environment includes 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.

7.2. Air Quality

The Agency does not anticipate disposal of the new products or the packaging material would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the cigarette butts of the new products. The chemicals in the cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated to compete with, or replace, other currently marketed cigarettes, the butt waste generated from the new products would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other cigarettes disposed of in the United States.

No changes in air quality from disposal of the packaging materials of the new products would be expected because (1) the paper and plastic components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3. Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. Although disposal of smoldering cigarettes has been implicated in many fire incidents,^{7,8} the new products are not expected to change the fire frequency as (1) the disposal of the new products would be the same as the disposal of cigarettes that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigarettes being disposed of because the new products are anticipated to compete with, or replace, other currently marketed cigarettes.

7.4. Water Resources

No changes in impacts on water resources are expected due to disposal of the cigarette butts from the new products because the chemicals in the new products would be the same as or similar to chemicals in currently marketed cigarettes. The new products would replace similar products currently on the market.

⁷ National Fire Protection Association. The smoking-material fire problem. Available at: <https://www.nfpa.org/News-and-Research/Data-research-and-tools/US-Fire-Problem/Smoking-Materials>. Accessed July 1, 2019.

⁸ UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed July 1, 2019.

7.5. Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products would notably affect the current cigarette butt waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other combusted, filtered cigarettes in the United States. The number of cigarette butts generated would be equivalent to the market projections (Confidential Appendix 1) and a portion of those would be littered.

7.6. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products would be handled in the same manner as the waste generated from disposal of other cigarettes in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7. Cumulative Impacts

A major existing environmental consequence of the use of the new products, as well as the original product and other conventional cigarettes, is littering of discarded cigarette filters or butts, which can persist in the environment for more than 18 months (Novotny and Zhao, 1999). Cigarette butts are among the most common forms of litter found on beaches (Claereboudt, 2004; Smith et al., 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson et al., 2014), roads, and streets (Healton et al., 2011; Patel et al., 2013). Cigarette butts have been found at densities averaging more than four cigarette butts per meter squared of urban environments (Pon and Becherucci, 2012).

Compounds in cigarette butts can leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigarette butts due to air emissions is not well studied. The chemicals in cigarette butts can be the original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the cigarette butts. Airborne emissions from cigarette butts after disposal depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the cigarette brand, cigarette length, filter material, tobacco filler, ingredients in the cigarette, number of puffs, and the mass transfer behavior of combustion products along the cigarette.⁹

However, the cumulative impacts from cigarette butts is declining because the use of cigarettes in the United States is declining.

7.8. Impacts of the No-Action Alternative

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

⁹ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed July 1, 2019.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

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Experience: Ten years in science education and three years in NEPA Review

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Reviewer:

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Education: MS in Environmental Science and PhD in Biochemistry

Experience: 11 years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

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CONFIDENTIAL APPENDIX 1

Modifications: New Products as Compared with the Original Product

STN	Component	Modification
EX0000827	Tipping Paper	Deletion of white tipping paper
		Addition of alternate white tipping paper
EX0000826	Cigarette Paper	Deletion of cigarette paper seam adhesive
EX0000827	Seam Adhesive	Addition of alternate cigarette paper seam adhesive

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections for the New Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Products

First- and fifth-year market volume projections for the new products were compared to the total forecasted use of cigarettes in the United States.¹⁰ The projected use of the new products account for a fraction of a percent of the forecasted cigarette use in the United States.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹¹	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹²
EX0000826	(b) (4)			
EX0000827				
Total				

¹⁰ The Agency used historical data regarding total use of cigarettes from 2002 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.657 billion cigarettes in the first year and 205.021 billion cigarettes in the fifth year of marketing the new products.

¹¹ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

¹² Ibid.