Environmental Assessment for a Marketing Order for a New Combusted Filtered Cigarette Manufactured by Santa Fe Natural Tobacco Company, Inc.

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

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1. Applicant and Manufacturer Information

Applicant Name	Santa Fe Natural Tobacco Company, Inc.
Applicant Address	3220 Knotts Grove Road, Oxford, NC 27565
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 Original Product Name

New Product Name	STN	Original Product Name
Natural American Spirit Original Blend Smooth Taste Box	EX0002160.PD1	Natural American Spirit Mellow Taste

Product Identification

Product Type	Cigarette
Product Subcategory	Combusted, Filtered
Number of Products per Retail Unit	Twenty cigarettes per box with ten boxes per carton.
Product Package	Packaging is a paper-lined paperboard box with a polypropylene film overwrap.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue an exemption from substantial equivalence (SE) reporting for a marketing order under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for a combusted, filtered cigarette. 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) 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 product into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the product exemption 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 product for which the applicant has obtained an exemption from demonstrating substantial equivalence.

The new product differs from the original product in the deletion of two additives, the addition of two additives, and an increase in the quantity of an existing additive (Confidential Appendix 1).

4. Alternative to the Proposed Action

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

5. Potential Environmental Impacts of the Proposed Action and Alternative – New Product Manufacture

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

- The new product would be manufactured in the same manner as the original product.
- The new product would compete with similar tobacco products on the market.
- Components of the new product are commonly used in other commercially marketed cigarettes.

Additionally, the applicant states that 1) new substances or new types of emissions released into the environment as a result of manufacturing the new product are not anticipated, 2) manufacturing the new product will not require additional resources (e.g., landfills, recycling centers, etc.) for disposal of manufacturing waste or additional environmental controls for air emission, water discharge, or solid waste disposal, 3) waste generated as a result of manufacturing the new product would be released to the environment, transferred to Publicly Owned Treatment Works (POTWs), and disposed in the same manner as other products manufactured in the same facility and products manufactured by other industries, 4) no additional equipment or facility expansion would be required, and 5) materials released into the environment would not exceed what is allowed under relevant environmental law.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new product would be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturing Facility [1]

The manufacturing facility is in Granville County, NC, in the Fishing Creek watershed[a] (hydrologic code 030201010201). [2] The facility is surrounded by small, isolated forest patches within a mixed commercial, agricultural, and residential landscape, with commercial property directly to the west, north, and southeast. Fishing Creek and Hachers Run flow approximately 1000-2000 ft beyond forest to the north/east and south/southwest of the facility, respectively.

5.2 Air Quality

The Agency does not anticipate that any new chemicals would be released into the environment due to new product manufacture. The applicant states that new product manufacture would not require additional environmental controls for air emissions.

EPA's TRI database showed that in 2020, the Santa Fe Natural Tobacco Company, Inc. manufacturing facility in Oxford, NC, released 1,935 pounds of nicotine and nicotine salts onsite to air and transferred 17,859 pounds of nicotine and nicotine salts offsite (Table 1). [3] The TRI database search did not show that the manufacturing facility released into the environment any other reportable toxicants associated with manufacturing tobacco products. No other hazardous air pollutants were reported. 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 Santa Fe Natural Tobacco Company, Inc. Manufacturing Facility in 2020

Production-Related Waste Managed or Released		Pounds
Recycled		0
Energy Recovery		0
Treated		0
Subtotal Waste Managed		*0*
Nicotine and Nicotine Salts	On-site Release	1,935
	Off-site Release	17,859
Subtotal Waste Released		*19,794*
Total Production-Related Waste		**19,794**

5.3 Water Resources

The Agency does not anticipate that new product manufacture would cause the discharge of any new chemicals into water. The applicant states that new substances or emission types released into the environment and that additional resources for manufacturing waste disposal or additional environmental controls for water discharge as a result of new product manufacture are not anticipated.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that new product manufacture would lead to changes in soil, land use, or zoning. The applicant states that there would be no expected facility expansion due to new product

[a] A watershed is an area of land where all bodies of water drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. Such bodies of water include the following: surface water from lakes, streams, reservoirs and wetlands; the underlying ground water; and rainfall. See https://water.usgs.gov/edu/watershed.html.

manufacture. 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 that new product manufacture 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 applicant states that new product manufacture would not require manufacturing facility expansion. Listed in Table 2, the U.S. FWS identifies seven endangered or threatened species in Granville County, NC [4], with critical habitat associated with lotic surface waters from the west to the south and east of the manufacturing facility. [5] The manufacturing facility is approximately 0.2 miles from Fishing Creek that, to the south, connects with the Tar River that is critical habitat for *F. masoni*, *E. lanceolata*, and *N. lewisi;* to the east the Tabbs River is also critical habitat for *E. lanceolata*; and to the north Aarons Creek is critical habitat for *F. masoni*. [5]

Table 2. Species Identified by USFWS in Granville County, North Carolina [4]

Species	Status
Harperella (*Ptilimnium nodosum*)	Endangered
Smooth coneflower (*Echinacea laevigata*)	Endangered
Carolina madtom (*Noturus furiosus*)	Endangered
Dwarf wedgemussel (*Alasmidonta heterodon*)	Endangered
Atlantic pigtoe (*Fusconaia masoni*)	Threatened
Yellow lance (*Elliptio lanceolata*)	Threatened
Neuse River waterdog (*Necturus lewisi*)	Threatened

5.6 Regulatory Compliance

The applicant states that the manufacturing facility is in compliance with all local, state, and federal environmental laws. The manufacturing facility submits release data to the EPA under provisions of the Toxic Release Inventory (TRI) program (permit # 27565SNTFN322KN). [3] The Agency's review of the EPA's Enforcement and Compliance History Online (ECHO) database did not indicate violations of the Clean Air Act (Operating Synthetic Minor, NC0000003703900102) or Clean Water Act (Minor, Permit Effective, NCG060231), or informal or formal enforcement actions associated with the manufacturing facility. [6]

5.7 Socioeconomics and Environmental Justice

No socioeconomic changes are anticipated due to new product manufacture. The Agency does not anticipate any impacts to employment, revenue, or taxes because the new product is intended to compete with other cigarettes manufactured at the facility and facility expansion is not required. There would be no increase in potential impacts to minorities in the area.

5.8 Solid Waste and Hazardous Materials

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

manufacture would not require additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or facility construction for new waste management are expected.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to new product manufacture and the applicant did not propose any land disturbance. Therefore, there would be no effects to floodplains, wetlands, or coastal zones.

5.10 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of cigarette manufacture at the listed facility because manufacture of similar products would continue.

6. Potential Environmental Impacts of the Proposed Action and Alternative – New Product Use

The Agency evaluated potential impacts to resources in the environment that may be affected by use of the new product 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 projected market volumes for the first and fifth years of marketing the new product in the United States (Confidential Appendix 2).

6.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow the new product to be sold to consumers in the United States.

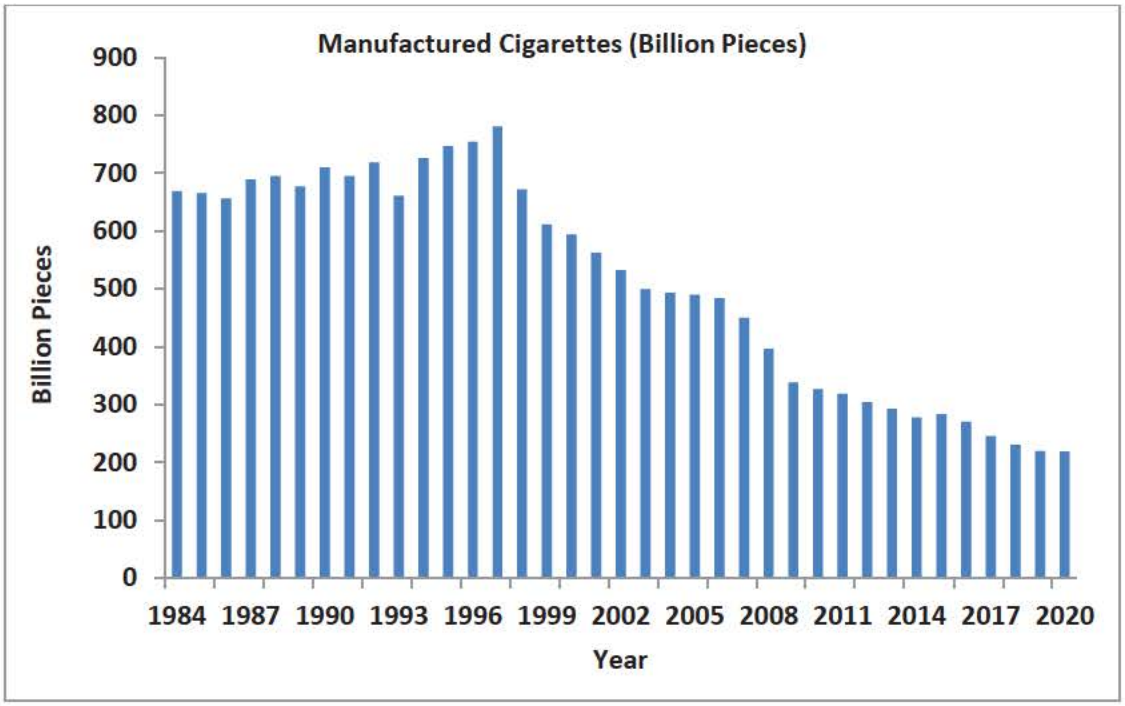
6.2 Air Quality

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. [7, 8]

There is no safe level of exposure to SHS. [9, 10] 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%. [11]
- 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. [9, 10]
- SHS causes more than 40,000 deaths a year. [11]

Figure 2. Use of Cigarettes in the United States, 1984 – 2020

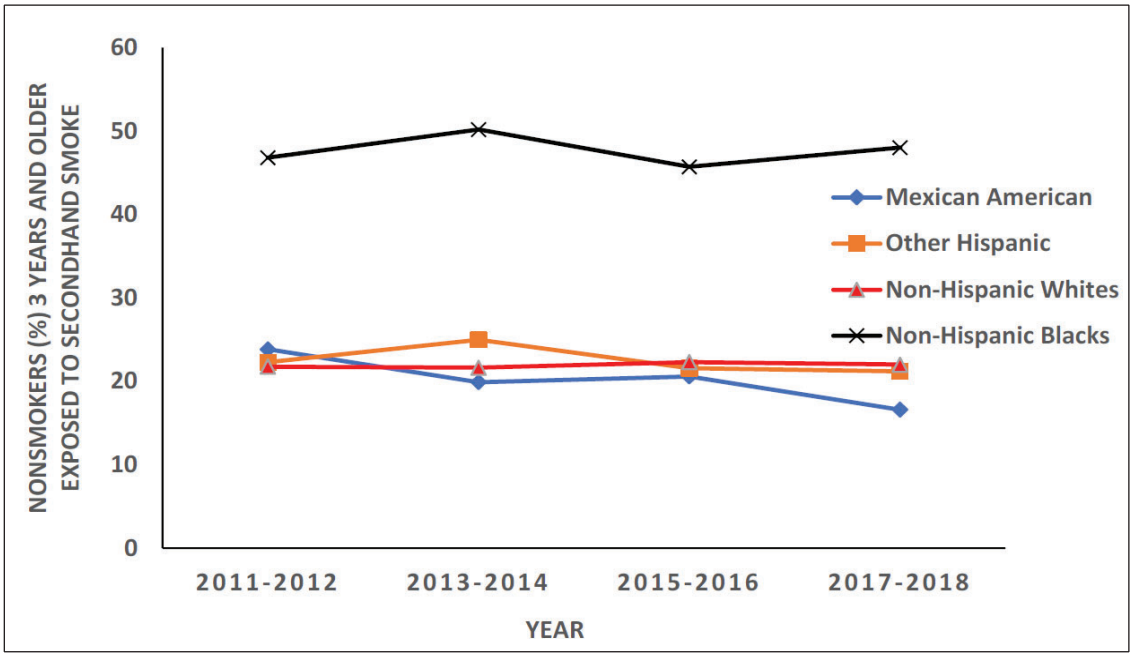


However, cigarette use in the United States is declining, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports[b] (Figure 2). [12] This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers. [13, 14] Despite 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 among nonsmokers from 87.5% in 1988-1991 to 25.1% in 2013-2014 [15] with the highest prevalence of exposure among non-Hispanic black (50.3%) compared to Mexican Americans (20%) and non-Hispanic whites (21.4%) in 2013-2014. However, no change in exposure occurred between 2011-2012 and 2013-2014. [15]

However, in recent years, a stagnation in the reduction in the rate of SHS exposure has been reported (Figure 3). [16]

[b] TTB sales data are used as proxy for consumption, assuming all products that are sold will be consumed in the United States.

Figure 3. Trends in the Exposure of Nonsmokers to Secondhand Smoke [16]



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws. [17] Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

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

6.3 Environmental Justice

No new emissions are expected due to new product use. Therefore, there will be no new disproportionate impacts to minority or low-income populations.

6.4 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of cigarette use because many other similar tobacco products will continue to be marketed in the United States.

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

The Agency evaluated potential impacts to resources in the environment that may be affected by new product disposal. The Agency found no significant impacts based on publicly available information such as the decline in cigarette use in the United States [12] and the applicant's submitted information, including the projected market volumes for the new product.

7.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing order would allow for the new product to be sold to consumers in the United States.

7.2 Air Quality

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

No changes in air quality are anticipated from disposal of cigarette butts from the new product. The chemicals in the cigarette butts are commonly found in butts from other currently marketed cigarettes. Because the new product is anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new product would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new product 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 new product packaging materials will be expected because, 1) 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) waste generated from packaging disposal [18] is a minuscule portion of the municipal solid waste in the United States per FDA's experience evaluating packaging waste generated from cigarettes.

7.3 Water Resources

No changes in impacts to water resources are expected due to disposal of the cigarette butts and packaging from the new product because the chemicals in the new product would be used in cigarettes currently on the market. Furthermore, the new product would compete with or replace market share held by similar products.

7.4 Biological Resources

The proposed action is 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, [19] disposal of the new product is not expected to change fire frequency because 1) new product disposal would be the same as disposal of cigarettes currently marketed in the United States, and 2) there would be no anticipated increase in the number of disposed cigarettes because the new product is anticipated to replace similar marketed cigarettes.

7.5 Solid Waste

A major existing environmental consequence of the use of the new product, as well as other conventional cigarettes, is littering of discarded cigarette filters or butts. [20] Cigarette butts are among the most common forms of litter found on beaches, [21, 22] near streams, night clubs, [23] bus stops, [24] roads, and streets. [25, 26] Cigarette butts have been found at densities averaging more than four cigarette butts per square meter of urban environments. [27]

Toxic compounds in cigarette butts leach into water, potentially threatening human health and the environment, especially marine ecosystems. [28, 29] The environmental toxicity of cigarette butt air emissions is not well studied. Chemicals in cigarette butts can be the original chemicals in unsmoked cigarettes or constitute associated pyrolysis and distillation products. What constitutes airborne emissions from cigarette butts after disposal depends on environmental conditions and chemicals in the

butts. These emissions can be influenced by several factors, such as the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette. [30]

The Agency does not foresee the introduction of the new product will notably affect the current cigarette butt waste generated from all cigarettes. The waste generated due to disposal of the new product will be handled in the same manner as any other waste generated from any other cigarettes disposed of in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2) and a portion of those will 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 product. The waste generated due to disposal of the new product is expected to be handled in the same manner as waste generated from other cigarettes in the United States. No new emissions are expected due to disposal of the new product. Therefore, there will be no new disproportionate impacts on minority or low-income populations.

7.7 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of cigarette and cigarette packaging disposal because many other similar tobacco products will continue to be marketed in the United States.

8. List of Preparers

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

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Education: Ph.D. in Biological Sciences
Experience: Twenty-three years in environmental management and compliance
Expertise: Environmental toxicology, risk assessment, population management, regulatory compliance

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Gregory Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science
Experience: Thirty-nine years in environmental compliance and analysis
Expertise: Environmental toxicology, risk assessment, regulatory compliance, NEPA analysis

9. A Listing of Agencies and Persons Consulted

None.

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CONFIDENTIAL APPENDIX 1

Comparison of the New Product to the Original Product

STN	Modification
EX0002160.PD1	• Deletion of a tobacco additive (cigarette sideseam adhesive) • Addition of a tobacco additive (alternate cigarette sideseam adhesive) • Deletion of a tobacco additive (cork tipping paper) • Addition of a tobacco additive (white tipping paper) • Increase in the quantity of an existing tobacco additive (tipping adhesive)

CONFIDENTIAL APPENDIX 2

Original and New Product Market Volume and Projected Percentage of United States Cigarette Use Attributed to the New Product

First and fifth year new product market projections[c] were compared to total forecasted cigarette use in the United States.[d] The new product accounts for about (b) (4) and (b) (4) in the first and fifth years after marketing orders are issued, respectively, of forecasted cigarette use in the United States.

STN	Market Volume (Number of Cigarettes)				
	Current Year	Projected			
		First Year		Fifth Year	
	Original Product	New Product	New Product as a Percent of Total Cigarettes Used [e]	New Product	New Product as a Percent of Total Cigarettes Used [f]
EX0002160.PD1	(b) (4)				

[c] Market volumes are used as proxy for use, assuming that all produced products will be consumed or used in the United States.

[d] The Agency used historical data regarding cigarette sales from 1997 to 2020 [12] as a proxy for consumption to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R^2 value of 0.9844, the forecasted number of cigarettes that would be used in the United States is estimated at 228.441 billion cigarettes in the first year and 161.201 billion cigarettes in the fifth year of marketing the new product.

[e] Projected Market Occupation of the New Product in the United States (%)=

$$\frac{\text{Projected Market Volume of the New Product (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} x\ 100$$

[f] Ibid.