

**Programmatic Environmental Assessment for Marketing  
Orders for Nine New Combusted Filtered Cigarettes  
Manufactured by Santa Fe Natural Tobacco Company, Inc.**

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

May 15, 2019

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**1. Applicant and Manufacturer Information**

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

**2. Product Information**

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

<b>New Product Name</b>	<b>STN</b>	<b>Original Product Name</b>
Natural American Spirit 100% US Grown Tobacco Mellow Taste	EX0000490	Natural American Spirit 100% US Grown Tobacco Mellow Taste
Natural American Spirit Full-Bodied Taste	EX0000491	Natural American Spirit Full-Bodied Taste
Natural American Spirit Mellow Taste	EX0000492	Natural American Spirit Mellow Taste
Natural American Spirit Made with Organic Tobacco Mellow Taste	EX0000493	Natural American Spirit Made with Organic Tobacco Mellow Taste
Natural American Spirit Made with Organic Tobacco Full-Bodied Taste	EX0000494	Natural American Spirit Made with Organic Tobacco Full-Bodied Taste
Natural American Spirit Smooth Mellow Taste	EX0000495	Natural American Spirit Smooth Mellow Taste
Natural American Spirit Perique Blend Rich Robust Taste	EX0000496	Natural American Spirit Perique Blend Rich Robust Taste
Natural American Spirit Perique Blend Rich Taste	EX0000497	Natural American Spirit Perique Blend Rich Taste
Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste	EX0000498	Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste

**Product Identification**

<b>Product Category</b>	Cigarette
<b>Product Subcategory</b>	Combusted filtered
<b>Product Number per Retail Unit</b>	Twenty cigarettes per pack with ten packs per paperboard carton
<b>Product Package</b>	The packaging materials consist of a foil inner liner, inner frame paper, paper board box, polypropylene outer wrap, polypropylene tear tape, and paperboard carton.

### **3. The Need for the Proposed Actions**

The proposed actions, requested by the applicant, are for the 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 nine 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 corresponding original products. These modifications are to filter adhesives (Confidential Appendix 1).

### **4. Alternatives to the Proposed Actions**

The no-action alternative is FDA does not issue the Exemption Requests for 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 may be affected by manufacturing the new products and found no significant impacts based on the Agency- gathered information and the following applicant-submitted information:

- Components of 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 products 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 products 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**

The new products would be manufactured at the address listed in section 1 of this document (Figure 1).

**Figure 1. Location of the Manufacturing Facility**



The manufacturing facility is located in Granville County in the Fishing Creek subwatershed, hydrologic unit code 03020101, in the Tar River basin.<sup>1,2</sup> The facility is surrounded by woodlands; bounded by a residential area to the north; mixed use residential and commercial lands, and Interstate 85 (a four-lane, divided highway) to the west; and a fresh produce farming establishment to the southeast.

The affected environment includes human and natural environments surrounding 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 new products are intended to replace similar tobacco products currently manufactured at the facility. The applicant also stated that manufacturing the new products would not require any additional environmental controls for water discharges.

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<sup>1</sup> 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>.

<sup>2</sup> USGS. National Water Information System: Mapper. Available at: <https://maps.waterdata.usgs.gov/mapper/index.html>. Accessed September 18, 2018.

## 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 that there would be no expected facility expansion or new construction due to manufacturing the new products. 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 Services' (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.<sup>3,4</sup> 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.

## 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.<sup>5</sup> 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.

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<sup>3</sup> U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/raleigh/species/cntylist/granville.html>. Accessed September 18, 2018.

<sup>4</sup> Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed September 18, 2018.

<sup>5</sup> U.S. EPA ECHO Detailed Facility Report: Santa Fe Natural Tobacco Company, Oxford, NC. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110001504202>. Accessed September 12, 2018.

## 5.7 Socioeconomics and Environmental Justice

No changes in socioeconomic measures are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment revenue, or taxes because the new products are intended to replace similar tobacco products currently manufactured at the facility.

Manufacturing the new products would not disproportionately impact minority populations, because although 63% of the population within a three-mile radius of the manufacturing facility is minority<sup>6</sup> per 2010 U.S. Census and American Community Survey data, no new chemical releases to the environment from manufacturing the new products were identified. The applicant stated that the new products are intended to replace portions of the currently marketed original products. In addition, the facility is not located in an Indian reservation.

## 5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered 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. The applicant stated that manufacturing the new products would not require any additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

## 5.9 Floodplains, Wetlands, and Coastal Zones

There would be no 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 2017, Santa Fe Natural Tobacco Company manufacturing facility in Oxford, North Carolina released 2,151 pounds of nicotine and nicotine salts to air onsite and 20,751 pounds of nicotine and nicotine salts offsite.<sup>7</sup> Nicotine and nicotine salts have known adverse developmental effects.<sup>8</sup> 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

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<sup>6</sup> U.S. EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110001504202>. Accessed September 12, 2018.

<sup>7</sup> U.S. Environmental Protection Agency (EPA). *TRI Data* available at: <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Release/27565SNTFN322KN>. Accessed on January 31, 2019.

<sup>8</sup> 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 May 24, 2018.

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	2,151
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-site Release		0	
		20,751	
<i>Subtotal Waste Released</i>		<i>22,902</i>	
<b>Total Production-Related Waste</b>		<b>22,902</b>	

According to the North Carolina Department of Environmental Quality, the condition of riparian buffers is generally poorer in the subwatershed surrounding the city of Oxford where the facility is located than the lower portions of the Fishing Creek watershed planning area, and stream stability and aquatic habitat are generally more degraded.<sup>9</sup> However, a three-phased local watershed planning program initiated by the North Carolina Ecosystem Enhancement Program for the Fishing Creek watershed produced a watershed management plan, which is currently under implementation.<sup>10</sup>

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, as many similar tobacco products would continue to be manufactured at the facility.

**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

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<sup>9</sup> North Carolina Department of Environmental Quality. *Fishing Creek Local Watershed Plan, Tar River Basin*. Available at: <https://files.nc.gov/ncdeq/PublicFolder/Work%20With/Watershed%20Planners/Fishing%20Creek%20WMP%20FINAL.pdf>. Accessed September 18, 2018.

<sup>10</sup> Ibid



applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new and original products (Confidential Appendix 2) 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 of the original products and any other marketed cigarettes; (2) the new products are expected to compete with, or replace, other currently marketed cigarettes, so the Agency does not expect that new or increased air emissions would be associated with use of the new products; and (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**

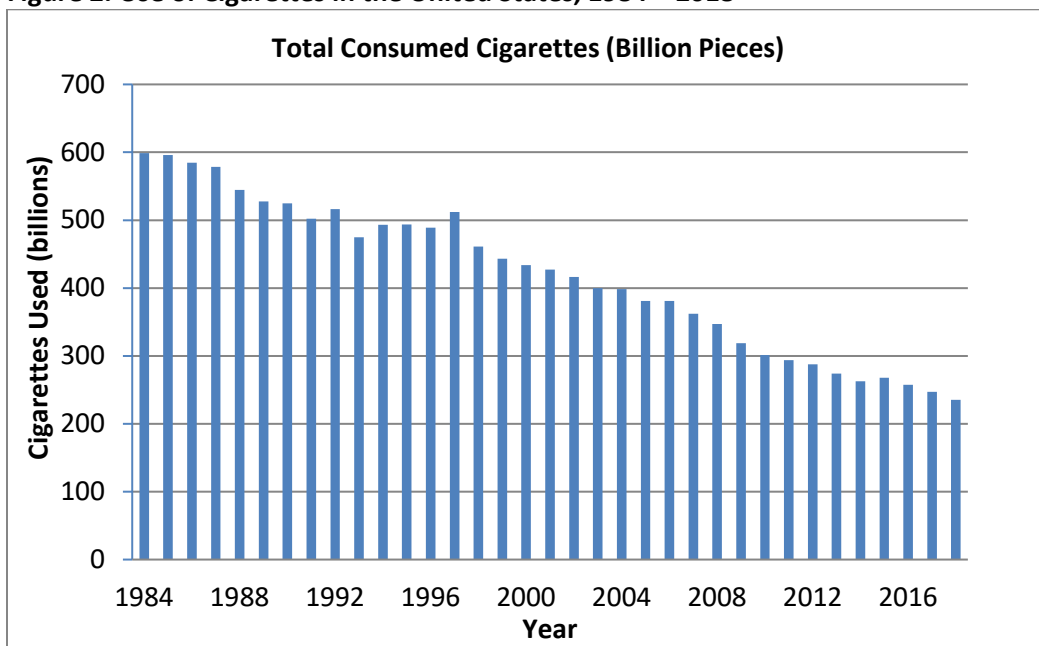
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, 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).<sup>11</sup> 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 September 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.

<sup>11</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed April 5, 2019.

## **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. Based on publicly available information such as the documented continuous decline of cigarette use in the United States, and the applicant's submitted information, including market volume projections for the new products, the Agency found no significant impacts.

### **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 new products 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,<sup>12,13</sup> the new products are not expected to change the fire frequency as the disposal of the new products would be the same as the disposal of cigarettes that are currently marketed in the United States.

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<sup>12</sup> National Fire Protection Association. The smoking-material fire problem. Available at: <https://www.nfpa.org/News-and-Research/Fire-statistics-and-reports/Fire-statistics/Fire-causes/Smoking-Materials>. Accessed May 22, 2018.

<sup>13</sup> UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed May 22, 2018.

#### **7.4. Water Resources**

No changes in any 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 in currently marketed cigarettes and the new products would compete with or replace other cigarettes currently on the market.

#### **7.5. Solid Waste**

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 2) 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 products 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 (Seco 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, types of tobacco, ingredients in the cigarette, number of puffs, and the mass transfer behavior of combustion products along the cigarette.<sup>14</sup>

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

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<sup>14</sup> NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed April 24, 2018.

## 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.

## 8. List of Preparers

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

### Preparer:

Susana Addo Ntim, PhD, Center for Tobacco Products

Education: PhD in Environmental Science

Experience: Six years in various scientific activities

Expertise: NEPA analysis; fate, transport, and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

### Reviewer:

Hoshing W. Chang, PhD, Center for Tobacco Products

Education: MS in Environmental Science and PhD in Biochemistry

Experience: Ten 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 Corresponding Original Products**

STN	Component	Modification
EX0000490 EX0000491 EX0000492 EX0000493 EX0000494 EX0000495 EX0000496 EX0000497 EX0000498	Filter adhesive	<div data-bbox="743 331 1352 436"> <p>Deletion of filter center line adhesive Addition of alternate filter center line adhesive</p> </div> <hr/> <div data-bbox="743 499 1352 562"> <p>Deletion of filter seam adhesive Addition of alternate filter seam adhesive</p> </div>

**CONFIDENTIAL APPENDIX 2. Current-Year Market Volume of the Original Products and Combined First- and Fifth-Year Market Volume Projections for the New and Original Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New and Original Products**

The applicant provided the current market volumes of the original products and combined first- and fifth-year projections for the new and original products, stating that the new products upon receiving market orders, would replace a percentage of the currently marketed original products without impacting the overall future projected volumes. The new and original products projections would not exceed the projections for the original products alone, if the new products did not receive marketing orders. The current-year market volumes of the original products and the combined first- and fifth-year market volume projections of the new and original products were compared to the total forecasted use of cigarettes in the United States.<sup>15</sup> The total projected volume of the new and original products in the first and fifth year of marketing account for [REDACTED] and [REDACTED] % of the forecasted cigarette use in the United States, respectively.

Projected Year	STN	Product	Market Volume (Cigarettes)	Product as a Percent of Total Cigarettes Used (%) <sup>16</sup>
Current	SE0000118	Original	(b)(4)	(b)(4)
	SE0006276	Original	(b)(4)	(b)(4)
	SE0006280	Original	(b)(4)	(b)(4)
	SE0006279	Original	(b)(4)	(b)(4)
	SE0006278	Original	(b)(4)	(b)(4)
	SE0006289	Original	(b)(4)	(b)(4)
	SE0006288	Original	(b)(4)	(b)(4)
	SE0000116	Original	(b)(4)	(b)(4)
	SE0000117	Original	(b)(4)	(b)(4)
<b>Total Current Year</b>			(b)(4)	(b)(4)
First Year	EX0000490	Combined New and Original	(b)(4)	(b)(4)
	EX0000491	Combined New and Original	(b)(4)	(b)(4)
	EX0000492	Combined New and Original	(b)(4)	(b)(4)
	EX0000493	Combined New and Original	(b)(4)	(b)(4)
	EX0000494	Combined New and Original	(b)(4)	(b)(4)
	EX0000495	Combined New and Original	(b)(4)	(b)(4)
	EX0000496	Combined New and Original	(b)(4)	(b)(4)
	EX0000497	Combined New and Original	(b)(4)	(b)(4)
	EX0000498	Combined New and Original	(b)(4)	(b)(4)
<b>Total First Year</b>			(b)(4)	(b)(4)

<sup>15</sup> The Agency used historical data regarding total use of cigarettes from 1984 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the bestfit trend line with an R<sup>2</sup> value of 0.98, the forecasted number of cigarettes that would be used in the United States is estimated at 233.43 billion cigarettes in the first year and 189.99 billion cigarettes in the fifth year of marketing the new product.

<sup>16</sup> Projected Market Occupation of the New and Original Products in the United States (%) =

$$\frac{\text{Projected Market Volume of the New and Original Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$$



Projected Year	STN	Product	Market Volume (Cigarettes)	Product as a Percent of Total Cigarettes Used (%) <sup>16</sup>
Fifth Year	EX0000490	Combined New and Original	(b)(4)	(b)(4)
	EX0000491	Combined New and Original	(b)(4)	(b)(4)
	EX0000492	Combined New and Original	(b)(4)	(b)(4)
	EX0000493	Combined New and Original	(b)(4)	(b)(4)
	EX0000494	Combined New and Original	(b)(4)	(b)(4)
	EX0000495	Combined New and Original	(b)(4)	(b)(4)
	EX0000496	Combined New and Original	(b)(4)	(b)(4)
	EX0000497	Combined New and Original	(b)(4)	(b)(4)
	EX0000498	Combined New and Original	(b)(4)	(b)(4)
<b>Total Fifth Year</b>			(b)(4)	(b)(4)