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

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

May 30, 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
Product Manufacturing Location:	3220 Knotts Grove Road Oxford, NC 27565

2. Product Information

New Product Names, Submission Tracking Numbers (STN), and Original Product Names

New Product Name	STN	Original Product Name
Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste	EX0000454	Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste
Natural American Spirit 100% US Grown Tobacco Mellow Taste	EX0000455	Natural American Spirit 100% US Grown Tobacco Mellow Taste
Natural American Spirit Full-Bodied Taste	EX0000456	Natural American Spirit Full-Bodied Taste
Natural American Spirit Mellow Taste	EX0000457	Natural American Spirit Mellow Taste
Natural American Spirit Made with Organic Tobacco Full-Bodied Taste	EX0000458	Natural American Spirit Made with Organic Tobacco Full-Bodied Taste
Natural American Spirit Made with Organic Tobacco Mellow Taste	EX0000459	Natural American Spirit Made with Organic Tobacco Mellow Taste
Natural American Spirit Perique Blend Rich Robust Taste	EX0000460	Natural American Spirit Perique Blend Rich Robust Taste
Natural American Spirit Perique Blend Rich Taste	EX0000461	Natural American Spirit Perique Blend Rich Taste
Natural American Spirit Smooth Mellow Taste	EX0000462	Natural American Spirit Smooth Mellow Taste

Product Identification

Product Category	Cigarette
Product Subcategory	Combusted filtered
Product Number per Retail Unit	Twenty cigarettes per pack with ten packs per carton
Product Package	The packaging materials consist of a foil inner liner, inner frame paper, paper board box, polypropylene film 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 in the cigarette filter adhesive (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 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:

- Ingredients in the cigarette filter adhesive are commonly used in other products manufactured at the facility.
- The new products are intended to compete and eventually replace portions of similar tobacco products currently manufactured at the facility.
- No facility expansion or new construction 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.[1,2] 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 applicant does not anticipate that manufacturing the new products would cause the release of any new chemicals or new type of emissions into the environment. The applicant stated 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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[1] 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.

[2] USGS. National Water Information System: Mapper. Available at: https://maps.waterdata.usgs.gov/mapper/index.html. Accessed February 5, 2019.

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 that 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.[3,4] 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 manufacturing facility has the following permits:

(1) Air permit number 08796R07 issued by the North Carolina Department of Environmental Quality.[5]
(2) Storm water permit number NCG060231 issued by the North Carolina Department of Environmental Quality.[6]

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

The Agency's search of the Environmental Protection Agency (EPA)'s Enforcement and Compliance History Online database did not reveal any violations of federal environmental laws and regulations.[7]

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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[3] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/raleigh/species/cntylist/granville.html. Accessed February 5, 2019.

[4] Critical habitat map available at: https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449. Accessed February 5, 2019.

[5] Air permit available at: https://files.nc.gov/ncdeq/Air%20Quality/permits/aapa_reports/all_permitted.pdf. Accessed May 29, 2019.

[6] U.S. Environmental Protection Agency (EPA) ECHO Detailed Facility Report: Santa Fe Natural Tobacco Company, Oxford, NC. Available at: https://echo.epa.gov/detailed-facility-report?fid=110001504202. Accessed February 5, 2019.

[7] Ibid.

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics 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[8] 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 would replace portions of similar tobacco products currently manufactured at the facility. Additionally, the facility is not located in or near Native American lands.

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, transferred to a publicly owned treatment works (POTW), and disposed of in landfills in the same manner as any other waste generated from any other products currently 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 Toxic Release Inventory (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 onsite and 20,823 pounds of nicotine and nicotine salts offsite (Table 1).[9] Nicotine and nicotine salts have known adverse developmental effects.[10] 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

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[8] 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.

[9] U.S. EPA. *TRI Data a*vailable at: https://oaspub.epa.gov/enviro/P2_EF_Query.p2_report?FacilityId=27565SNTFN322KN&pReport=2. Searched on September 12, 2018.

[10] 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.

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
Subtotal Waste Managed		0
On-Site Release	Ammonia	0
	Nicotine and Nicotine Salts	2,151
Off-Site Release	Ammonia	0
	Nicotine and Nicotine Salts	20,823
Total Production-Related Waste		**22,974**

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. 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.[11]

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 impact 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 combined projected market volumes for the new and original products (Confidential Appendix 2) and the documented decline in cigarette use in the United States.

[11] North Carolina Department of Environmental Quality. *Fishing Creek Local Watershed Plan, Tar River Basin*. Available at: https://ncdenr.s3.amazonaws.com/s3fs-public/Mitigation%20Services/Watershed_Planning/Tar-Pamlico_River_Basin/Fishing_Creek/Fishing%20Creek%20WMP%20FINAL.pdf. Accessed May 29, 2018.

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 that 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 products and any other marketed cigarettes; (2) the new products are expected to compete with, or replace, other currently marketed cigarettes; 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:

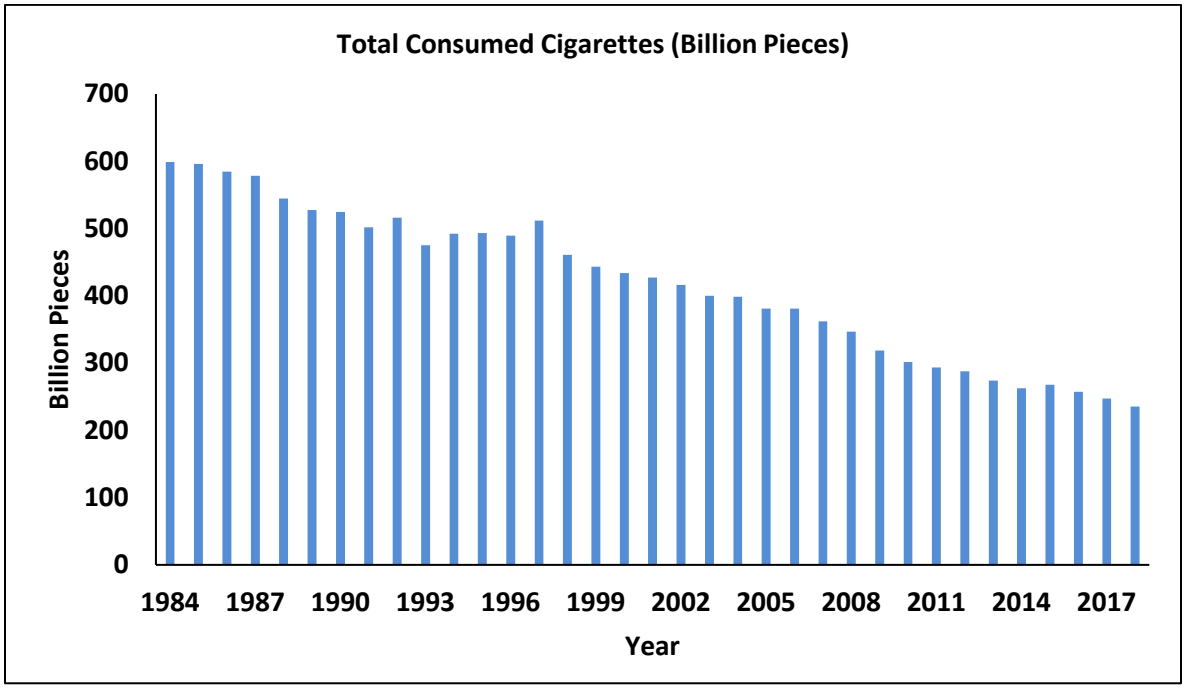
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent 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).[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 (Homa et al., 2015; Yao et al., 2016). Despite the considerable

[12] U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: https://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed March 7, 2018.

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.

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

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on the TTB data which shows 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 new products package materials 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 new products 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,[13,14] 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.

7.4. Water Resources

No changes in impacts on water resources would be 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.

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[13] 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.

[14] UC Davis Health News. Available at: https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763. Accessed May 22, 2018.

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 handled in the same manner as any other waste generated from any other combusted, filtered cigarettes manufactured in the United States. The number of cigarette butts generated would be equivalent to the market projections (Confidential Appendix 2) and an unspecified 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, Oliver, and Thomson, 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, types of tobacco, ingredients in the cigarette and tobacco filler, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[15]

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.

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[15] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed April 24, 2018.

8. List of Preparers

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

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- Education: B.S. in Biology
- Experience: Five years in various scientific activities
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- Education: Ph.D. in Plant Molecular Biology and Virology
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- Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

American Lung Association. 2018. Smokefree Air Laws. www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html (updated September 7, 2018). Accessed January 8, 2019.

Burton B. Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspectives*. 2011;*119*(2):A70-A74.

Becherucci ME, Pon JPS. What is left behind when the lights go off? Comparing the abundance and composition of litter in urban areas with different intensity of nightlife use in Mar del Plata, Argentina. *Waste Management*. 2014;34(8):1351-1355.

Claereboudt MR. Shore litter along sandy beaches of the Gulf of Oman. *Marine Pollution Bulletin*. 2004;49(9-10): 770-777.

Healton CG, Cummings KM, O'Connor RJ, Novotny TE. Butt really? The environmental impact of cigarettes. *Tobacco Control*. 2011;20:I1.

Homa DM, Neff LJ, King BA, Caraballo RS, Bunnell RE, Babb SD, Garrett BE, Sosnoff CS, Wang L. Vital signs: disparities in nonsmokers' exposure to secondhand smoke —United States, 1999–2012. *MMWR Morbidity Mortality Weekly Report*. 2015;*64*(4):103-108.

Kadir AA, Sarani NA. Cigarette butts pollution and environmental impact - a review. *Applied Mechanics and Materials*. 2015;773-774:1106-1110.

Matt GE, Quintana PJE, Destaillats H, Gundel LA, Sleiman M, Singer BC, Jacob P, Benowitz N, Winickoff JP, Rehan V, Talbot P, Schick SF, Samet J, Wang Y, Hang B, Martins-Green M, Pankow JF, Hovell ME. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*. 2011;*119*(9):1218-1226.

Novotny TE, Zhao F. Consumption and production waste: Another externality of tobacco use. *Tobacco Control*. 1999;8(1):75-80.

Patel V, Thomson GW, Wilson N. Cigarette butt littering in city streets: A new methodology for studying and results. *Tobacco Control*. 2013;22(1):59-62.

Pon JPS, Becherucci ME. Spatial and temporal variations of urban litter in Mar del Plata, the major coastal city of Argentina. *Waste Management*. 2012;32(2):343-348.

Smith CJ, Livingston SD, Doolittle DJ. An international literature survey of "IARC Group 1 carcinogens" reported in mainstream cigarette smoke. *Food and Chemical Toxicology*. 1997;35(10-11):1107-1130.

U.S. Department of Health and Human Services. 2014. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006a. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Environmental Protection Agency. (2016). Advancing Sustainable Materials Management: Facts and Figures.

Wilson N, Oliver J, Thomson G. Smoking close to others and butt littering at stops: Pilot observational study. *PeerJ*. 2014;2.

Yao T, Sun HY, Wang Y, Lightwood J, Max W. Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*. 2016;*131*:357-366.

CONFIDENTIAL APPENDIX 1. Modifications: New Products as Compared with the Corresponding Original Products

STN	Component	Modification
EX0000454 EX0000455 EX0000456		Deletion of Purchased Filter (b)(4) [redacted] Addition of Purchased Plug (b)(4) [redacted]
EX0000457 EX0000458 EX0000459 EX0000460 EX0000461 EX0000462	Filter Adhesive	Deletion of Purchased Filter Sideseam (b)(4) [redacted] Addition of Purchased Plug Seam (b)(4) [redacted]

CONFIDENTIAL APPENDIX 2. Combined First- and Fifth-Year Market Volume Projections for the New and Corresponding 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 combined first- and fifth-year projections for the new and original products, stating that upon receiving market orders, the new products would replace a portion of similar products currently manufactured at the facility. The combined first- and fifth-year market volume projections for the new and original products were compared to the total forecasted use of cigarettes in the United States.[16] The total projected volumes of the new and original products in the first and fifth year account for (b)(4) and (b)(4) of the forecasted cigarette use in the United States, respectively. The original products are not currently on the market. However, they are products that can be marketed 90 days after FDA receives their abbreviated report through the Exemption Request pathway.

Projected Year	STN	Product	Market Volume (Cigarettes)	Product as a Percent of Total Cigarettes Used (%)[17]
First Year	EX0000454	Combined New and Original	(b)(4)	(b)(4)
	EX0000455	Combined New and Original	(b)(4)	(b)(4)
	EX0000456	Combined New and Original	(b)(4)	(b)(4)
	EX0000457	Combined New and Original	(b)(4)	(b)(4)
	EX0000458	Combined New and Original	(b)(4)	(b)(4)
	EX0000459	Combined New and Original	(b)(4)	(b)(4)
	EX0000460	Combined New and Original	(b)(4)	(b)(4)
	EX0000461	Combined New and Original	(b)(4)	(b)(4)
	EX0000462	Combined New and Original	(b)(4)	(b)(4)
		Total First Year	(b)(4)	(b)(4)
Fifth Year	EX0000454	Combined New and Original	(b)(4)	(b)(4)
	EX0000455	Combined New and Original	(b)(4)	(b)(4)
	EX0000456	Combined New and Original	(b)(4)	(b)(4)
	EX0000457	Combined New and Original	(b)(4)	(b)(4)
	EX0000458	Combined New and Original	(b)(4)	(b)(4)
	EX0000459	Combined New and Original	(b)(4)	(b)(4)
	EX0000460	Combined New and Original	(b)(4)	(b)(4)
	EX0000461	Combined New and Original	(b)(4)	(b)(4)
	EX0000462	Combined New and Original	(b)(4)	(b)(4)
		Total Fifth Year	(b)(4)	(b)(4)

[16] 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 R^2 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.

[17] Projected Market Occupation of the New and Original Products in the United States (%)=

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