

**Programmatic Environmental Assessment for Eight Exemption
Requests by Santa Fe Natural Tobacco Company, Inc.**

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

November 6, 2018

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1. Applicant and Manufacturer Information

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

2. Product Information

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

New Product Name	STN	Original Product Name
Natural American Spirit 100% US Grown Tobacco Mellow Taste	EX0000263	Natural American Spirit 100% US Grown Tobacco Mellow Taste
Natural American Spirit Made with Organic Tobacco Mellow Taste	EX0000264	Natural American Spirit Made with Organic Tobacco Mellow Taste
Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste	EX0000265	Natural American Spirit 100% US Grown Tobacco Full-Bodied Taste
Natural American Spirit Mellow Taste	EX0000266	Natural American Spirit Mellow Taste
Natural American Spirit Full-Bodied Taste	EX0000267	Natural American Spirit Full-Bodied Taste
Natural American Spirit Perique Blend Rich Robust Taste	EX0000268	Natural American Spirit Perique Blend Rich Robust Taste
Natural American Spirit Smooth Mellow Taste	EX0000269	Natural American Spirit Smooth Mellow Taste
Natural American Spirit Perique Blend Rich Taste	EX0000270	Natural American Spirit Perique Blend Rich Taste

Product Identification

Product Category	Cigarette
Product Subcategory	Combusted, filtered
Product Number per Retail Unit	Twenty cigarettes per pack with ten packs per paperboard carton
Product Package	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 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 eight 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 difference between the new products and the corresponding original products is deletion of one additive and the replacement of that additive with one from an alternate supplier.

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not issue exemptions from demonstrating substantial equivalence for marketing orders for the new tobacco products.

5. Potential Environmental Impacts of the Proposed Actions and Alternative – 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 filter tow are commonly used in other products manufactured at the facility and used throughout the cigarette industry.
- The new products are intended to replace portions 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.
- 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 Agency 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 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.

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 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, or land use and 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.^{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 agency verified the applicant's statement using information available on the Environmental Protection Agency (EPA)'s Enforcement and Compliance History Online (ECHO) that the facility is in compliance with air 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 Toxic Release Inventory (TRI) data to the EPA (permit # 27565SNTFN322KN).

The Agency's search of EPA's ECHO database did not reveal any violations of federal environmental laws and regulations.⁵

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.

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

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

⁵ 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 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 percent of the population within a three-mile radius of the manufacturing facility is minority⁶ 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. Additionally, 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 will 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 manufactured in the same facility and in a similar manner to other combusted, filtered cigarettes manufactured in the United States. 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 will incrementally increase or change the chemicals released to the environment from the facility tobacco manufacturing. A search in EPA's TRI database showed that in 2016, Santa Fe Natural Tobacco Company manufacturing facility in Oxford, North Carolina released 2,935 pounds of nicotine and nicotine salts onsite and 23,225 pounds of nicotine and nicotine salts to land offsite.⁷ Nicotine and nicotine salts have known adverse developmental effects.⁸ 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

⁶ 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.

⁷ U.S. Environmental Protection Agency (EPA). *TRI Data* available at: https://oaspub.epa.gov/enviro/P2_EF_Query.p2_report?FacilityId=27565SNTFN322KN&pReport=2. Searched on September 12, 2018.

⁸ 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.

released into the environment any other 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
Subtotal Waste Managed		0
On-site Release	Ammonia	0
	Nicotine and Salts	2,935
Off-site Release	Ammonia	0
	Nicotine and Salts	23,225
Total Production-Related Waste		26,160

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.⁹ 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.¹⁰

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 No-Action Alternative

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

6. Potential Environmental Impacts of the Proposed Actions and Alternative – 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

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

¹⁰ See footnote #8

projected market volumes for the new and original 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 nationwide.

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 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 (Confidential Appendix 1); 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

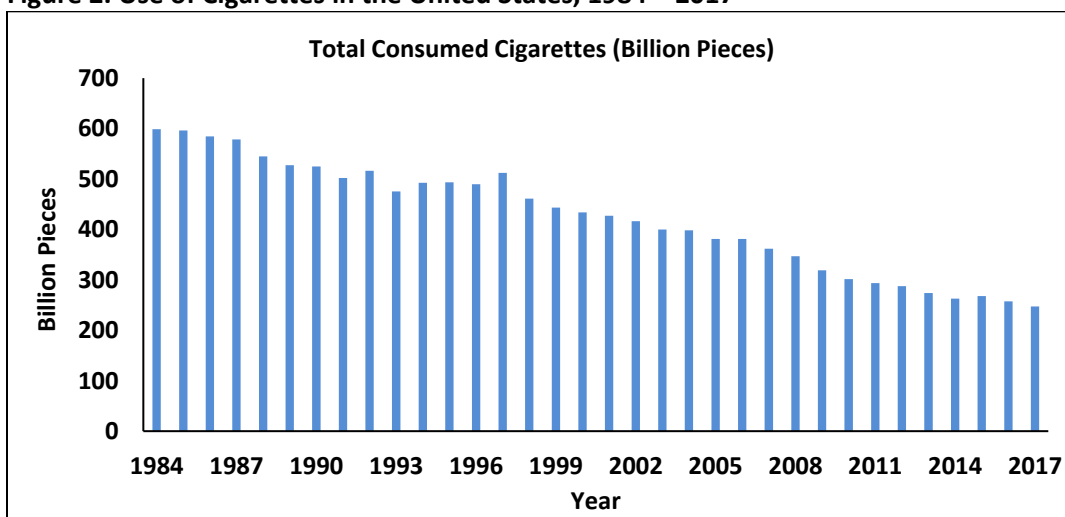
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, 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).¹¹ 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; other studies). 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 – 2017



As of December 2015, 26 states and the District of Columbia have implemented comprehensive smoke-free laws (Tynan, Holmes, Promoff, Hallett, Hopkins, & Frick, 2016). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

6.5 No-Action Alternative

The environmental impact 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 Alternative – 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 publicly available information such as the documented

¹¹ 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.

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 nationwide.

7.2. Air Quality

The Agency does not anticipate disposal of the 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 (Confidential Appendix 2). 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,^{12,13} 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 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 are the same as in currently marketed cigarettes and the new products would compete with or replace other cigarettes currently on the market.

¹² 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.

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

7.5. 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.

7.6. 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 10 years (Novotny and Zhao, 1999). Cigarette butts are among the most common forms of litter found on beaches (Claereboudt, 2004; Smith, Livingston and Doolittle, 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson, Oliver, and Thomson, 2014), roads, and streets (Healton, Cummings, O'Connor and Novotny, 2011; Patel, Thomson and Wilson, 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 and tobacco fillers, number of butts, and the mass transfer behavior of combustion products along the cigarette.¹⁴

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

7.8 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 (PEA):

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

Preparer:

Susana Addo Ntim, PhD, Center for Tobacco Products

Education: PhD in Environmental Science

Experience: Six years in various scientific activities

Expertise: 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.

10. References

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Patel, V., G. W., Thomson, and N., Wilson. (2013). Cigarette butt littering in city streets: A new

methodology for studying and results. *Tobacco Control*. 22(1): 59-62.

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

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CONFIDENTIAL APPENDIX 1. 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 portion 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.¹⁵ The total projected volume of the new and original products in the first and fifth year account for (b) (4)(b) (4) 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 (%) ¹⁶
Current Year	SE0000118	Original	(b) (4)	(b) (4)
	SE0006279	Original	(b) (4)(b) (4)	(b) (4)
	SE0000117	Original	(b) (4)	(b) (4)
	SE0006280	Original	(b) (4)(b) (4)	(b) (4)
	SE0006276	Original	(b) (4)(b) (4)	(b) (4)
	SE0006288	Original	(b) (4)(b) (4)	(b) (4)
	SE0006289	Original	(b) (4)(b) (4)	(b) (4)
	SE0000116	Original	(b) (4)	(b) (4)
Total Current Year			(b) (4)(b) (4)	(b) (4)
First Year	EX0000263	Combined New and Original	(b) (4)	(b) (4)
	EX0000264	Combined New and Original		
	EX0000265	Combined New and Original		
	EX0000266	Combined New and Original		
	EX0000267	Combined New and Original		
	EX0000268	Combined New and Original		
	EX0000269	Combined New and Original		
	EX0000270	Combined New and Original		
Total First Year			(b) (4)(b) (4)	(b) (4)
Fifth Year	EX0000263	Combined New and Original	(b) (4)	(b) (4)
	EX0000264	Combined New and Original		
	EX0000265	Combined New and Original		
	EX0000266	Combined New and Original		
	EX0000267	Combined New and Original		
	EX0000268	Combined New and Original		
	EX0000269	Combined New and Original		
	EX0000270	Combined New and Original		
Total Fifth Year			(b) (4)(b) (4)	(b) (4)

¹⁵ The Agency used historical data regarding total use of cigarettes from 2002 to 2017 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9786, the forecasted number of cigarettes that would be used in the United States is estimated at 229.59 billion cigarettes in the first year and 203.67 billion cigarettes in the fifth year of marketing the new product.

¹⁶ Current or Projected Market Occupation of the New and Original Products in the United States (%) = $\frac{\text{Current or Projected Market Volume of the New and Original Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

CONFIDENTIAL APPENDIX 2. Projected Waste of Cigarette Butts in the First and Fifth Years of Marketing the New and Original Products

$\sum_{i=1}^8 A_i = \sum_{i=1}^8 (B_i \times C_i \times D_i \times G)$ $D_i = \frac{E}{F_i}$	<p><i>A_i</i>: Projected waste generation of cigarette butts of the new and original products (metric tons)</p> <p><i>B_i</i>: Projected market volume of the new and original products (number of individual cigarettes)</p> <p><i>C_i</i>: Weight of cigarette (gram)</p> <p><i>D_i</i>: Cigarette butt ratio</p> <p><i>E</i>: Cigarette butt length¹⁷</p> <p><i>F_i</i>: Length of cigarette (millimeter)</p> <p><i>G</i>: 1.0 x 10⁻⁶ metric tons/gram</p>
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Projected Year	Product	Market Volume (Cigarettes)	Weight of Cigarette (g)	Length of Cigarette (mm)	Waste of Cigarette Butt (Metric Tons)
		<i>B_i</i>	<i>C_i</i>	<i>F_i</i>	<i>A_i</i>
Current Year	Original	(b) (4)	(4)		
	Original				
	Original				
	Original				
	Original				
	Original				
	Original				
	Original				
Total Current Year					(b) (4)
First-Year	Combined New and Original	(b) (4)	(4)		
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
Total First Year					(b) (4)
Fifth-Year	Combined New and Original	(b) (4)	(4)		
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
	Combined New and Original				
Total Fifth Year					(b) (4)

If all the projected cigarette butt waste generated from use of the new and original products is disposed of in landfills, the projected waste of (b) (4) metric tons in the current year, (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new and original products would be negligible fractions of the 262.2 million metric tons of total waste reported in the United States in 2015 (EPA, 2018).

¹⁷ ISO 15592-3 (Section 9.3) prescribes a standard termination line for machine smoking (cigarette butt length) of 27 mm. This value is an estimate of the cigarette butt length that is disposed of as solid waste following use.