

**Environmental Assessment for Marketing Order for A New
Combusted Filtered Cigarette Manufactured by R.J. Reynolds
Tobacco Company**

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

June 6, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	R.J Reynolds Tobacco Company
Applicant Address:	401 North Main Street Winston-Salem, NC 27101
Manufacturer Name:	R.J. Reynolds Tobacco Company
Product Manufacturing Location:	7855 King-Tobacoville Road Tobacoville, NC 27050

2. Product Information

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

New Product Name	STN	Original Product Name
Newport Menthol Gold Box 100s	EX0000521	Newport Lights Menthol Gold Box 100s

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 solid bleached sulphate inner frame, box, and carton; foil inner liner; and polypropylene film overwrap.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue exemption from substantial equivalence (SE) reporting for marketing order under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for a combusted, filtered cigarette. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) 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 product into interstate commerce for commercial distribution in the United States. The applicant must obtain written notification that FDA has granted the product exemption from demonstrating substantial equivalence under section 905(j)(3) before

submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new product for which the applicant has obtained exemption from demonstrating substantial equivalence.

The new product is made by modifying the original product. These modifications are to the filter tow, tipping paper, and cigarette paper (Confidential Appendix 1).

4. Alternatives to the Proposed Action

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

5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

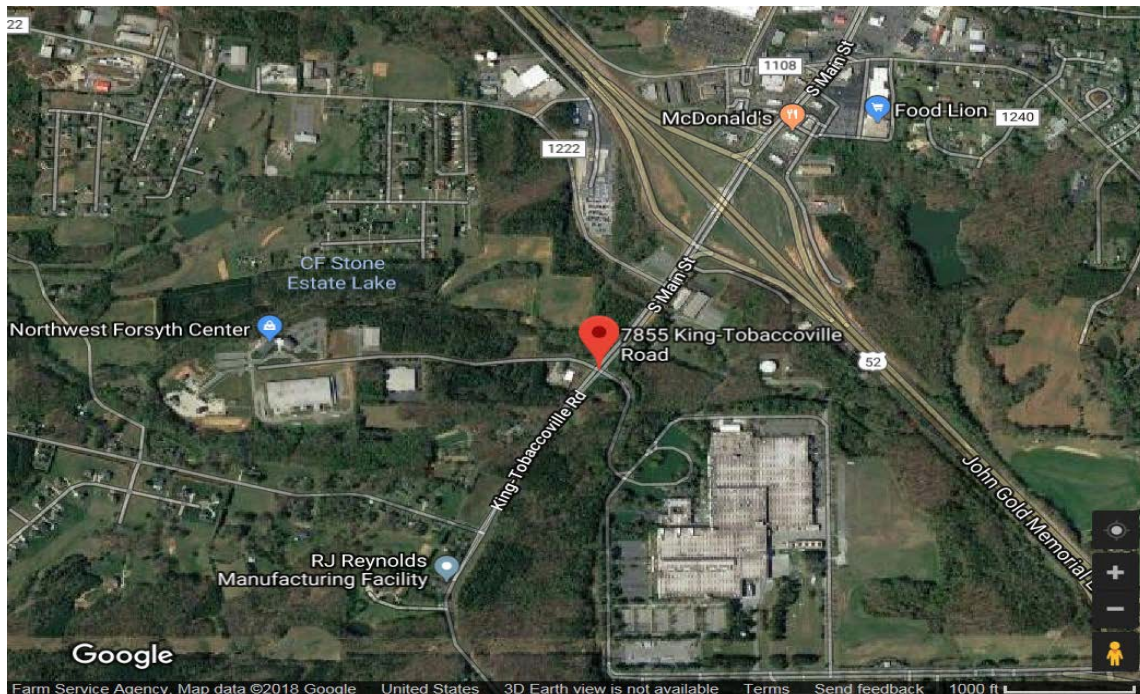
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new product and found no significant impacts based on the Agency- gathered information and the following applicant-submitted information:

- The new product is intended to replace the original product and will compete with other products manufactured at the facility.
- No facility expansion is expected due to manufacturing the new product.

5.1 Affected Environment

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

Figure 1. Location of the Manufacturing Facility



The manufacturing facility is located in Forsyth County, NC in Headwaters Muddy Creek watershed, hydrologic unit code 03040101, which is the largest of the Yadkin River tributaries.^{1,2} The facility is surrounded by woodlands; bounded by the city of King, NC to the north; US 52 (a four-lane, divided highway) to the east; and mixed use residential, commercial, and agricultural land to the south and west.

The affected environment includes human and natural environments surrounding the facility.

5.2 Air Quality

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

5.3 Water Resources

The Agency does not anticipate that manufacturing the new product would cause the discharge of any new chemicals into water. The new product is intended to replace similar tobacco products currently manufactured at the facility. The applicant also stated that manufacturing the new product would not require any additional environmental controls for water discharges.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new product 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 product. 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 product 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 two threatened species (one bog turtle and one northern long-eared bat), one endangered plant, and one at-risk fresh water mussel are listed in Forsyth 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.

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 May 23, 2018.

³ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/raleigh/species/cntylist/forsyth.html>. Accessed May 24, 2018.

⁴ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed May 24, 2018.

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)⁵ database. ECHO shows that the facility is in compliance with air emission, storm water, and wastewater requirements under the following permits:

- (1) Air permit number 00745-TV-39 issued by the Forsyth County Office of Environmental Assistance Protection⁶
- (2) Storm water permit number NCG060079 issued by the North Carolina Department of Environmental Quality.
- (3) Waste water permit number IUP 3001 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 # 27050RJRYN7855A).

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

5.7 Socioeconomics and Environmental Justice

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

Manufacturing the new product would not disproportionately impact minority populations, because only 9% of the population within a three-mile radius of the manufacturing facility is minority per 2010 U.S. Census and American Community Survey data.⁷ In addition, 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 product 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 product 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 product 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 U.S. EPA ECHO Detailed Facility Report: R.J. Reynolds Tobacco Company, Tobaccoville, NC. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000345225>. Accessed October 24, 2018.

⁶ Air permit available at: https://www.co.forsyth.nc.us/EAP/assets/doc/00745_TV_permit.pdf Accessed October 29, 2018.

⁷ See footnote 5

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new product 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 the proposed action would 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 2017, R.J. Reynold's manufacturing facility in Tobaccoville, North Carolina released 8,956 pounds of ammonia and 17,839 pounds of nicotine and nicotine salts to air (a total of 26,795 pounds), and 2,515 pounds of ammonia and 4,547 pounds of nicotine and nicotine salts (a total of 7,062 pounds) offsite. No TRI-reportable chemicals were released to water and land (Table 1).⁸ No other hazardous air pollutants were reported. Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts have known adverse developmental effects.⁹ The TRI database search did not show that the R.J. Reynolds manufacturing facility disposed of, treated, or released into the environment any other reportable toxicants associated with manufacturing tobacco products. In addition, EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at R.J. Reynolds Facility

Production-Related Waste Managed or Released		Chemical Mass (pounds)	
Recycled		0	
Energy Recovery		0	
Treated*		3,040	
<i>Subtotal Waste Managed</i>		<i>3,040</i>	
On-Site Release	Air	Ammonia	8,956
		Nicotine and Nicotine Salts	17,839
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
		Nicotine and Nicotine Salts	0
Off-Site Release	Ammonia	2,515	
	Nicotine and Nicotine Salts	4,547	
<i>Subtotal Waste Released</i>		<i>33,857</i>	
Total Production-Related Waste		36,897	
* Ammonia only			

⁸U.S. Environmental Protection Agency (EPA). *TRIData* <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/27050RJRYN7855A>. Accessed March 13, 2019.

⁹U.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.

According to the North Carolina Department of Environmental Quality, water quality in Headwaters Muddy Creek watershed where the facility is located is relatively good compared to other sub basins in the greater Yadkin-Pee Dee River basin.¹⁰

The applicant stated that manufacturing the new product 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 Action and Alternatives – Use of the New Product

The Agency considered potential impacts to resources in the environment that could be affected by use of the new product and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new product (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 order would allow for the new tobacco product 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 product, 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 product would be released in the same manner as the combustion products of the original product and any other marketed cigarettes; (2) the new product is 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 product; and (3) the ingredients in the new product is used in other currently marketed tobacco products.

6.3. Environmental Justice

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

¹⁰North Carolina Department of Environmental Quality. *Yadkin River Headwaters*. Available at: https://files.nc.gov/ncdeq/Water%20Quality/Planning/BPU/BPU/Yadkin/Yadkin%20Plans/2010%20Plan/2_03040101%20Yadkin%20River%20Headwaters-2010.pdf. Accessed May 24, 2018.

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:

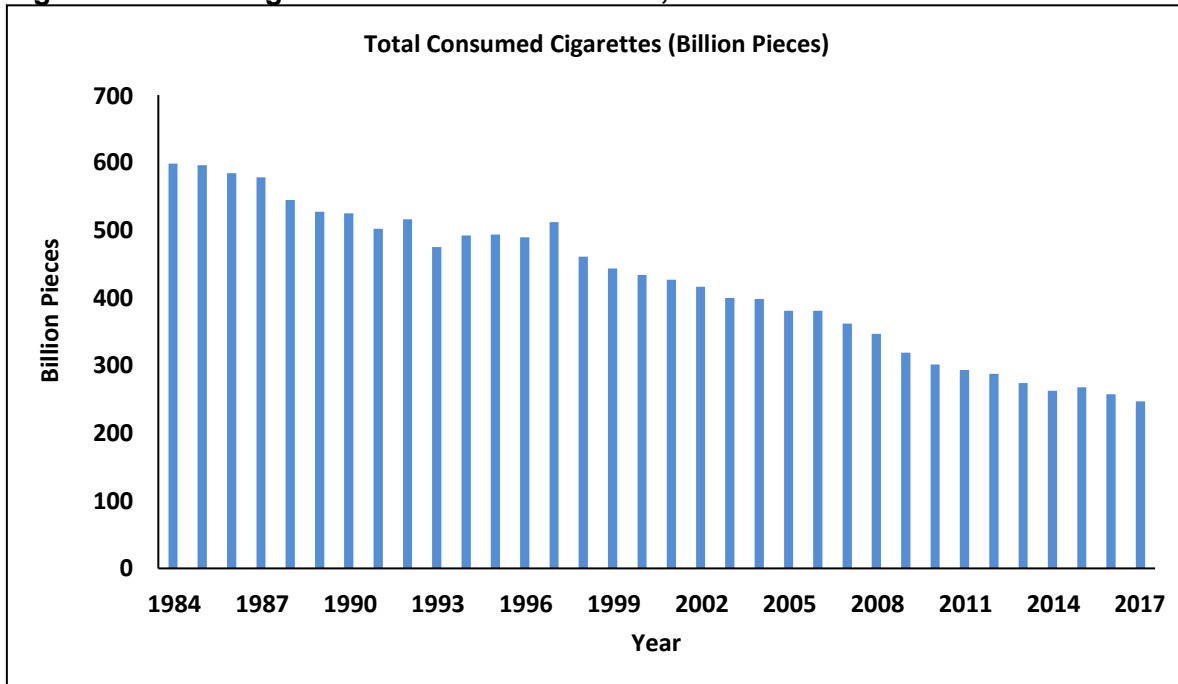
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent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

¹¹U.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.

Figure 2. Use of Cigarettes in the United States, 1984 – 2017



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 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 Action and Alternatives – Disposal of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new product. 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 product, 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 order would allow for the new tobacco product to be sold to consumers in the United States.

7.2. Air Quality

The Agency does not anticipate disposal of the new product or 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 product. The chemicals in the new product cigarette butts are commonly used in other currently marketed cigarettes. Because the new product is anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new product would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new product is 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 product 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 action is not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. Although disposal of smoldering cigarettes has been implicated in many fire incidents,^{12,13} the new product is not expected to change the fire frequency as the disposal of the new product 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 product because the chemicals in the new product would be the same as in currently marketed cigarettes and the new product 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 product would notably affect the current cigarette butt waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new product 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 product. The waste generated due to disposal of the new product would be handled in the same manner as the waste generated from disposal of other cigarettes in the

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.

United States. No new emissions are expected due to disposal of the new product; 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 product as well as 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.¹⁴

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

7.8 Impacts of 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 environmental assessment:

Preparer:

Mehran Niazi, PhD, Center for Tobacco Products
Education: PhD in Environmental Sciences
Experience: Twelve years in environmental fate and transport and environmental modeling
Expertise: Water quality modeling, environmental fate and transport modeling

Reviewer:

Gregory Gagliano, MS, Center for Tobacco Products
Education: BS and MS in Environmental Science

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

Experience: Thirty-six years in environmental toxicology
Expertise: Ecotoxicology, environmental risk assessment, NEPA analysis

9. A Listing of Agencies and Persons Consulted

Not applicable.

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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. (2018). Advancing Sustainable Materials Management: Facts and Figures.

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

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

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

STN	Modification
EX0000521	Deletion of non-fire standard compliant (non-FSC) cigarette paper and addition of FSC cigarette paper Deletion of cork-on-white tipping paper and addition of alternate cork-on-white tipping paper Deletion of printed monogram ink on barrel Deletion of filter tow and addition of alternate filter tow

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

The applicant provided the first- and fifth-year projections for the new product. The first- and fifth-year market volume projections of the new product were compared to the total forecasted use of cigarettes in the United States.¹⁵ The total projected volume of the new product in the first and fifth year account for 0.17 and 0.12 % of the forecasted cigarette use in the United States, respectively.

Projected Year	STN	Market Volume (Cigarettes)	Product as a Percent of Total Cigarettes Used (%)
First Year	EX0000521		
Fifth Year	EX0000521		

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 bestfit trendline with an R² value of 0.9786, the forecasted number of cigarettes that would be used in the United States is estimated at 236.258 billion cigarettes in the first year and 210.922 billion cigarettes in the fifth year of marketing the new product.