

**Programmatic Environmental Assessment for Marketing
Orders for New Cigarettes Manufactured by R.J. Reynolds
Tobacco Company**

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

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

New Product Name	STN	Original Product Name
True Blue 100 Soft Pack	EX0000631	True 100s
True Menthol Green 100 Soft Pack	EX0000633	True Menthol 100s

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 soft pack packaging materials consist of a foil inner liner, paper label and closure, polypropylene film overwrap, polypropylene tear tape, and solid bleached sulphate paperboard carton. The box packaging materials consist of a foil inner liner, inner frame paper liner, polypropylene film overwrap, and solid bleached sulphate 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 two combusted, filtered cigarettes. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States.

The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The new products are made by modifying the corresponding original products. These modifications are to the ingredients in cigarette paper, tipping paper, filter tow, plug wrap, and printed monogram ink on barrel (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

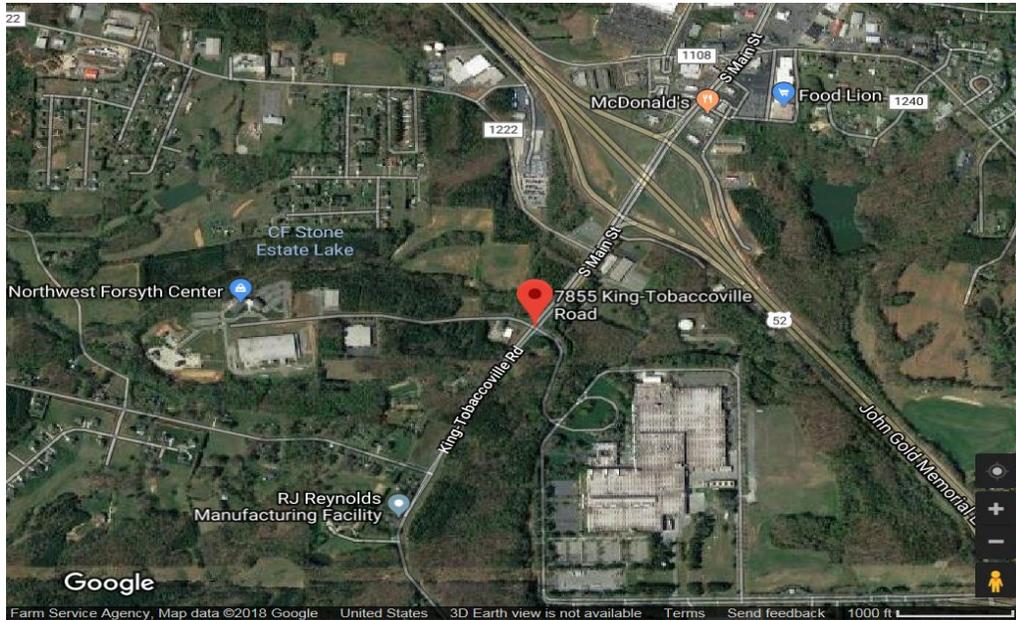
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- The new products are intended to compete with 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 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 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

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.

manufactured at the facility. The applicant also stated that manufacturing the new products 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 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 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.

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 00745-TV-39 issued by the Forsyth County Office of Environmental Assistance Protection.⁵
- (2) Storm water permit number NCG060079 issued by the North Carolina Department of Environmental Quality.⁶

Additionally, the facility submits release data to the EPA under the provisions of the Toxic Release Inventory (TRI) program (permit # 27050RJRYN7855A).

The Agency's search of the Environmental Protection Agency (EPA)'s Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the federal environmental laws and regulations.⁷ The applicant also stated that they did not identify any adverse effects on species or critical

³ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/raleigh/species/cntylist/forsyth.html>. Accessed Aug 21, 2019.

⁴ Critical habitat map available at: <https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449>. Accessed Aug 21, 2019.

⁵ Air permit available at: https://www.co.forsyth.nc.us/EAP/assets/doc/00745_TV_permit.pdf Accessed August 21, 2019.

⁶ 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 11, 2019.

⁷ Ibid.

habitats of species identified under ESA or the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

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 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.⁸ 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 products would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility. The applicant stated that manufacturing the new products would not require any additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

5.10 Cumulative Impacts

The Agency does not anticipate the proposed actions would incrementally increase or change the chemicals released to the environment from the tobacco manufacturing facility. A search in EPA's TRI database showed that in 2018, R.J. Reynold's manufacturing facility in Tobaccoville, North Carolina released 8,399 pounds of ammonia and 19,639 pounds of nicotine and nicotine salts to air (a total of 28,038 pounds), and 885 pounds of ammonia and 4,884 pounds of nicotine and nicotine salts (a total of 5,769 pounds) offsite. No TRI-reportable chemicals were released to water and land (Table 1).⁹ 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.¹⁰ 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

⁸ Ibid.

⁹ U.S. Environmental Protection Agency (EPA). *TRI Data* <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/27050RJRYN7855A>. Searched on Oct 7, 2019.

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 Aug 21, 2019.

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 in 2018

Production-Related Waste Managed or Released		Chemical Mass (pounds)
Recycled		0
Energy Recovery		0
Treated*		5,815
<i>Subtotal Waste Managed</i>		<i>5,815</i>
On-Site Release	Ammonia	8,399
	Nicotine and Nicotine Salts	19,639
Off-Site Release	Ammonia	885
	Nicotine and Nicotine Salts	4,884
<i>Subtotal Waste Released</i>		<i>33,807</i>
Total Production-Related Waste		39,622
* Ammonia only		

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.¹¹

The applicant stated that manufacturing the new products will not require additional environmental controls for air emission, water discharge, or solid waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

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 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

¹¹ North 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 August 21, 2019.

projected market volumes for the new 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 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 of 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:

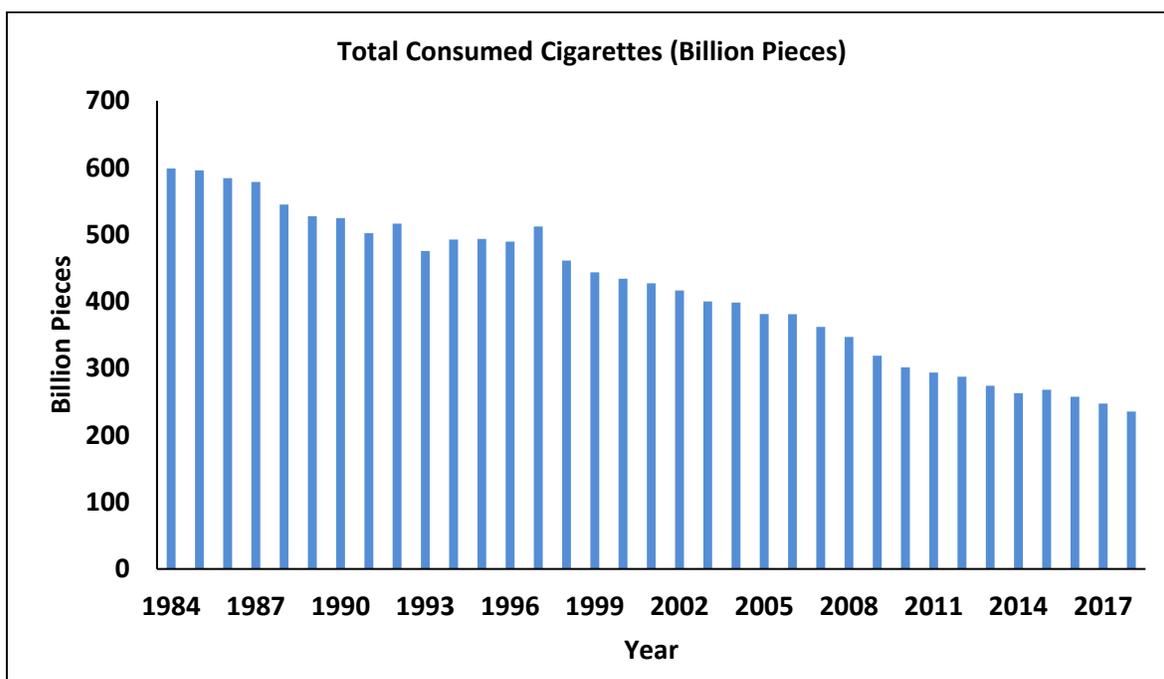
- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent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

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.

in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016). Despite the considerable ethnic and racial disparities in SHS exposure in vulnerable populations, data from the National Health and Nutrition Examination Survey showed a decline in SHS exposure from 1999-2000 to 2011-2012 with the highest prevalence of exposure among non-Hispanic subpopulations (46.8%), compared to Mexican Americans (23.9%) and non-Hispanic whites (21.8%) in 2011-2012 (Homa et al., 2015). There were also significant declines in SHS exposure prevalence noted in the 2000 and 2010 National Health Interview Survey Cancer Control Supplements. SHS exposure declined in Hispanics from 16.3% in 2000 to 3.1% in 2010, non-Hispanic Asians from 13.4% in 2000 to 3% in 2010, and non-Hispanic blacks from 31.2% in 2000 to 11.5% in 2010 as compared to exposures in non-Hispanic whites, which declined from 25.8% in 2000 to 9.7% in 2010 (Yao et al., 2016).

Figure 2. Use of Cigarettes in the United States, 1984 – 2018



As of March 2019, 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 used in the United States.

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

7.1. Affected Environment

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

7.2. Air Quality

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

No changes in air quality are anticipated from disposal of the cigarette butts of the new products. The chemicals in the new products' cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new products would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other cigarettes disposed of in the United States.

No changes in air quality from disposal of the 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 (1) the disposal of the new products and packaging materials would be the same as the disposal of cigarettes that are currently marketed in the United States, and (2) there would be no anticipated increase in number of cigarettes being disposed of as the new products are anticipated to replace similar marketed cigarettes.

7.4. Water Resources

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

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 and packaging waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new products would be in the same manner as any other waste generated from any other combusted, filtered cigarettes marketed in the United States. The number of cigarette butts generated would be equivalent to the market projections (Confidential Appendix 2) and a portion of those would be littered.

7.6. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products would be handled in the same manner as the waste generated from disposal of other cigarettes in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7. Cumulative Impacts

A major existing environmental consequence of the use of the new products, as well as other conventional cigarettes, is littering of discarded cigarette filters or butts (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 (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 disposed of in the United States.

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:

Preparer:

Dilip Venugopal, Ph.D., Center for Tobacco Products
Education: M.S. in Ecology and Ph.D. in Entomology
Experience: Sixteen years in various scientific activities
Expertise: NEPA analysis, environmental impact analysis and risk assessment, applied ecology, geo-statistics

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products
Education: M.S. in Environmental Science and Ph.D. 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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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.

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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	Modification from Original Product
EX0000631	Deletion of non-FSC cigarette paper and addition of FSC cigarette paper. Deletion of white tipping paper and addition of an alternate white tipping paper. Deletion of plug wrap and addition of an alternate plug wrap.
EX0000633	Deletion of tobacco (b) (4) [REDACTED]. Deletion of tobacco (b) (4) [REDACTED]. An increase in existing tobacco (b) (4) [REDACTED]. An increase in existing tobacco (b) (4) [REDACTED]. Deletion of the printed monogram ink on barrel.

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

First- and fifth-year market volume projections of the new products were compared to the total forecasted use of cigarettes in the United States.¹⁶ The projected use of the new products in the first and fifth year of marketing after marketing orders are issued account for less than (b)(4)% of the forecasted cigarette use in the United States.

STN	Projected Market Volume			
	First Year		Fifth Year	
	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁷	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁸
EX0000631	(b) (4)			
EX0000633				
Total				

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 R² 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 Products in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

¹⁸ See footnote # 16.