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

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

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Table of Contents

Table of Contents 2

1. Applicant and Manufacturer Information 3
2. Product Information 3
3. The Need for the Proposed Actions 3
4. Alternative to the Proposed Actions 4
5. Potential Environmental Impacts of the Proposed Actions and Alternative - Manufacturing the New Products 4
   - 5.1 Affected Environment 4
   - 5.2 Air Quality 5
   - 5.3 Water Resources 6
   - 5.4 Soil, Land Use, and Zoning 6
   - 5.5 Biological Resources 6
   - 5.6 Regulatory Compliance 7
   - 5.7 Socioeconomics and Environmental Justice 7
   - 5.8 Solid Waste and Hazardous Materials 8
   - 5.9 Floodplains, Wetlands, and Coastal Zones 8
   - 5.10 Impacts of the No-Action Alternative 8
6. Potential Environmental Impacts of the Proposed Actions and Alternative – Use of the New Products 8
   - 6.1 Affected Environment 8
   - 6.2 Air Quality 8
   - 6.3 Environmental Justice 10
   - 6.4 Impacts from No-Action Alternative 10
7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products 11
   - 7.1 Affected Environment 11
   - 7.2 Air Quality 11
   - 7.3 Water Resources 11
   - 7.4 Biological Resources 11
   - 7.5 Solid Waste 12
   - 7.6 Socioeconomics and Environmental Justice 12
   - 7.7 Impacts from No-Action Alternative 12
8. List of Preparers 12
9. A Listing of Agencies and Persons Consulted 13
10. References 13

CONFIDENTIAL APPENDIX 1 16

Comparison of the New Products to the Corresponding Original Products 16

CONFIDENTIAL APPENDIX 2 17

Market Volume Projections for the New Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Products 17

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 Address:	7855 King Tobaccoville Road Tobaccoville, NC 27050

2. Product Information

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

New Product Name	STN	Original Product Name
Camel Classic Gold Box	EX0002401.PD1	Camel Classic Gold Box
Camel Classic Blue Box	EX0002401.PD3	Camel Classic Blue Box

Product Identification

Product Type	Cigarettes
Product Subcategory	Filtered
Number of Products per Retail Unit	Twenty cigarettes per pack with ten packs per carton.
Product Package	The packaging materials consist of an innerframe and box composed of sulphate board, foil innerliner, and polypropylene film overwrap.

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 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 SE 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 will 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 SE 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 SE.

The new products differ from the corresponding original products in the deletion and addition of multiple ingredients (Confidential Appendix 1).

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new 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:

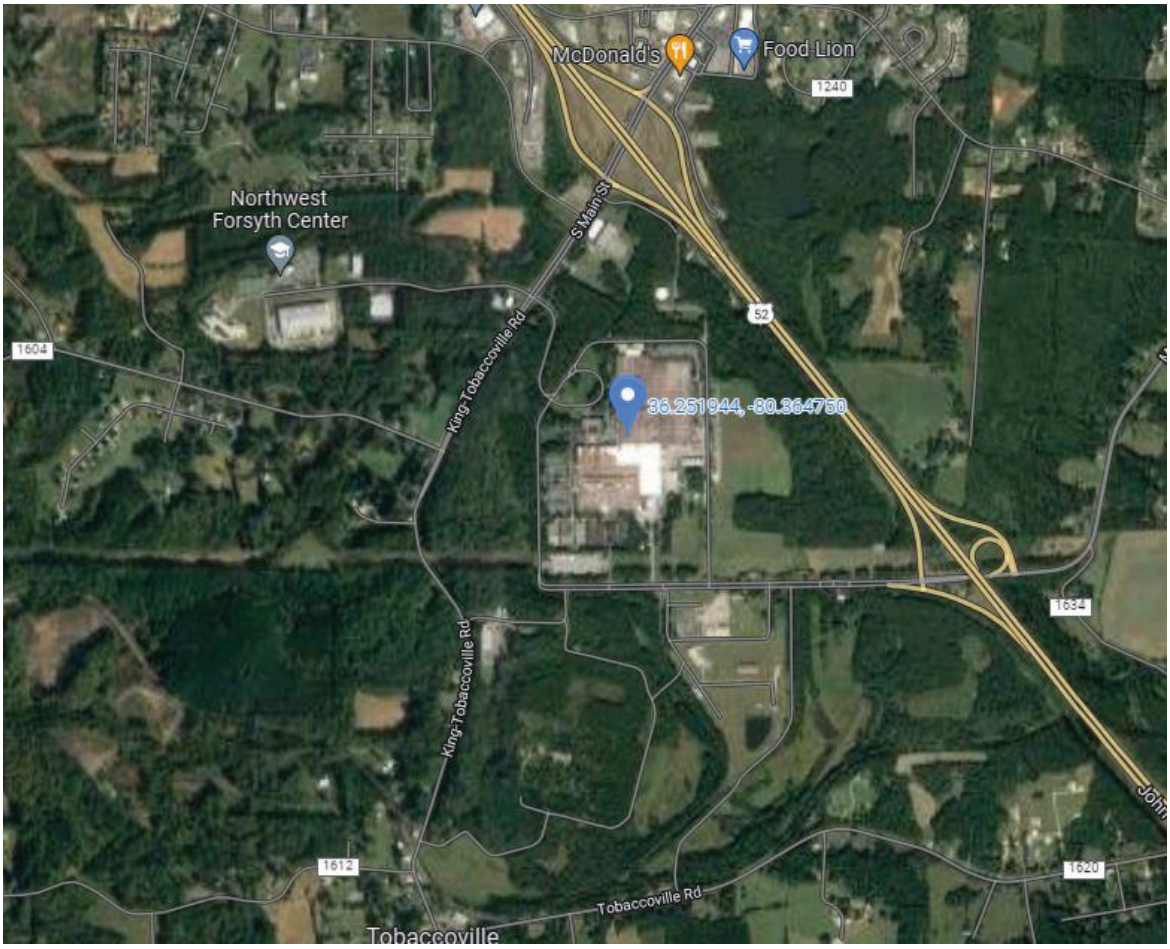
- The new products will be manufactured in the same manner as the original products.
- The new products will compete with similar tobacco products currently manufactured at the same facility.
- Components of the new products are commonly used in other commercially marketed cigarettes currently manufactured at the facility.

Additionally, the applicant stated that (1) manufacturing the new products will not require additional environmental controls for air emission, water discharge, or solid waste disposal; (2) materials released into the environment will not exceed what is allowed under relevant environmental law; and (3) no additional equipment or facility expansion will be required.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products will be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturing Facility [1]



The manufacturing facility is located in Forsyth County, North Carolina (NC) in Headwaters Muddy Creek watershed, * hydrologic unit code 03040101, which is the largest of the Yadkin River tributaries. [2] The manufacturing 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.

5.2 Air Quality

The Agency does not anticipate that any new chemicals will be released into the environment due to manufacturing the new products. The applicant stated that manufacturing the new products will not require additional environmental controls for air emissions.

A search in EPA's TRI database showed that in 2021, R.J. Reynolds Tobacco Company manufacturing facility in Tobaccoville, NC released 7,426 pounds of ammonia and 14,801 pounds of nicotine and nicotine salts to air (totaling 22,227 pounds) and transferred 1,261 pounds of ammonia and 4,320

* 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.

pounds of nicotine and nicotine salts (totaling 5,581 pounds) offsite (Table 1). [3] The TRI database search did not show that the R.J. Reynolds manufacturing facility released into the environment any other reportable toxicants associated with manufacturing tobacco products. No other hazardous air pollutants were reported. 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 Manufacturing Facility in 2021

Production-Related Waste Managed or Released		Chemical Mass (pounds)
Recycled		0
Energy Recovery		0
Treated		12,212
Subtotal Waste Managed		*12,212*
On-site Release	Ammonia	7,426
	Nicotine and Nicotine Salts	14,801
Off-site Release	Ammonia	1,261
	Nicotine and Nicotine Salts	4,320
Subtotal Waste Released		*27,808*
Total Production-Related Waste		**40,020**

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products will cause the discharge of any new chemicals into water. The applicant stated that there will be no change in how the new products are manufactured. Additionally, the applicant stated that components in the new products reflect ingredients used in other tobacco products at the facility; therefore, manufacturing the new products will not require additional environmental controls for water discharge.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products will lead to changes in soil, land use, or zoning. The applicant stated that there will be no expected facility expansion due to manufacturing the new products. Therefore, there will 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 will 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 applicant stated that manufacturing the new products will not require expansion of the manufacturing facilities. Additionally, U.S. Fish and Wildlife Service (FWS) maps show that the facilities are not within or near a critical habitat, or endangered animal and plant species. [4]

The U.S. FWS identifies two vertebrates, one clam, and one flowering plant as being present in Forsyth County [5] as listed in Table 2:

Table 2. Species Identified by USFWS in Forsyth County, North Carolina

Species	Status
Bald eagle (*Haliaeetus leucocephalus)*	Protected*
Bog turtle (*Glyptemys muhlenbergii)*	Threatened (S/A)**
James spinymussel (*Parvaspina collina collina*)	Endangered
Schweinitz's sunflower (*Helianthus schweinitzii*)	Endangered
*Protected under the Bald and Golden Eagle Protection Act	
**Threatened due to similarity of appearance	

Because the proposed actions do not require expansion of the manufacturing facility, and the listed species are not found in the immediate vicinity of the facility, there will be no impacts to protected species or their potential habitat.

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 statement, including review of the following permits:

(1) Permit for discharge of stormwater at the manufacturing site in a regulated outfall issued by the State of North Carolina Department of Environmental Quality Division of Energy, Mineral, and Land Resources with number NCG060079. [6]
(2) Permit for management of hazardous waste generated in the manufacturing facility issued by the North Carolina Department of Environmental and Natural Resources with number NCD982076739. [6]

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

The Agency's search of EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations at the manufacturing facility. [6]

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 compete with other cigarettes manufactured at the facility and facility expansion is not required.

Manufacturing the new products will not disproportionately impact minority populations, because only 10% of the population within a three-mile radius of the manufacturing facility is minority per 2010 U.S.

Census and American Community Survey data. [6] 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 will notably affect the current manufacturing waste generated from the facility production of all filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products will 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 will 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 will be no facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance. Therefore, there will be no effects on floodplains, wetlands, or coastal zones.

5.10 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative will not change the existing condition of manufacturing cigarettes at the listed facility, as many similar tobacco products will continue to be manufactured.

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

The Agency evaluated potential impacts to resources in the environment that may 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 projected market volumes for the first- and fifth years of marketing the new products in the United States (Confidential Appendix 2). [†]

6.1 Affected Environment

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

6.2 Air Quality

The impacts from use of cigarette 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

[†] Market volumes are used as proxy for use, assuming that all produced products will be consumed or used in the United States.

secondary pollutants, thirdhand smoke (THS). These pollutants coexist in mixtures in the environment alongside SHS. [7, 8]

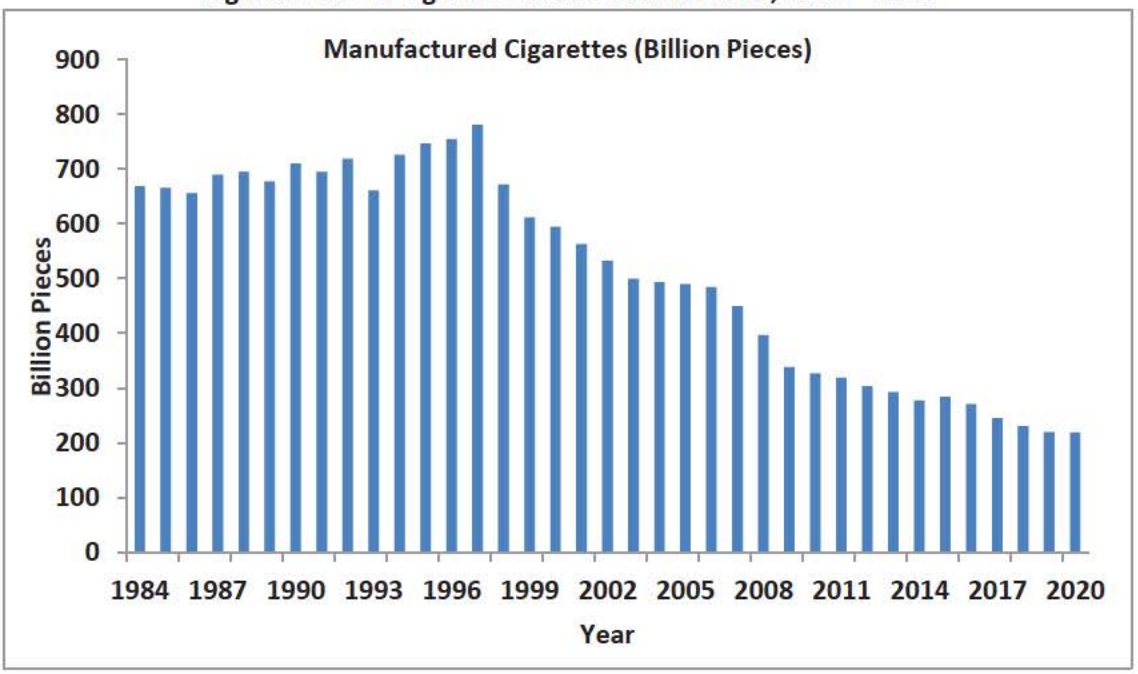
There is no safe level of exposure to SHS. [9, 10] Even low levels of SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30%. [11]
- 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. [9, 10]
- SHS causes more than 40,000 deaths a year. [11]

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. [13, 14] 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 among non-smokers from 87.5% in 1988-1991 to 25.1% in 2013-2014 with the highest prevalence of exposure among non-Hispanic Black (50.3%), compared to Mexican Americans (20%) and non-Hispanic Whites (21.4%) in 2013-2014. [15] However, no change in exposure occurred between 2011-2012 and 2013-2014. [15]

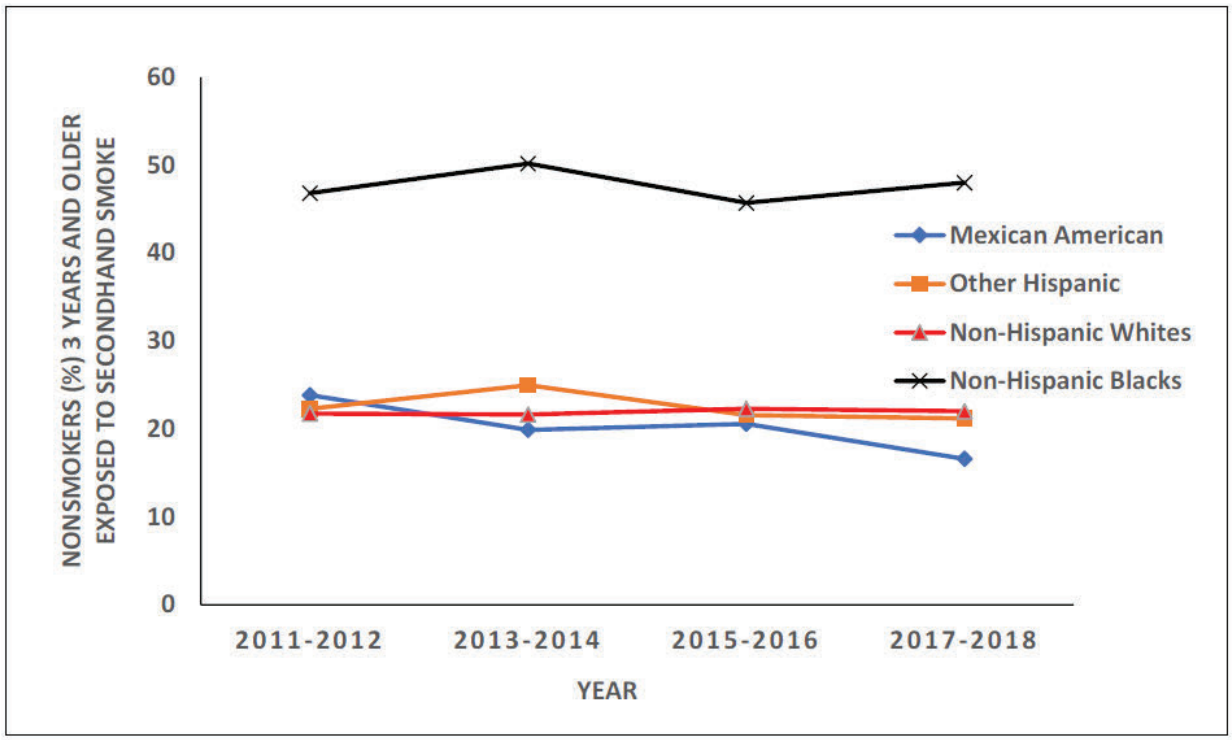
In recent years, a stagnation in reduction in rate of SHS exposure has been reported (Figure 3). [16]

Figure 2. Use of Cigarettes in the United States, 1984 – 2020



[‡] TTB sale data is used as a proxy for consumption.

Figure 3. Trends in the Exposure of Nonsmokers to Secondhand Smoke [16]



As of December 2020, 28 states and the District of Columbia had implemented comprehensive smoke-free laws. [17] Such laws are also expected to reduce the levels of non-users' exposure to SHS and THS.

The Agency does not anticipate new chemicals will 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 will 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 will be no new disproportionate impacts on minority or low-income populations.

6.4 Impacts from No-Action Alternative

The environmental impact of the no-action alternative will not change the existing condition of use of cigarettes, as many similar tobacco products will 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 evaluated potential impacts to resources in the environment that may be affected by disposal of the new products. The Agency found no significant impacts based on publicly available information such as the documented continuous decline in use of cigarettes in the United States, and the applicant's submitted information, including the projected market volumes for the new products.

7.1 Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders will allow for the new 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 will 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 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 will replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other cigarettes disposed of in the United States.

No changes in air quality from disposal of the packaging materials in the new products will 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 in the United States [18] per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3 Water Resources

No changes in 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 are used in cigarettes currently on the market. Furthermore, the new products will compete with or replace market share held by similar products.

7.4 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, [19] the disposal of the new products is not expected to change the fire frequency because (1) the disposal of the new products will be the same as the disposal of cigarettes that are currently marketed in the United States, and (2) there will be no anticipated increase in number of cigarettes being disposed of as the new products are anticipated to replace similar marketed cigarettes.

7.5 Solid Waste

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. [20] Cigarette butts are among the most common forms of litter found on beaches, [21, 22] near streams, night clubs, [23] bus stops, [24] roads, and streets. [25, 26] Cigarette butts have been found at densities averaging more than four cigarette butts per meter squared of urban environments. [27]

Toxic compounds in cigarette butts leach out into water, potentially threatening human health and the environment, especially marine ecosystems. [28, 29] 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. [30]

The Agency does not foresee the introduction of the new products will notably affect the current cigarette butt waste generated from all cigarettes. The waste generated due to disposal of the new products will be handled in the same manner as any other waste generated from any other cigarettes disposed of in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2) and a portion of those will 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 is expected to be handled in the same manner as the waste generated from other cigarettes in the United States. No new emissions are expected due to disposal of the new products; therefore, there will be no new disproportionate impacts on minority or low-income populations.

7.7 Impacts from No-Action Alternative

The environmental impact of the no-action alternative will not change the existing condition of disposal of cigarettes and cigarette packaging, as many other similar tobacco products will continue to be marketed in the United States.

8. List of Preparers

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

Preparer:

Alex Lowe, Ph.D., Center for Tobacco Products
- Education: Ph.D. in Biology
- Experience: Twelve years in environmental science
- Expertise: Ecosystem science, human impacts, and water quality

Reviewer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
Education: Ph.D. in Environmental Science and Management
Experience: Six years in environmental science, three years in toxicology
Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

9. A Listing of Agencies and Persons Consulted

Not applicable.

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CONFIDENTIAL APPENDIX 1

Comparison of the New Products to the Corresponding Original Products

STN	Modification
EX0002401.PD1	• Deletion of a white tipping paper and addition of an alternative white tipping paper • Deletion of a tipping adhesive and addition of an alternative tipping adhesive • Deletion of (b) (4) • Addition of (b) (4) • Increase in the quantity of (b) (4) • Decrease in the quantity of (b) (4)
EX0002401.PD3	• Deletion of a cork tipping paper and addition of a white tipping paper • Deletion of seven tobacco additives (six single flavor ingredients [(b) (4) , and one complex flavor ingredient [(b) (4)]) • Addition of (b) (4) • Increase in the quantity of (b) (4) • Decrease in the quantity of (b) (4)

CONFIDENTIAL APPENDIX 2

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.[§] The projected use of the new products in the first and fifth year of marketing account for about (b) (4) %, respectively, of the forecasted cigarette use in the United States. (b) (4)

(b) (4)

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	Projected Market Volume			
	First-Year		Fifth-Year	
	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used [**]	New Product (Cigarettes)	New Product as a Percent of Total Cigarettes Used [††]
EX0002401.PD1	(b) (4)			
EX0002401.PD3				
Total				

[§] The Agency used historical data regarding total use of cigarettes from 1997 to 2020 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 0.9844, the forecasted number of cigarettes that would be used in the United States is estimated at 228.441 billion cigarettes in the first year and 161.201 billion cigarettes in the fifth year of marketing the new products.

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

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

[††] Ibid.