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

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

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1. Applicant and Manufacturer Information

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

2. Product Information

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

New Product Name	STN	Predicate Product Name
Camel Crush Menthol	SE0014763	Camel Light Box with Menthol Capsule
Camel Crush Menthol Silver	SE0014764	Camel Light Box with Menthol Capsule

Product Identification

Product Category	Cigarette	
Product Subcategory	Combusted filtered	
Product Number per	Twenty cigarettes per pack with ten packs per carton.	
Retail Unit		
Product Package	The packaging materials consist of a foil inner liner, inner frame paper, sulfate	
	board box, and polypropylene pack overwrap, and sulfate board carton.	

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders under the provisions of sections 910 and 905(j) of the Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to the single predicate product. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency two substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the predicate product. The predicate product is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new products differ from the predicate product in the ingredients in the cigarette paper, the tipping paper, the menthol capsule, and the monogram ink on the 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:

- Components of the cigarette papers and tipping papers are commonly used in other products manufactured at the facility and used throughout the cigarette industry.
- The new products are intended to compete with similar tobacco products currently on the market.
- 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).

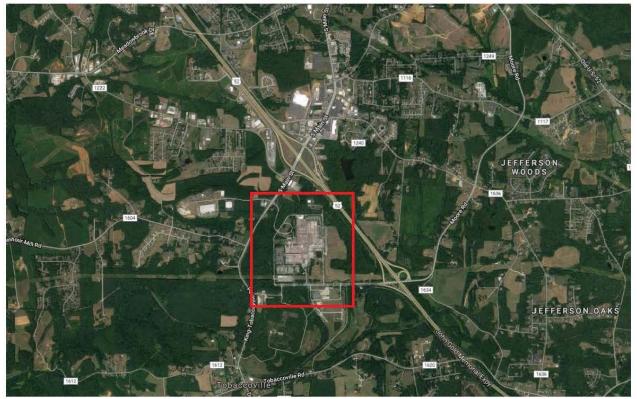


Figure 1. Location of the Manufacturer

The manufacturing facility is 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 the water. 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, 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). A search of the U.S. Fish and Wildlife Services' (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

¹ A watershed is an area of land where all bodies of water, such as; surface water from lakes, streams, reservoirs and wetlands, the underlying ground water, and rainfall, drain to a common outlet such as the outflow of a reservoir, mouth of a bay, or any point along a stream channel. See https://water.usgs.gov/edu/watershed.html.

² USGS. National Water Information System: Mapper. Available at: <u>https://maps.waterdata.usgs.gov/mapper/index.html</u>. Accessed May 23, 2018.

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 applicant provided detailed information for the following air emission, storm water, and wastewater permits:

- (1) Air permit number 00745-TV-39 issued by the Forsyth County Office of Environmental Assistance Protection. The applicant also stated that the facility complies with the requirements of this permit, which include submission of annual emissions inventories, compliance certification statements, and semiannual reporting.
- (2) Storm water permit number NCG060079 issued by the North Carolina Department of Environmental Quality; expires October 31, 2018. The applicant stated that the facility complies with the requirements of this permit, which include maintaining storm water pollution prevention plans, quantitative and qualitative discharge monitoring, and site inspections.
- (3) Waste water permit number IUP 3001 issued by the North Carolina Department of Environmental Quality; expires June 30, 2022. The applicant stated that the facility complies with the requirements of this permit, which include quantitative and qualitative discharge monitoring, and flow monitoring and reporting.

The applicant also stated that the facility performs the following additional activities to comply with the applicable environmental regulations:

- maintaining and complying with five separate Spill Prevention Control and Countermeasure plans, as required by the U.S. Environmental Protection Agency (EPA) Oil Pollution Prevention Regulations;
- reporting greenhouse gas emissions to EPA on an annual basis;
- submitting EPA Tier 2 to EPA TRI (facility ID number 27050RJRYN7855A) and North Carolina Right-to-Know reports; and
- complying with Department of Homeland Security Chemical Antiterrorism Standards and with applicable solid and hazardous waste regulations.

The Agency's search of EPA's Enforcement and Compliance History Online (ECHO) did not reveal any violations of federal environmental laws and regulations.⁵

³ U.S. Fish and Wildlife Services (U.S. FWS), available at: <u>https://www.fws.gov/raleigh/species/cntylist/forsyth.html</u>. Accessed October 26, 2018.

⁴ Critical habitat map available at: <u>https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449</u>. Accessed October 26, 2018.

⁵ U.S. EPA ECHO Detailed Facility Report: R.J. Reynolds Tobacco Company, Richmond, VA. Available at: <u>https://echo.epa.gov/detailed-facility-report?fid=110000345225</u>. Accessed October 26, 2018.

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 products. The Agency does not anticipate any impacts on employment revenue or taxes because no expansion of the manufacturing facility would be needed to manufacture the new products.

Manufacturing the new products would not disproportionately impact minority populations, because only nine percent 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 an Indian reservation.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee the introduction of the new products to 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 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 floodplains, wetlands, or coastal zones.

5.10 Cumulative Impacts

The Agency does not anticipate the proposed actions to incrementally increase or change the chemicals released to the environment from the facility's tobacco manufacturing. A search in EPA's Toxic Release Inventory (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) but no TRI-reportable chemicals were released to land or water (Table 1).⁷ No other hazardous air pollutants were reported. Ammonia's adverse health effects are ocular and

⁶ U.S. EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <u>https://echo.epa.gov/detailed-facility-report?fid=110000345225</u>. Accessed October 26, 2018.

⁷ U.S. Environmental Protection Agency (EPA). *TRI Data Form R & A Download*. Available at: <u>https://www3.epa.gov/enviro/facts/tri/form_ra_download.html</u>. Searched on November 1, 2018.

respiratory; nicotine and nicotine salts have known adverse developmental effects.⁸ 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.

Production-Related Waste Managed or Released				
Recycled				
		0		
		3,040		
Subtotal Waste Managed				
Air	Ammonia	8,956		
	Nicotine and Salts	17,839		
Mator	Ammonia	0		
vvater	Nicotine and Salts	0		
Land -	Ammonia	0		
	Nicotine and Salts	0		
Off-site Release Ammonia				
4	Nicotine and Salts	3,256		
Subtotal Waste Released				
Production-Related	d Waste	33,579		
	Air Water Land Subtotal Waste Relea	Air Air Air Air Air Ammonia Water Land Ammonia Nicotine and Salts Ammonia Nicotine and Salts Ammonia		

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

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.⁹

5.11 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 marketed.

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's address and clicking on the facility's location on the map. Accessed Jun 14, 2018.

⁹ 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%20Yadki n%20River%20Headwaters-2010.pdf. Accessed Jun 14, 2018.

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 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 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 predicate product 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 2); 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 new 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 a mixture 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).¹⁰ 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).

As of December 2015, 26 states and the District of Columbia have implemented comprehensive smokefree laws (Tynan et al., 2016). Such laws are expected to reduce the levels of exposure of non-users to SHS and THS.

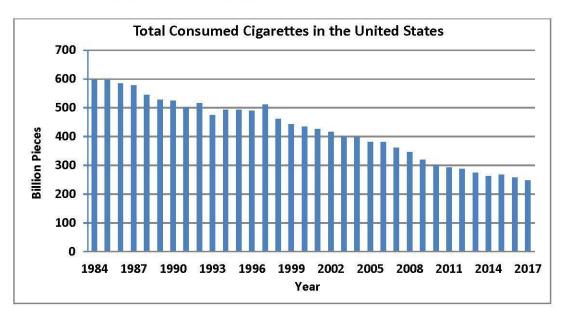


Figure 2. Use of Cigarettes in the United States, 1984 – 2017

¹⁰ U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: https://www.ttb.gov/tobacco/tobaccostats.shtml. Accessed March 7, 2018.

6.5. No-Action Alternative

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

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

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on 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 is the entire 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 materials 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 3). Therefore, the fate and effects of any materials emitted into the air from disposal of the new products 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 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,^{11,12} 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 are anticipated to compete with or replace other currently marketed cigarettes.

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 is expected to 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 new 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 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 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 affected by several factors, such as the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco fillers, number of buffs, and the mass transfer behavior of combustion products along the cigarette.¹³

¹¹ 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.

¹² UC Davis Health News. Available at: <u>https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763</u>. Accessed May 22, 2018.

¹³ NIST Technical Report 8147 available at: <u>http://dx.doi.org/10.6028/NIST.IR.8147</u>. Accessed April 24, 2018.

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

7.7. 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):

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Hoshing W. Chang, Ph.D., Center for Tobacco Products Education: M.S. in Environmental Science and Ph.D. in Biochemistry Experience: Ten years in NEPA practice Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

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STN	Component	Modification		
	Cigarette paper	Non-FSC ¹⁴ cigarette paper to FSC cigarette paper		
SE0014763	Tipping paper	Alternate cork-on-white tipping paper		
	Filter with capsule	Alternate capsule with direct menthol application		
	Monogram ink	Deletion of monogram ink on the barrel		
	Cigarette paper	Non-FSC cigarette paper to FSC cigarette paper		
SE0014764	Tipping paper	Cork-on-white tipping paper to white tipping paper		
3E0014704	Filter with capsule	Alternate capsule with direct menthol application		
	Monogram ink	Deletion of monogram ink on the barrel		

Confidential Appendix 1: Comparison of New and Predicate Products

¹⁴ FSC stands for fire standards compliant

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 for the new products were compared to the total forecasted use of cigarettes in the United States.¹⁵ The new products account for a minor percentage (**b**) (**4**) of the total forecasted cigarette use in the United States.

	Projected Market Volume				
	First-Year		Fifth-Year		
STN	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁶	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁷	
SE0014763			1 4 \		
SE0014764			(4)		
Total					

¹⁷ See footnote # 15.

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 236.26 billion cigarettes in the first year and 210.92 billion cigarettes in the fifth year of marketing the new products.

¹⁶ Projected Market Occupation of the New Product in the United States (%)=

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

CONFIDENTIAL APPENDIX 3

Projected Waste of Cigarette Butts in the First and Fifth Years of Marketing the New Products

3 3	A_l : Projected waste generation of cigarette butts of the new product (metric tons)
$A_i = \sum (B_i \times C_i \times D_i X G)$	<i>Bi</i> : Projected market volume of the new product (number of individual cigarettes
$\sum_{i=1}^{2}$ $\sum_{i=1}^{2}$	C _i : Weight of cigarette (gram)
	D _i : Cigarette butt ratio
D = E	E: Cigarette butt length ¹⁸
$\nu_i - \frac{1}{F_i}$	<i>F_i</i> : Length of cigarette (millimeter)
-200 8 0	$G: 1.0 \times 10^{-5}$ metric tons/gram

Projected Year	STN	Market Volume (# of pieces) B;	Cigarette Weight (grams) Ci	Cigarette Length (mm) Fi	Cigarette Butt Waste (tons) Aı
First-Year	SE0014763	(b) (A)	0.9579	83	(h) (1)
	SE0014764	(D)(4)	0.9573	83	(U)(4)
	Total				(~) (~)
Fifth-Year	SE0014763		0.9579	83	
	SE0014764		0.9573	83	
	Total				

If all the projected cigarette butt waste generated from use of the new products is disposed of in landfills, the projected waste of (b) (4) metric tons in the first year and (b) (4) metric tons in the fifth year of marketing the new products would be negligible fractions of the 262.4 million metric tons of total waste reported in the United States in 2015 (U.S. EPA, 2018).

¹⁸ 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.