Environmental Assessment for Exemption Request by John Middleton Company

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

August 27, 2018

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1. Applicant and Manufacturer Information

Applicant Name:	John Middleton Company
Applicant Address:	2325 Bells Road, Richmond, Virginia 23234
Manufacturer Name:	John Middleton Company
Product Manufacturing Address:	2211 Bells Road, Richmond, Virginia 23234

2. Product Information

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

New Product Name	STN	Amendment STNs	Predicate Product Name
Black & Mild	EX0000244	EX0000250 EX0000261	Black & Mild

Product Identification

Product Type	Cigar
Product Subtype	Tipped, unfiltered
Quantity per Retail Sale Unit	Sold individually, twenty-five individually wrapped cigars per box.
Product Package	The packaging materials consist of a polypropylene single stick overwrap, paper board pack, polypropylene pack overwrap, polypropylene tear tape, and corrugated board shipping case.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, are for FDA to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the introduction of a combusted, unfiltered cigar into interstate commerce for commercial distribution in the United States. 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 an 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 an

exemption from demonstrating substantial equivalence.

Modifications to the original product compared to the new product are minor ingredient changes in the cigar filler, wrapper and binder (Confidential Appendix 1).

4. Alternative to the Proposed Action

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

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

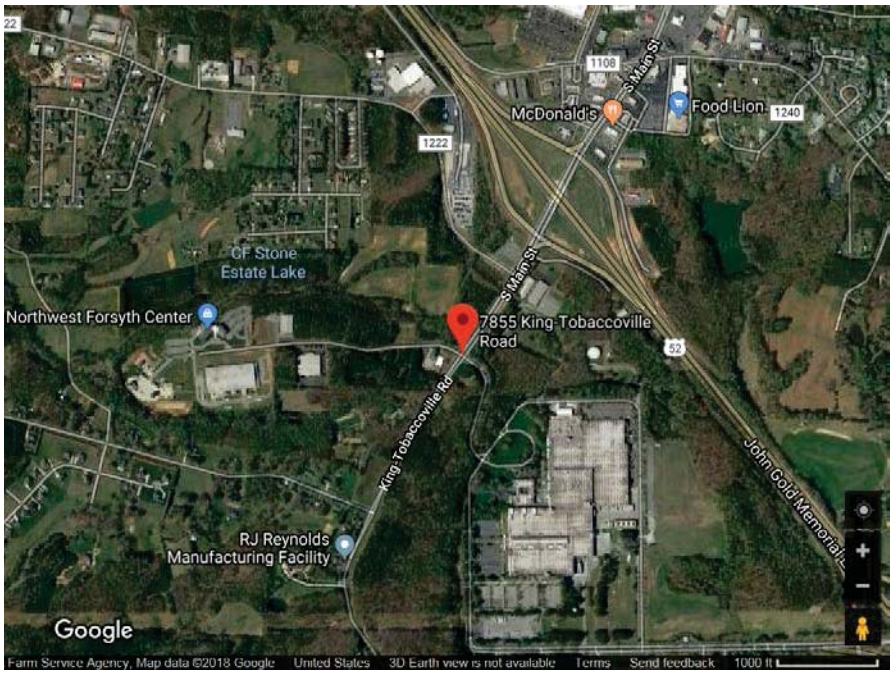
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new product and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- Components of the cigar papers, wrappers and binders are commonly used in other product manufactured at the facility and used throughout the cigar industry.
- The new product would not be commercially marketed simultaneously with the original product if marketing order is granted for the new product.
- The new product is intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.
- No facility expansion or new construction 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 Manufacturer



The manufacturing facility is in Richmond County, VA in Falling Creek-James River watershed, hydrologic unit code 02080206, in proximity to the James River in the east.[1,2] The facility is surrounded by residential and commercial areas in the western portion in proximity to the community of Clapton, VA and mixed natural areas and agricultural land to the east.

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

5.2 Air Quality

The Agency does not anticipate any new chemicals or new type of emissions would be released into the environment due to manufacturing the new product. The applicant stated that manufacturing the new product is not expected to result in changes of 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 any new chemicals to be discharged into the 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, or land use and 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 Services' (U.S. FWS) critical habitat and endangered species list shows three threatened species (two flowering plants – sensitive joint-vetch and small whorled pogonia, and the northern long-eared bat) and one endangered fresh water mussel are listed in Richmond 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.

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[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: https://maps.waterdata.usgs.gov/mapper/index.html. Accessed Aug 2, 2018.

[3] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://ecos.fws.gov/ecp0/reports/species-by-current-range-county?fips=51159 Accessed Aug 2, 2018.

[4] Critical habitats map available at: https://databasin.org/maps/new#datasets=d579d87eb54f4374a77ea53e7ef66449. Accessed, Aug 2, 2018.

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) Stationary source permit to construct and operate (Registration no. 52608) cigar tobacco process in accordance with provisions of the Virginia State Air Pollution Control Board Regulations for the Control and Abatement of Air Pollution, issued by the Department of Environmental Quality, Commonwealth of Virginia.
(2) Waste water permit number 2149 issued by the Division of Wastewater Treatment, City of Richmond; expires July 31, 2020. 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 Agency's search of EPA's Enforcement and Compliance History Online (ECHO) did not reveal any violations of the federal environmental laws and regulations.[5] The applicant also stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics 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.

A high percentage minority (81%) and low-income population (49% below poverty level) reside within three miles of the manufacturing facility, per 2010 U.S. Census and American Community Survey data.[6] However, manufacturing the new product is not expected to disproportionately impact minority populations, as no new exposure is anticipated. 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 product to notably affect the current manufacturing waste generated from the facility's production of all combusted, filtered cigars. The Agency anticipates the waste generated due to manufacturing the new product would be released to the environment, transferred to a publicly owned treatment works (POTW), and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility and in a similar manner to other combusted, filtered cigars manufactured in the United States. 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.

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[5] U.S. EPA ECHO Detailed Facility Report: Altria Compounds, LLC, Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110055530910. Accessed Aug 2, 2018.

[6] U.S. EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: https://echo.epa.gov/detailed-facility-report?fid=110055530910. Accessed Aug 2, 2018.

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's tobacco manufacturing. The manufacturing facility which has the potential to generate and manage 2,200 pounds of monthly hazardous waste does not report to EPA's Toxic Release Inventory database, as it is considered a minor facility.[7,8] EPA's Enforcement and Compliance History Online 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. The applicant stated that manufacturing the new product would not require revised or new air, waste water, or storm water permits.

5.11 No Action Alternative

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

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 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. The applicant intends to market the new tobacco products to consumers throughout the United States.

6.1. 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 cigars 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 products and any other marketed cigars; (2) the new product is expected to compete with, or replace, other currently

[7] U.S. Environmental Protection Agency (EPA). *TRI Data Form R & A Download*. Available at: https://www3.epa.gov/enviro/facts/tri/form_ra_download.html. Searched on Aug 2, 2018.

[8] U.S. EPA. https://myrtk.epa.gov/info/report.jsp?IDT=FRS&ID=110055530910. The site allows for searching the industrial facilities that manage toxic waste chemicals. Accessed Aug 2, 2018.

marketed cigars, so the Agency does not expect that new or increased air emissions would be associated with use of the new product (Confidential Appendix 2); and (3) the ingredients in the new product are used in other currently marketed tobacco products.

6.2. Environmental Justice

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

6.3. Cumulative Impacts

The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigars, cigarettes, cigarillos and pipes. 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).

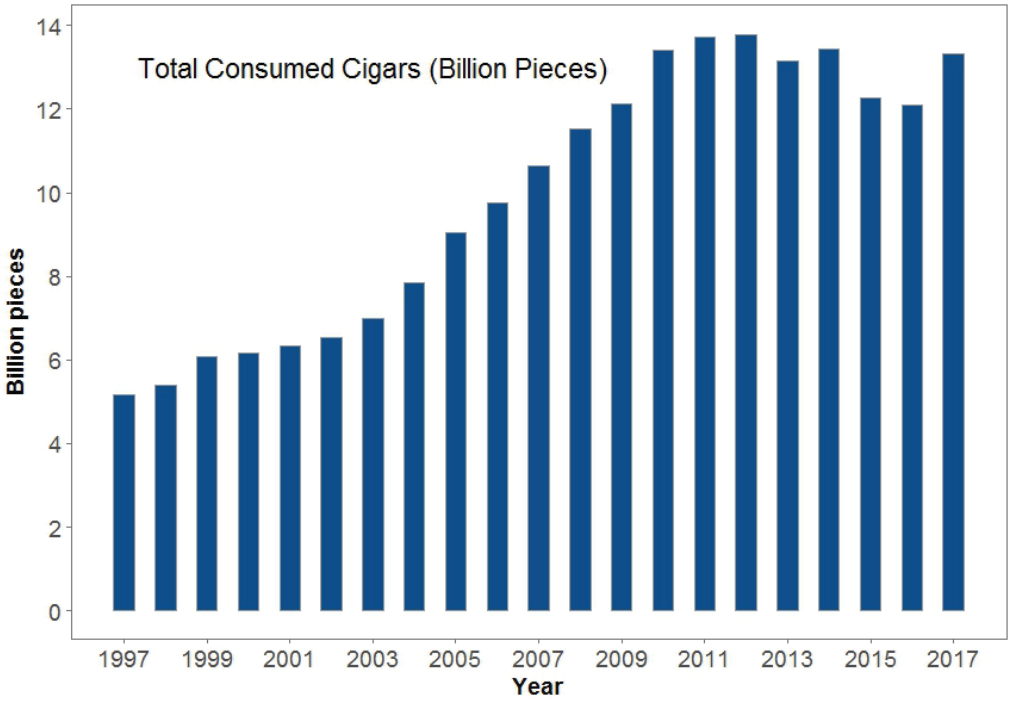
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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).

The consumption of cigars in the United States increased significantly from 1997 to 2011. Since 2011 through 2017, the trend of cigar usage has stabilized with a minor decrease overall, per the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).[9]

[9] 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.

Figure 2. Cigar consumption in the United States, 1997 – 2017



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

6.4. No Action Alternative

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

7. Potential Environmental Impacts of the Proposed Action and Alternative – 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 TTB data which shows relatively stable rates of cigar use in the United States since 2010, 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. The applicant intends to market the new tobacco product to consumers throughout the United States.

7.2. Air Quality

The Agency does not anticipate disposal of the 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 cigar butts and plastic filter tips of the new product. The chemicals in the new product cigar butts are commonly used in other currently marketed cigars. Because the new products are anticipated to compete with or replace other currently marketed cigars, the butt waste generated from the new product 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 product is anticipated to be the same as any materials from other cigars disposed of in the United States.

No changes in air quality from disposal of the new product 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 product packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from tobacco products.

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 tobacco products like cigars and cigarettes has been implicated in many fire incidents,[11,12] 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 cigars 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 cigar butts from the new product because the chemicals in the new product are the same as in currently marketed cigars and the new product is anticipated to compete with or replace other currently marketed cigars.

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 product. The waste generated due to disposal of the new product is expected to be handled in the same manner as the waste generated from disposal of other cigars in the United States. No new emissions are expected due to disposal of the new product; therefore, there would be no new disproportionate impacts on minority or low-income populations.

7.6. Cumulative Impacts

The use of the new product may impact the environment through littering of discarded cigar plastic filter tips. The environmental impacts from cigar butt litter are not well studied and potentially pose similar environmental risk as cigarette butts which can persist in the environment for more than 10 years (Novotny and Zhao, 1999). Like cigarettes, compounds in cigar butts can leach out into water, potentially threatening human health and the environment, especially aquatic and marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigar and cigarette butts due to air emissions is not well studied. Airborne emissions from cigar and 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 brand, length, filter material, types of tobacco, ingredients in the cigar tobacco fillers, number of butts, and the mass transfer behavior of combustion products along the cigar.[10]

However, the significant cumulative impacts from cigar butt is not of concern as TTB data shows relatively stable rates of cigar usage in the United States since 2010.

7.7. No Action Alternative

The environmental impact of the no-action alternative would not change the existing condition of disposal of cigars and cigar 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 (EA):

Preparer:

Dilip Venugopal, Ph.D., Center for Tobacco Products
Education: M.S. in Ecology and Ph.D. in Entomology
Experience: Seventeen 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 NEPA practice
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

[10] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed April 24, 2018.

10. References

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CONFIDENTIAL APPENDIX 1

Modifications: The New Product as Compared with the Original Product

STN	Component	Modification
EX0000244	Cigar tobacco filler	Replacement of (b) (4) with an equal amount of (b) (4)
	Cigar wrapper	Replacement of (b) (4) with an equal amount of (b) (4)
	Cigar binder	Replacement of (b) (4) with an equal amount of (b) (4)

CONFIDENTIAL APPENDIX 2

First- and Fifth-Year Market Volume Projections for the New Product and Percentage of Cigar Use in the United States Projected to be Attributed to the New Product

First- and fifth-year market volume projections for the new product were compared to the total forecasted use of cigars in the United States.[11] The new product accounts for a fraction of a percent of the forecasted cigar use in the United States. In addition, the applicant stated that they intend to discontinue marketing the original product if a marketing order is issued for the new product and that the new product would replace the currently marketed original product.

STN	Projected Market Volume			
	First-Year		Fifth-Year	
	New Product (# of Cigars)	New Product as a Percent of Total Cigars Used [12]	New Product (# of Cigars)	New Product as a Percent of Total Cigars Used [13]
EX0000244	(b) (4)			

[11] The Agency used historical data regarding total use of cigars from 1997 to 2017 to mathematically estimate the total number of cigars used in the United States. Using the best-fit trend line with an R^2 value of 0.91, the forecasted number of cigars that would be used in the United States is estimated at 13.67 billion cigars in the first year and 13.66 billion cigars in the fifth year of marketing the new product.

[12] Calculated as

$$\frac{\text{Projected Market Volume of the New Product (cigar pieces)}}{\text{Projected Use of Cigars in United States (cigar pieces)}} x\ 100$$

[13] See footnote # 12.

CONFIDENTIAL APPENDIX 3

Projected Waste of Cigar Butts in the First and Fifth Years of Marketing the New Product

A : Projected waste generation of cigar butts of the new product (metric tons) B : Projected market volume of the new product (number of individual cigars) C : Weight of cigar (gm) D : Cigar butt ratio E : Mouth Piece Weight (gm) F : Mouth Piece Length (mm) G : Tobacco Rod Length (mm) H : Length of Cigar (mm) Z: $1x\ 10^{-6}$	$A = (B \times C \times D \times Z) + (B \times E \times Z)$ $D = \big((F + G) - H\big) \div H$

STN		EX0000244	
Projected Year		First-Year	Fifth-Year
Market Volume (# of cigars)	*B*	(b) (4) [redacted]	
Cigar Weight (grams)	*C*	4.127	4.127
Mouth Piece Weight (gm)	*E*	0.8	0.8
Mouth Piece Length (mm)	*F*	33.81	33.81
Tobacco Rod Length (mm)	*G*	106	106
Cigar Length (mm)	*H*	126.9	126.9
Cigar Butt Waste (tons)	*A*	(b) (4) [redacted]	

If all the projected cigar butt waste, including the plastic mouth piece, generated from use of the new product is disposed of in landfills, the projected waste of (b) (4) [redacted] metric tons in the first year and (b) (4) [redacted] metric tons in the fifth year of marketing the new product 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).