Environmental Assessment for a Marketing Order for One New Cigarette Manufactured by Philip Morris USA Inc.

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

December 3, 2018

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1. Applicant and Manufacturer Information

Applicant Name:	Altria Client Services LLC
Applicant Address:	2325 Bells Road Richmond, Virginia 23234
Manufacturer Name:	Philip Morris USA Manufacturing Center
Product Manufacturing Address:	3601 Commerce Road Richmond, VA 23234

2. Product Information

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

STN	New Product Name	Predicate Product Name
SE0014786	Marlboro 72's Gold Pack Box	Marlboro 72's Gold Pack Box

Product Identification

Product Type	Cigarettes
Product Subcategory	Combusted Filtered
Number of Products per Retail Unit	Twenty cigarettes per pack with ten packs per carton
Product Package	The cigarette pack consists of a foil inner liner, inner frame paperboard, hard pack paperboard box, polypropylene outer film, polypropylene tear tape, and paperboard carton.

3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for FDA to issue a marketing order under the provisions of sections 910 and 905(j) of the Food, Drug, and Cosmetic Act after finding the new tobacco product substantially equivalent to the predicate product. The applicant wishes to introduce the new tobacco product into interstate commerce for commercial distribution in the United States and submitted to the Agency one substantial equivalence (SE) report to obtain a marketing order. The Agency shall issue the marketing order if the new product is found substantially equivalent to the predicate product. The predicate product received a marketing order from the FDA on December 1, 2015.

The new product differs from the predicate product in the ingredients in the cigarette paper and tipping adhesive (Confidential Appendix 1).

4. Alternatives to the Proposed Action

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

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

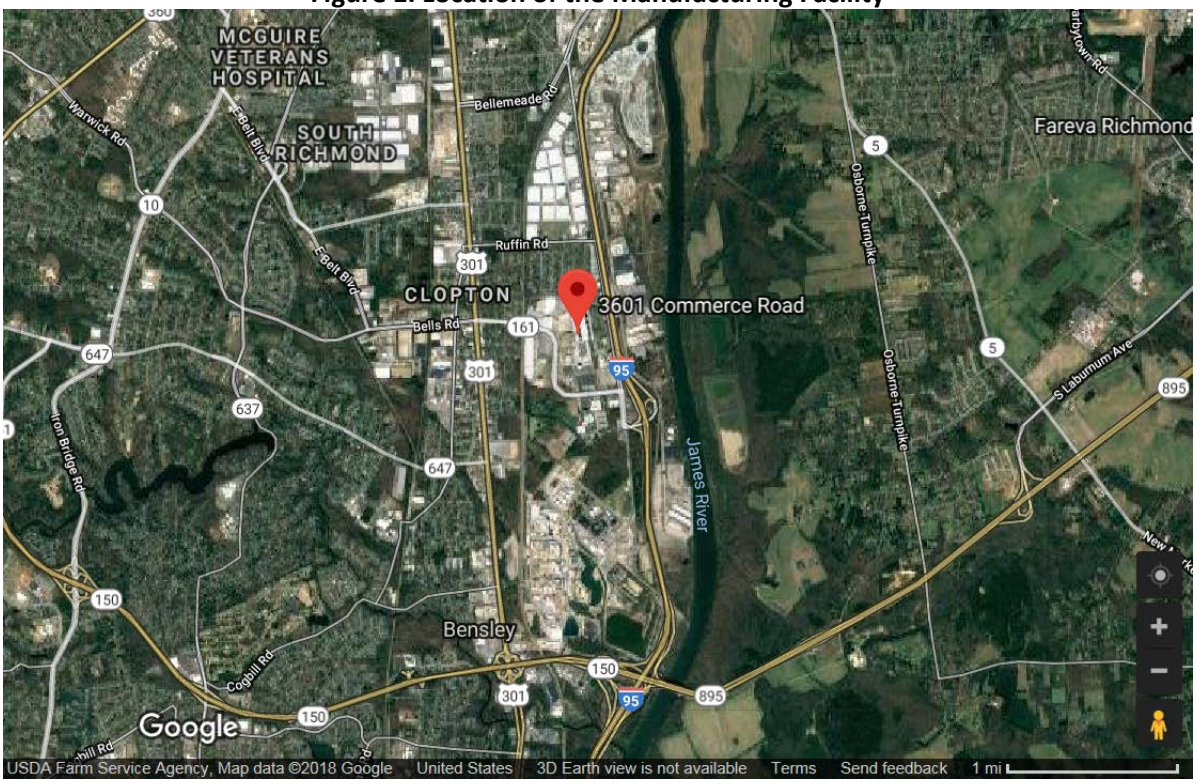
The Agency considered potential impacts that may be affected by manufacturing the new product and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- The packaging materials and ingredients in the cigarette paper and tipping adhesive in the new product are commonly used in other products currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new product.
- No increase in the facility production beyond its current permitted production capacity is expected due to manufacturing the new product.

5.1 Affected Environment

The new product is manufactured at 3601 Commerce Road, Richmond, VA (Figure 1).

Figure 1. Location of the Manufacturing Facility



The manufacturing facility is surrounded by a residential development across a road to the north; a two-lane divided road and an interstate freeway (I-95) to the east; two hotels, a fast food restaurant, and a gas station at the southeast corner; undeveloped forested land and a petroleum product pumping

station and delivery terminal to the south; and a railroad to the west with a spur into the manufacturing facility.[1]

The facility is located in the James River watershed, which occupies the central portion of Virginia and covers 24% of total land area of the state of Virginia.[2,3] Land use within the watershed is 65% forest, 19% agriculture and farming, and 12% urbanized area.[4]

5.2 Air Quality

The Agency does not anticipate that manufacturing the new product would lead to release of new chemicals into the air. The applicant stated that manufacturing the new product is not expected to result in changes in air emissions; accordingly, the applicant concluded that manufacturing the new product would not require revised or new air permits.

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 applicant stated that manufacturing the new product is not expected to result in changes in wastewater discharge and therefore, would not require revised or new wastewater discharge permits.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new product would lead to changes in soil, land use, or zoning. No facility expansion or new construction due to manufacturing the new product would be expected. Therefore, no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use would be anticipated.

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 applicant stated that there are no plans of expanding the facility production beyond its current permitted level. The applicant reviewed the U.S. Fish and Wildlife Services' (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species (two plants, and one northern long-eared bat), and one endangered

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[1] Google. 2018. Map of 3601 Commerce Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. August 16, 2018.

[2] 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 and http://www.dcr.virginia.gov/soil-and-water/document/wshedguideb2b.pdf.

[3] Virginia Department of Environmental Quality. Available at: http://deq.state.va.us/Portals/0/DEQ/Water/SWRP/App%20B%20James%20River%20Basin%20Summary.pdf. Accessed August 16, 2018

[4] Ibid.

freshwater mussel species are listed in the city of Richmond and the bordering counties (Henrico and Chesterfield Counties).[5,6] However, the applicant stated that none of these species are found near the manufacturing facility. The Agency searched the U.S. FWS maps and verified the accuracy of the listed species.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all federal, state, and local environmental regulations, including the Clean Air Act, the Clean Water Act and the Resource Conservation and Recovery Act. The manufacturing facility is registered for waste generation under EPA ID# VAD000819466. The applicant provided detailed information for the following air emission and wastewater permits:

(1) Air permits: Title V Air Permit number PRO50076 and a Stationary Source Permit, issued in accordance with applicable U.S. Environmental Protection Agency (EPA) and Virginia Department of Environmental Quality (VA DEQ) regulations.
(2) Wastewater permit: Industrial User Permit number 2149 from the local publicly owned treatment works (POTW) in the City of Richmond. The permit requires compliance with the relevant effluent limitations (40 C.F.R. §§ 400 – 699) to ensure the wastewater is of a certain quality for effective treatment at the POTW facility. The applicant stated that the facility submits regular discharge monitoring reports to VA DEQ.

The Agency's search for the manufacturing facility in EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations.[7]

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

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 products manufactured at the facility.

No changes in impacts on environmental justice are anticipated. The applicant stated that the future year projections of cigarette production at the facility, including the new product, are within the existing permitted manufacturing capacity and would not require facility expansion. Also, as discussed, the emissions and discharges from the facility are not expected to change because of manufacturing the new product. Thus, though 2010 U.S. Census and American Community Survey data show that 80% of the population within a three-mile radius of the manufacturing facility is minority,[8] no disproportionate

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[5] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/endangered/. Accessed August 16, 2018.

[6] Critical habitat maps available at: https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449.

[7] EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed September 27, 2018.

[8] EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed September 27, 2018.

impacts to environmental justice populations would occur as a result of manufacturing the new product. In addition, the facility is not located within an Indian reservation.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new product would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered cigarettes. The waste generated due to manufacturing the new product would be handled in the same manner as any other waste generated from any other products manufactured in the same facility or from any other combusted, filtered cigarettes manufactured in the United States.

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 to incrementally increase or change the chemicals released to the air from the facility due to the tobacco manufacturing. A search in EPA's Toxic Release Inventory (TRI) database showed that in 2017, Philip Morris USA's manufacturing facility in Richmond, Virginia released 18,713 pounds of ammonia and 10,683 pounds of nicotine and nicotine salts to air, (a total of 29,396 pounds), but released no other hazardous air pollutants at reportable levels (Table 1).[9] Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts, have known adverse developmental effects.[10] The applicant stated that the facility does not anticipate any future increased production beyond its current permitted capacity and therefore, a revised or new air permit would not be required. The TRI database search did not show that the Philip Morris USA manufacturing facility disposed of, treated, or released into the environment any other 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.

[9] 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 August 14, 2018.

[10] 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 August 14, 2018.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Philip Morris USA Facility in 2017

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			126,020
Energy Recovery			0
Treated			104,427
Subtotal Waste Managed			*230,447*
On-site Release	Air	Ammonia	18,713
		Nicotine and Nicotine Salts	10,683
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-site Release			60,822
Subtotal Waste Released			*90,218*
Total Production-Related Waste			**320,665**

The applicant does not anticipate manufacturing the new product would require a revised or new waste water permit.

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 in the United States.

6. Potential Environmental Impacts of the Proposed Action and Alternatives – Use of the New Product

The Agency evaluated potential impacts to resources in the environment that may 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 marketing orders would allow for the new tobacco product to be sold to consumers nationwide.

6.2 Air Quality

The Agency does not anticipate new chemicals would be released into the environment as a result of use of the new product, relative to chemicals released into the environment due to use of other cigarettes already on the market, because: (1) the combustion products from the new product would be released in the same manner as the combustion products of other marketed cigarettes; (2) the new

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

6.3 Environmental Justice

No new emissions are expected due to use of the new product. Therefore, there would be no 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).

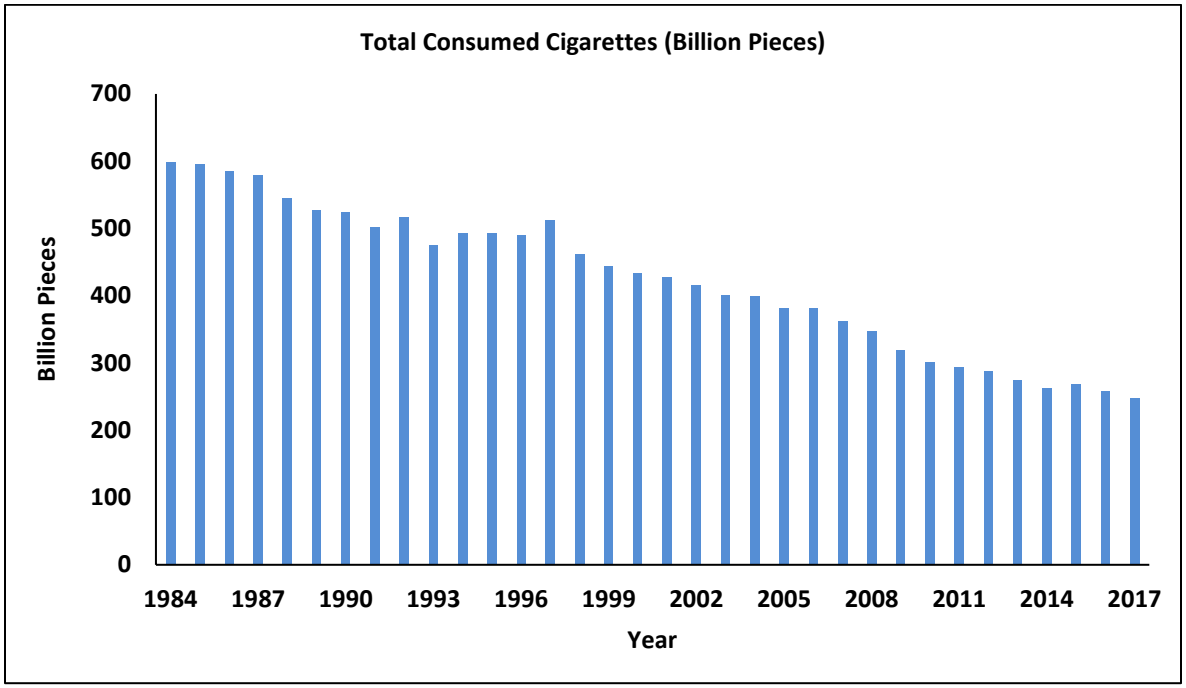
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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. Such exposure 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, use of cigarettes in the United States is declining according to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).[11] This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS exposure in children and nonsmokers living in homes of smokers (Homa et al., 2015; Yao et al., 2016; other studies). 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. Exposure to SHS 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).

[11] 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. Use of Cigarettes in the United States, 1984 – 2017



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

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 Product

The Agency evaluated potential impacts to resources in the environment that may be affected by disposal of the new product. 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 product.

7.1 Affected Environment

The affected environment includes human and natural environments in the United States; the marketing order would allow for the new tobacco product to be sold to consumers nationwide.

7.2 Air Quality

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

No changes in air quality are anticipated from disposal of the cigarette butts of the new product. The chemicals in the cigarette butts are commonly used in other currently marketed cigarettes. Because the new product is anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new product would replace the same type of waste (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 cigarettes disposed of in the United States.

No changes in air quality from disposal of the packaging materials in the new product would be expected because; (1) the paper components of the packages are more likely to be recycled or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the packaging is a minuscule portion of the municipal solid waste per FDA's experience in evaluating the packaging waste generated from cigarettes.

7.3 Water Resources

No changes in impacts on water resources are expected due to disposal of the cigarette butts from the new product because the chemicals in the new product are the same or similar to chemicals in the currently marketed cigarettes. The new product would replace similar products currently on the market.

7.4 Biological Resources

The proposed action is not expected to change the continued existence of any endangered species, or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. Although disposal of smoldering cigarettes has been implicated in many fire incidents,[12, 13] the disposal of the new product is not expected to change the fire frequency because (1) the disposal of the new product is similar to 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 product is anticipated to replace similar 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 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 other cigarettes 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.

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[12] National Fire Protection Association. The smoking-material fire problem. Available at: https://www.nfpa.org/News-and-Research/Fire-statistics-and-reports/Fire-statistics/Fire-causes/Smoking-Materials. Accessed August 16, 2018.

[13] UC Davis Health News. Available at: https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763. Accessed August 16, 2018.

7.6 Cumulative Impacts

A major existing environmental consequence of the use of the new product as well as other conventional cigarettes is littering of discarded cigarette filters or butts, which can persist in the environment for more than 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 influenced by several factors, such as the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco fillers, number of puffs, and the mass transfer behavior of combustion products along the cigarette.[14]

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

7.7 No Action Alternative

The environmental impact 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 in the United States.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this environmental assessment (EA):

Preparer:

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

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

[14] NIST Technical Report 8147 available at: http://dx.doi.org/10.6028/NIST.IR.8147. Accessed August 16, 2018.

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

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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

Comparison of the New Product to the Predicate Product

STN	Component	Change
SE0014786	Cigarette paper	Change from (b) (4) to (b) (4), removal of (b) (4), decrease in amount of (b) (4), increases in amounts of (b) (4), (b) (4), and (b) (4) in new product, added (b) (4) and (b) (4) to bands, and increase in weight in new product
	Tipping adhesive	Addition of (b) (4) in new product

CONFIDENTIAL APPENDIX 2

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

First- and fifth-year market volume projections for the new product were compared to the total forecasted use of cigarettes in the United States.[15] The projected use of the new product accounts for (b) (4) of the forecasted cigarette use in the United States. In addition, the applicant stated that the new product would compete with similar tobacco products currently on the market.

STN	Projected Market Volume			
	First-Year		Fifth-Year	
	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[16]
SE0014786	(b) (4)	(b) (4)	(b) (4)	(b) (4)

[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 R^2 value of 0.9786, the forecasted number of cigarettes that would be used in the United States is estimated at 236.258 billion cigarettes in the first year and 210.922 billion cigarettes in the fifth year of marketing the new product.

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

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

CONFIDENTIAL APPENDIX 3

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

$\sum_{i=1}^{1} A_i = \sum_{i=1}^{1} (B_i \times C_i \times D_i \, X \, G)$ $D_i = \frac{E}{F_i}$	A_i: Projected waste generation of cigarette butts of the new product (metric tons) B_i: Projected market volume of the new product (number of individual cigarettes C_i: Weight of cigarette (gram) D_i: Cigarette butt ratio E: Cigarette butt length[17] F_i: Length of cigarette (millimeter) G: 1.0 x 10^{-6} metric tons/gram

Projected Year	STN	*Market Volume (# of cigarettes)* B_i	*Cigarette Weight (grams)* C_i	*Cigarette Length (mm)* F_i	*Cigarette Butt Waste (tons)* A_i
First-Year	SE0014786	(b) (4)	0.8283	72	(b) (4)
Fifth-Year	SE0014786	(b) (4)	0.8283	72	(b) (4)

If all the projected cigarette butt waste generated from use of the new product is disposed of in landfills, the projected waste of (b) (4) metric tons and (b) (4) metric tons in the first and fifth year of marketing the new product, respectively, would be negligible fractions of the 238.05 million metric tons of total waste reported in the United States in 2015 (EPA, 2018).

[17] 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.