

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

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

February 1, 2019

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1. Applicant and Manufacturer Information

Applicant Name:	Philip Morris USA Inc.
Applicant Address:	2325 Bells Road Richmond, VA 23234
Manufacturer Name:	Philip Morris USA Inc.
Product Manufacturing Address:	3601 Commerce Road Richmond, VA 23234

2. Product Information

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

STN	New Product Name	Predicate Product Name
SE0014795	Marlboro Midnight Menthol Box	Marlboro Menthol Box

Product Identification

Product Category	Cigarette
Product Subcategory	Combusted filtered
Number of Products per Retail Unit	Twenty cigarettes per pack with ten packs per paperboard carton.
Product Package	The pack consists of a foil inner liner, inner frame paper, paperboard box, polypropylene outer film, and polypropylene tear tape.

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 Federal 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 a substantial equivalence (SE) report to the agency 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 is a grandfathered product commercially marketed in the United States as of February 15, 2007.

The new product differs from the predicate product in the cigarette length, and in ingredients and chemical constituents (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

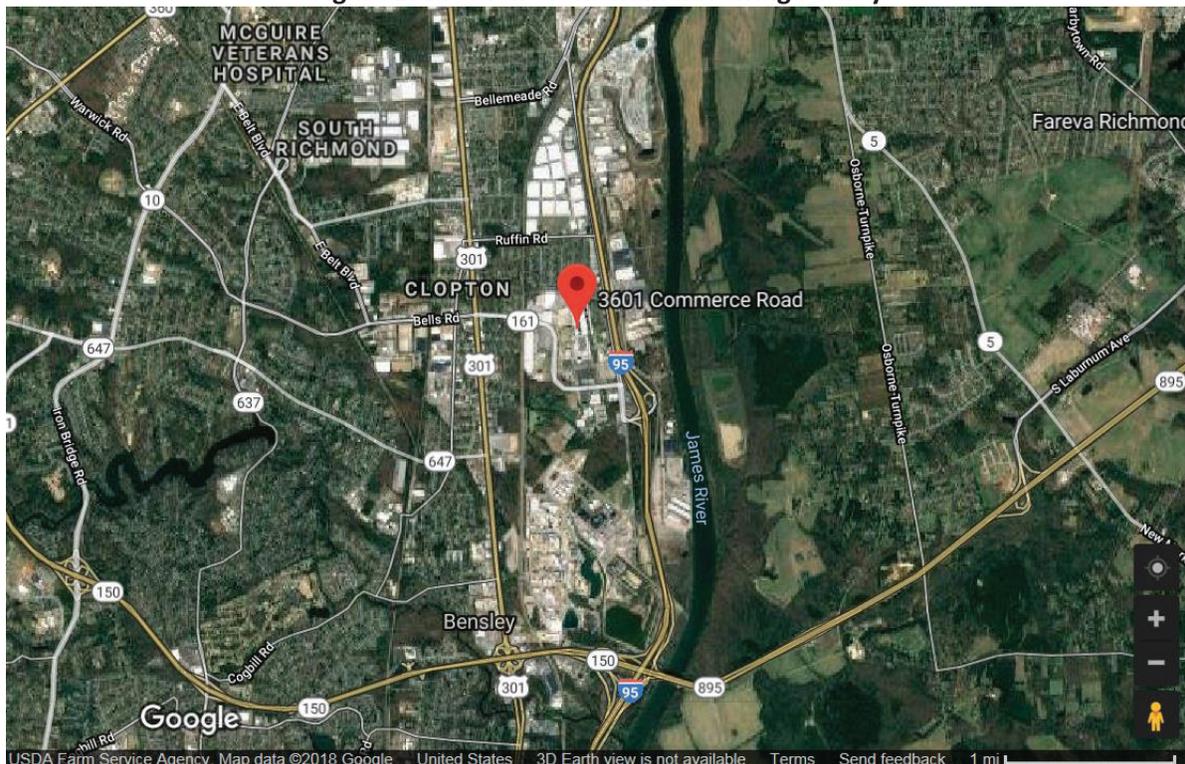
The Agency considered potential environmental impacts that may be affected by manufacturing the new product and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- The packaging materials and ingredients in the new product are commonly used in other products currently manufactured at the facility.
- 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.
- 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 new product is intended to replace similar tobacco products currently manufactured at the facility. 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 is 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

¹ Google. 2018. Map of 3601 Commerce Road, Richmond, VA 23234. Retrieved from Google Maps: www.google.com/maps. December 3, 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 December 3, 2018

⁴ See footnote #3

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 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 the 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 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 tobacco products currently 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

⁵ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/endangered/>. Accessed December 3, 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 December 3, 2018, 2018.

the population within a three-mile radius of the manufacturing facility is minority,⁸ no disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new product.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee 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 .

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 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 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.

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 December 3, 2018.

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 December 3, 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. <https://myrtk.epa.gov/info/report.jsp?IDT=TRI&ID=23234PHLLP3601C> Accessed December 3, 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	
<i>Subtotal Waste Managed</i>		<i>230,447</i>	
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	
<i>Subtotal Waste Released</i>		<i>90,218</i>	
Total Production-Related Waste		320,665	

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

5.11 Impacts of the No-Action Alternative

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

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 because the marketing order would allow for the new tobacco product to be sold to consumers nationwide.

6.2 Air Quality

The Agency does not anticipate the release of new chemicals 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 is 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).

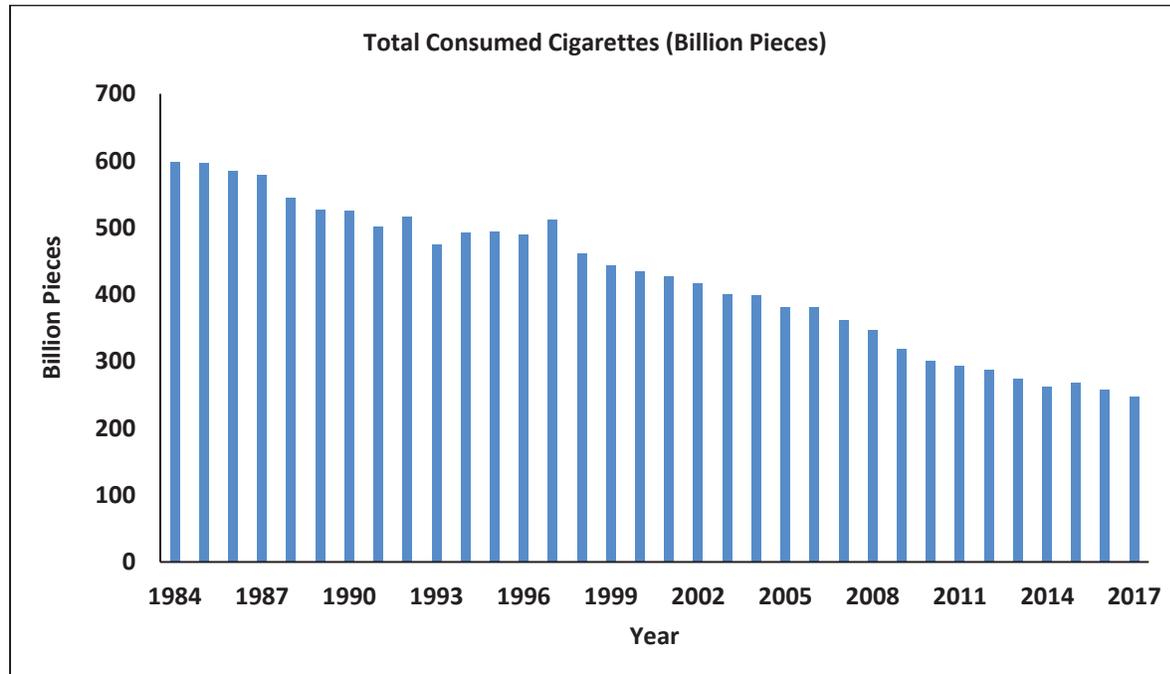
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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 Impacts of the No-Action Alternative

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

7. Potential Environmental Impacts of the Proposed Action 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 because 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 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. 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 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 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 Solid Waste

The Agency does not foresee the introduction of the new product would notably affect the current cigarette butt waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new product would be in the same manner as any other waste generated from any other combusted, filtered cigarettes manufactured in the United States. The number of cigarette butts

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.

generated is equivalent to the market projections (Confidential Appendix 2) and a portion of those are 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 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.

7.7 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 are declining because the use of cigarettes in the United States is declining.

7.8 Impacts of the No-Action Alternative

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

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

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: Sixteen years in various scientific activities

Expertise: NEPA analysis, environmental impact analysis and risk assessment, applied ecology, geo-statistics

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: M.S. in Environmental Science and Ph.D. in Biochemistry

Experience: Ten years in NEPA practice

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

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CONFIDENTIAL APPENDIX 1

Comparison of the New Product to the Predicate Product

STN	Component	Change from Predicate Product
SE0014795	Cigarette	Decrease in weight due to removal of ingredients and other changes in ingredient amounts. Decrease in total length of cigarette
	Tobacco filler	Decrease in the (b) (4) [redacted] and (b) (4) [redacted] tobacco Increase in (b) (4) [redacted], and (b) (4) [redacted] (b) (4) [redacted]
	Design characteristics	Decrease in puff count, band width, filter length, and filter ventilation Increase in base paper porosity and total denier
	Chemical constituents	Increase in (b) (4) [redacted] levels Increase in ammonia levels in the mainstream smoke

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 replace 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 ¹⁷
SE0014795	(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 a linear 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 236.579 billion cigarettes in the first year and 209.827 billion cigarettes in the fifth year of marketing the new product.

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

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

¹⁷ Ibid.