

**Programmatic Environmental Assessment for Marketing
Orders for Sixteen New Cigarettes Manufactured by Philip
Morris USA, Inc.**

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

June 6, 2018

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1. Applicant and Manufacturer Information

Applicant Name: Philip Morris USA, Inc.
Applicant Address: 2325 Bells Road
 Richmond, Virginia 23234
Manufacturer Name: Philip Morris USA, Inc.
Address Where the Product is Manufactured: 3601 Commerce Road
 Richmond, Virginia 23234

2. Product Information

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

New Product Name	STN	Predicate Product Name
Marlboro 25's Box	SE0004287	Marlboro Box 25's
Marlboro Blend No. 27 Box	SE0004290	Marlboro Blend No. 27 Box
Marlboro Blend No. 27 Soft Pack	SE0004291	Marlboro Blend No. 27 Box
Marlboro Box	SE0004292	Marlboro Box
Marlboro Gold Pack Box	SE0004295	Marlboro Lights Box
Marlboro Gold Pack Soft Pack	SE0004296	Marlboro Lights Box
Marlboro Menthol Box	SE0004297	Marlboro Menthol Box
Marlboro Menthol Soft Pack	SE0004298	Marlboro Menthol Box
Marlboro Menthol Gold Pack Box	SE0004299	Marlboro Lights Menthol Box
Marlboro Menthol Gold Pack Soft Pack	SE0004300	Marlboro Lights Menthol Box
Marlboro Red Label Box	SE0004303	Marlboro Medium Box
Marlboro Red Label Soft Pack	SE0004304	Marlboro Medium Box
Marlboro Soft Pack	SE0004305	Marlboro Soft Pack
Marlboro Eighty-Threes Box	SE0004306	Marlboro Soft Pack
Marlboro Special Blend (Red Pack) Box	SE0004309	Marlboro Medium 100's Box
Parliament (White Pack) Box	SE0004310	Parliament Lights Box

Product Identification

Product Type	Cigarette
Product Subtype	Combusted, filtered
Product Package	Twenty cigarettes per pack with ten packs per paperboard carton The soft packs consist of a foil inner liner, paper label, paper closure, polypropylene outer wrap, and polypropylene tear tape. The hard packs consist of a foil inner liner, paperboard inner frame, paperboard hard pack blank, polypropylene outer wrap, and polypropylene tear tape.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for FDA to issue marketing orders finding the new tobacco products substantially equivalent to the corresponding predicate products under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States.

The Agency shall issue a marketing order if, after considering the substantial equivalence (SE) reports submitted by the applicant, the new products are found substantially equivalent to the corresponding predicate products. The predicate products were on the market as of February 15, 2007.

The new products' modifications compared to the corresponding predicate products are changes in the packaging design from a box to a soft pack for five new products (SE0004291, SE0004296, SE0004298, SE0004300, SE0004302, and SE0004304) and from a soft pack to a box for one new product (SE0004306). In addition, there are ingredient and tobacco blend changes for all the new tobacco products (Confidential Appendix 1).

4. Alternative to the Proposed Actions

The no-action alternative is FDA does not issue the marketing orders for the new tobacco products.

5. Potential Environmental Impacts of the Proposed Actions and Alternative –Manufacturing the New Products

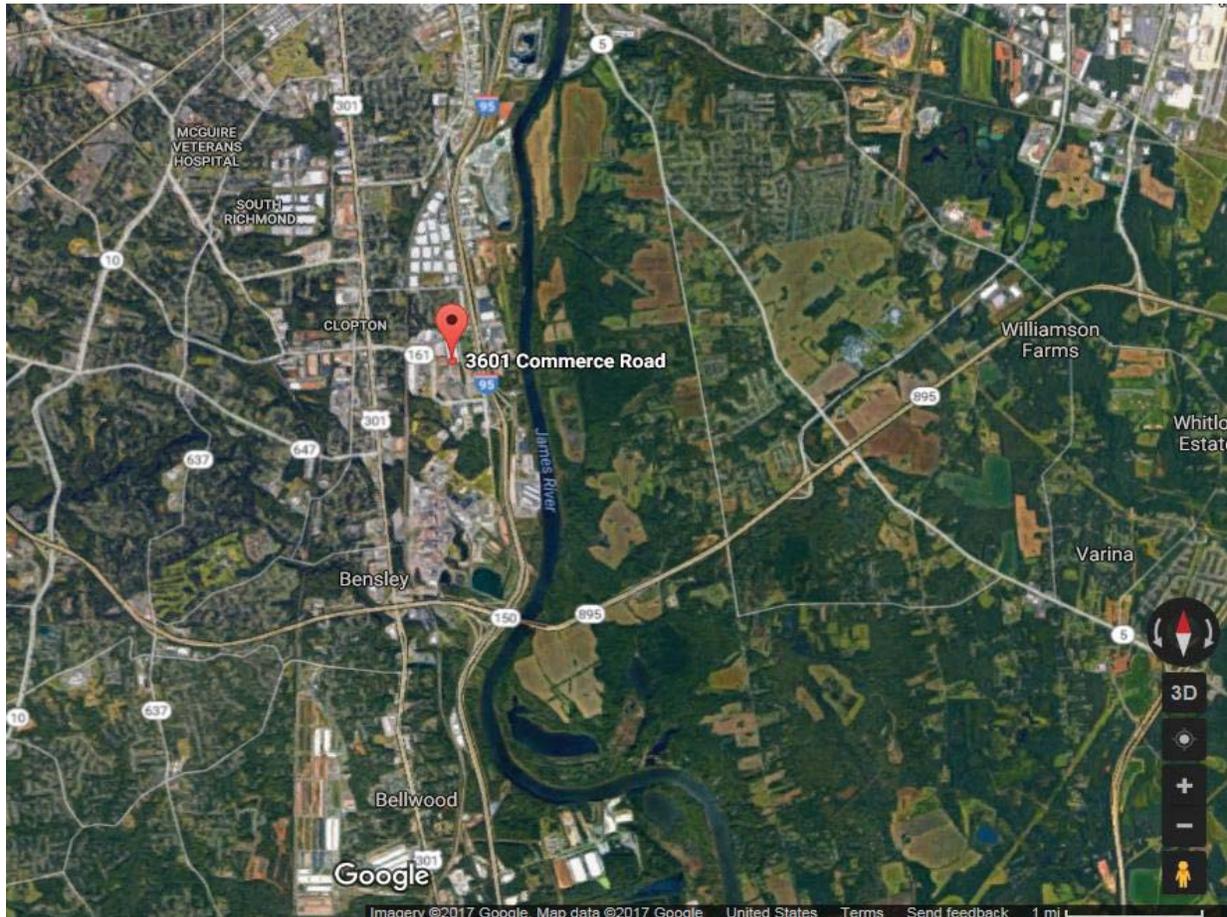
The Agency considered potential environmental impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on Agency-gathered information and the following information submitted by the applicant:

- The packaging materials, ingredients, and tobacco blend of the new products are similar to other cigarettes currently manufactured at the facility.
- The new products are intended to replace other tobacco products currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products
- No expected increase in the facility's production due to manufacturing the new products beyond its current permitted production capacity.

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 facility is located in the James River watershed, which occupies the central portion of Virginia and covers approximately 10,265 square miles (24% of total land area of the state of Virginia).^{1 2} Land use within the watershed is predominantly forest (65%), with agriculture and farming accounting for approximately 19% and urbanized area of 12%.³

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

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> and

² 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 April 17, 2018

³ See Virginia Department of Conservation and Recreation at: <http://www.dcr.virginia.gov/soil-and-water/wsheds>. Accessed April 17, 2018.

5.2 Air Quality

The Agency does not anticipate any new substances or new type of emissions to be released into the environment because of manufacturing the new products. 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 revised or new air permits.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause any new chemicals to be discharged into the water. The new products are intended to replace other tobacco products currently manufactured at the facility.

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 expected 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 to jeopardize the continued existence of any listed species, nor 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 future plans of expanding the facility's production beyond its current permitted level. The applicant consulted 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 freshwater mussel species are listed in the city of Richmond and the bordering counties (Henrico and Chesterfield Counties).^{4,5} 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 applicant provided detailed information for the following air emission and wastewater permits:

⁴ U.S. Fish and Wildlife Services (U.S. FWS), available at: <https://www.fws.gov/endangered/>.

⁵ Critical habitat map available at: <https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449>

- (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 of the U.S. EPA Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations.⁶

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 products. The Agency does not anticipate any impacts on employment, revenue, or taxes.

No changes in impacts on environmental justice are anticipated. The applicant stated that the manufacturing facility is operating at 75% of its permitted capacity and the future year projections of cigarette production at the facility, including the new products, are within the existing capacity and would not require expansion. Also, as discussed, the emissions and discharges from the facility are not expected to change because of manufacturing the new products. 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,⁷ no disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new products. In addition, the facility is not located within 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's production of all combusted, filtered cigarettes. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment, transferred to a 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 cigarettes manufactured in the United States.

⁶ U.S. EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed April 18, 2018.

⁷ U.S. EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed April 18, 2018.

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 on 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 air from the facility's tobacco manufacturing. A search in the U.S. EPA Toxic Release Inventory (TRI) database showed that in 2016, Philip Morris USA manufacturing facility in Richmond, Virginia released 20,347 pounds of ammonia and 11,671 pounds of nicotine and nicotine salts to air, (a total of 32,018 pounds), but no other hazardous air pollutants at reportable levels (Table 1).⁸ Ammonia's health effects are ocular and respiratory; nicotine and its salt, has known developmental effects.⁹ 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, the U.S. EPA's ECHO database did not show that the facility released the following reportable criteria pollutants: ozone, lead, particulate matter, or sulfur dioxide, at or above the reportable threshold levels to air.

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

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			113,477
Energy Recovery			0
Treated			114,203
<i>Subtotal Waste Managed</i>			<i>227,680</i>
On-site Release	Air	Ammonia	20,347
		Nicotine and Salts	11,671
	Water	Ammonia	0
		Nicotine and Salts	0
	Land	Ammonia	0
		Nicotine and Salts	0
Off-site Release			85,415
<i>Subtotal Waste Released</i>			<i>117,433</i>
Total Production-Related Waste			345,113

⁸ 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 March 7, 2018.

⁹ 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 May 24, 2018.

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

5.11 No Action Alternative

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

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

The Agency considered potential environmental impacts to resources in the environment that may be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered was 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. The applicant intends to distribute and sell the new tobacco products to consumers in the United States.

6.2. Air Quality

The Agency does not anticipate new substances would be released into the environment as a result of use of the new products, relative to 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 of the predicate products and 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.

Although there are small percentage changes in tobacco blend in the new products compared to the corresponding predicate products (Confidential Appendix 1), which could affect air quality, these changes fall within industry standards.

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

When burned, cigarettes produce environmental tobacco smoke or secondhand smoke (SHS). 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. The mixture of these pollutants, called thirdhand smoke (THS), coexists in the environment alongside SHS (Burton, 2011; Matt et al., 2011).

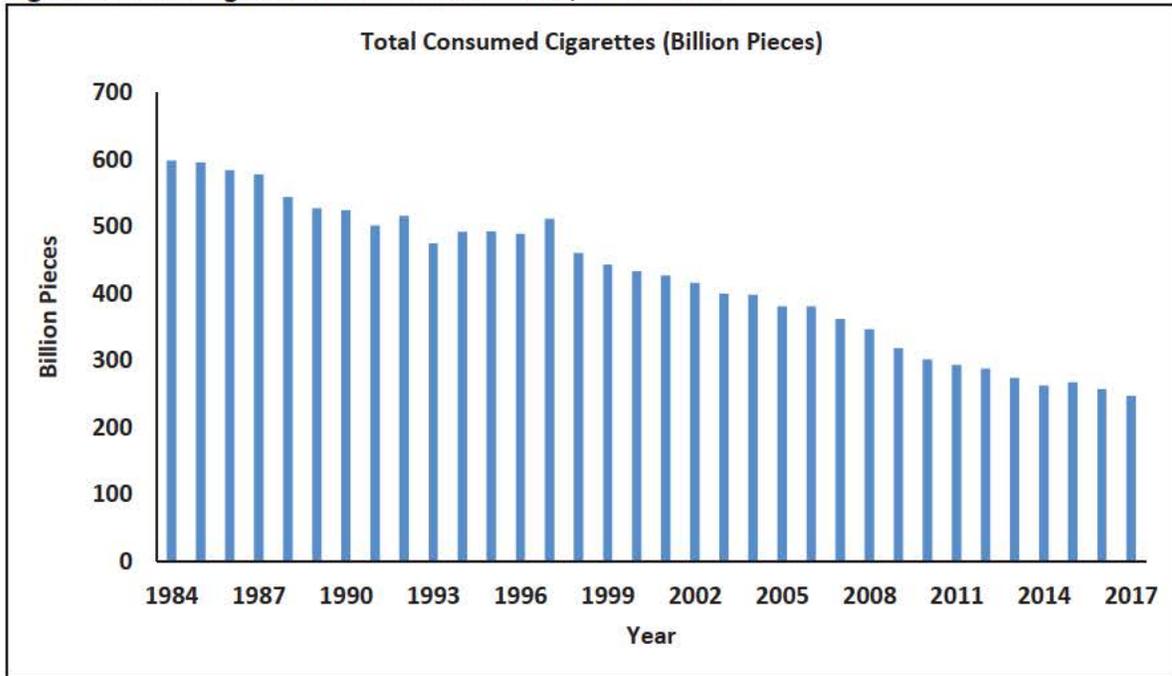
The impacts from use of cigarette products include exposure to SHS and THS. There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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, and 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, 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 at 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. The 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).

¹⁰ 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, 27 states including the District of Columbia have implemented comprehensive smoke-free laws (Tynan, Holmes, Promoff, Hallett, Hopkins, & Frick, 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 impact 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 Alternative – Disposal of the New Products

The Agency considered potential environmental 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 in use of cigarettes in the United States, and the applicant's submitted information, including the projected market volumes for the new products, 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 distribute and sell the new tobacco products to consumers in the United States.

7.2. Air Quality

The Agency does not anticipate disposal of the products 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 cigarettes 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 replace other currently marketed cigarettes, the butt waste generated from the new products would replace 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 in the United States.

No changes in air quality from disposal of the packaging materials of the new products 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 is a minuscule portion of the municipal solid waste based on 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, nor 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 disposal of the new products is not expected to change the fire frequency as it is similar to the disposal of cigarettes that are currently marketed in the United States.

7.4. Water Resources

No changes in 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 would replace the currently marketed products.

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. 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.

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: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed May 22, 2018.

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 some of the most common forms of litter found on beaches (Claereboudt, 2004; Smith, Livingston and Doolittle, 1997), near streams, night clubs (Becherucci and Pon, 2014), bus stops (Wilson, Oliver, and Thomson, 2014), roads, and streets (Healton, Cummings, O'Connor and Novotny, 2011; Patel, Thomson and Wilson, 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 butt which are 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 butts, and the mass transfer behavior of combustion products along the cigarette.¹³

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

7.8 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.

8. List of Preparers

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

Preparers:

Ronald L. Edwards Jr., M.S., Center for Tobacco Products

Education: M.S. in Biology

Experience: 23 years in environmental regulation and laboratory toxicology

Expertise: Heavy metal analysis, water quality, environmental remediation, FDA, EPA, and USDA investigator

Rudaina Alrefai-Kirkpatrick, Ph.D., Center for Tobacco Products

Education: Ph.D. in Plant Molecular Biology and Virology

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

Experience: 25 years in various scientific activities including 7 years in NEPA practice
Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

Reviewer:

Hoshing W. Chang, Ph.D., Center for Tobacco Products
Education: M.S. in Environmental Science and Ph.D. in Biochemistry
Experience: 10 years in NEPA practice
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

Burton, B. (2011). Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspectives*, 119(2), A70-A74. DOI [10.1289/ehp.119-a70](https://doi.org/10.1289/ehp.119-a70)

Becherucci, M. E., and J. P. S., Pon. (2014). What is left behind when the lights go off? Comparing the abundance and composition of litter in urban areas with different intensity of nightlife use in mar del plata, argentina. *Waste Management*, 34(8): 1351-1355.

Claereboudt, M. R. (2004). Shore litter along sandy beaches of the gulf of oman. *Marine Pollution Bulletin*, 49(9-10): 770-777.

Healton, C. G., K. M., Cummings, R. J., O'Connor, and T. E., Novotny. (2011). Butt really? The environmental impact of cigarettes. *Tobacco Control*. 20: 11-11.

Homa, D.M., Neff, L.J., King, B.A., Caraballo, R.S., Bunnell, R.E., Babb, S.D., Garrett, B.E. . . & Wang, L. (2015). Vital signs: disparities in nonsmokers' exposure to secondhand smoke —United States, 1999–2012. *MMWR Morbidity Mortality Weekly Report*, 64(4), 103-108. Available from <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6404a7.htm>. Accessed November 5, 2017.

Kadir, A. A., and N. A., Sarani. (2015). Cigarette butts pollution and environmental impact - a review. *Applied Mechanics and Materials*, 773-774: 1106-1110.

Matt, G.E., Quintana, P.J.E., Destailats, H., Gundel, L.A., Sleiman, M., Singer, B.C., Jacob, B. . . & Hovell, M.E. (2011). Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*, 119(9), 1218-1226. <http://dx.doi.org/10.1289/ehp.1103500>.

Novotny, T. E., and F., Zhao. (1999). Consumption and production waste: Another externality of tobacco use. *Tobacco Control*. 8(1): 75-80.

Patel, V., G. W., Thomson, and N., Wilson. (2013). Cigarette butt littering in city streets: A new methodology for studying and results. *Tobacco Control*. 22(1): 59-62.

Seco Pon, J. P., and M. E., Becherucci. (2012). Spatial and temporal variations of urban litter in mar del plata, the major coastal city of argentina. *Waste Management*. 32(2): 343-348.

Smith, C. J., S. D., Livingston, and D. J., Doolittle. (1997). An international literature survey of "IARC group I carcinogens" reported in mainstream cigarette smoke. *Food and Chemical Toxicology*. 35(10-11): 1107-1130.

Tynan, M.A., Holmes, C.B., Promoff, G., Hallett, C., Hopkins, M., & Frick, B. (2016). State and Local comprehensive smoke-free laws for worksites, restaurants, and bars—United States, 2015. *MMWR Morbidity Mortality Weekly Report*, 65(24), 623-626. Available from <https://www.cdc.gov/mmwr/volumes/65/wr/mm6524a4.htm>. Accessed April 26, 2018.

U.S. Department of Health and Human Services. 2014. The Health Consequences of Smoking—50 Years of Progress. A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006a. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General—Secondhand Smoke: What It Means to You (Consumer Booklet). Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Coordinating Center for Health Promotion, Office on Smoking and Health. Atlanta, GA.

U.S. Environmental Protection Agency. (2016). Advancing Sustainable Material Management: Facts and Figures. Retrieved from https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf. Accessed March 7, 2018.

Wilson, N., J., Oliver, and G., Thomson. (2014). Smoking close to others and butt littering at stops: Pilot observational study. *PeerJ* 2.

Yao, T., Sun, H.Y., Wang, Y., Lightwood, J., & Max, W. (2016). Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*, 131, 357-366. DOI [10.1177/003335491613100220](https://doi.org/10.1177/003335491613100220).

Confidential Appendix 1:

Modifications in the New Products as Compared with the Corresponding Predicate Products

STN	Component	Modification
SE0004287, SE0004290 – SE0004292, SE0004297 – SE0004300	Cigarette paper (CP)	Added alternate banded (b) (4)
SE0004295 – SE0004296, SE0004303 – SE0004304, SE0004309 – SE0004310	Cigarette paper	Added alternate banded (b) (4)
SE0004297 – SE0004298	Tipping paper	Decreased ventilation
SE0004303 – SE0004304, SE0004309	Tipping paper	Increased ventilation
SE0004291, SE0004296, SE0004298, SE0004300, SE0004302, SE0004304	Package design	Change from box to soft pack
SE0004306	Package design	Change from soft pack to box
SE0004297 through SE0004300	Ingredients	Increase in (b) (4)
SE0004299 and SE0004300	Ingredients	Decreased (b) (4) composition in (b) (4)
SE0004310	Tobacco filler	(b) (4) was substituted for (b) (4)
SE0004287, SE0004292, SE0004295, SE0004296, SE0004303, SE0004304, SE0004309, SE0004297, SE0004298, SE0004299, SE0004300, SE0004305, SE0004306, and SE0004310	Tobacco Blend	Tobacco blend changes in tobacco leaf - (b) (4)

14 (b) (4)
15
16

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.¹⁷ Although the projected use of the new products would account for (b)(4) of the forecasted cigarette use in the United States, the applicant stated that the new products would replace the predicate products that are currently on the market.

STN	Market Volume			
	First-Year		Fifth-Year	
	New Products (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁸	New Products (# of Cigarettes)	New Product as a Percent of Total Cigarette Used ¹⁹
SE0004287	(b) (4)			
SE0004290				
SE0004291				
SE0004292				
SE0004295				
SE0004296				
SE0004297				
SE0004298				
SE0004299				
SE0004300				
SE0004303				
SE0004304				
SE0004305				
SE0004306				
SE0004309				
SE0004310				
Total				

¹⁷ The Agency used historical data regarding total use of cigarettes from 2002 to 2017 to mathematically estimate the total amount 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 will 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.

¹⁸ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Products (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

¹⁹ See footnote # 19

CONFIDENTIAL APPENDIX 3

Projected Calculated Waste of Cigarette Butts in the First and Fifth-Year Marketing the New Products

$\sum_{i=1}^3 A_i = \sum_{i=1}^3 (B_i * C_i) D_i$	<i>A_i</i> : Projected total waste generation of the product (metric tons) <i>B_i</i> : Market Volume (Pieces) <i>C_i</i> : Cigarette Butt Weight (grams) <i>D_i</i> : 1.0 x 10 ⁻⁶ metric tons/gram
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Projected Year	STN	Market Volume (Pieces) <i>B_i</i>	Cigarette Butt Weight (Grams) <i>C_i</i>	Cigarette Butt Waste (Tons) <i>A_i</i>
First-Year	SE0004287	(b) (4)		
	SE0004290			
	SE0004291			
	SE0004292			
	SE0004295			
	SE0004296			
	SE0004297			
	SE0004298			
	SE0004299			
	SE0004300			
	SE0004303			
	SE0004304			
	SE0004305			
	SE0004306			
	SE0004309			
	SE0004310			
	Total			
Fifth-Year	SE0004287	(b) (4)		
	SE0004290			
	SE0004291			
	SE0004292			
	SE0004295			
	SE0004296			
	SE0004297			
	SE0004298			
	SE0004299			
	SE0004300			
	SE0004303			
	SE0004304			
	SE0004305			
	SE0004306			
	SE0004309			
	SE0004310			
	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 and (b) (4) metric tons in the first and fifth year of marketing the new products would be a negligible fraction of the 234.47 million metric tons of total waste reported in the United States in 2014 (U.S. EPA, 2016).