

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

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

August 9, 2018

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### 1. Applicant and Manufacturer Information

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

### 2. Product Information

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

<b>New Product Name</b>	<b>STN</b>	<b>Predicate Product Name</b>
Marlboro Box	SE0013711	Marlboro Box

#### Product Identification

<b>Product Type</b>	Cigarette
<b>Product Subtype</b>	Combusted, filtered
<b>Product Package</b>	Twenty cigarettes per pack with ten packs per paperboard carton. The hard pack consists of an outer board blank, foil inner liner, pack inner frame, polypropylene outer film, and tear tape.

### 3. The Need for the Proposed Action

The proposed action, requested by the applicant, is for the Food and Drug Administration (FDA) to issue a marketing order finding the new tobacco product substantially equivalent to the predicate product 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 product into interstate commerce for commercial distribution in the United States. The Agency shall issue a marketing order if, after considering the substantial equivalence (SE) report submitted by the applicant, the new product is found substantially equivalent to the predicate product. The predicate product was on the market as of February 15, 2007.

The new product differs from the predicate product in tobacco weight, tobacco blend, cigarette paper ingredients and weight, tipping paper ingredients, and filter plug wrap ingredient weights. (Confidential Appendix 1).

### 4. Alternative to the Proposed Action

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

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

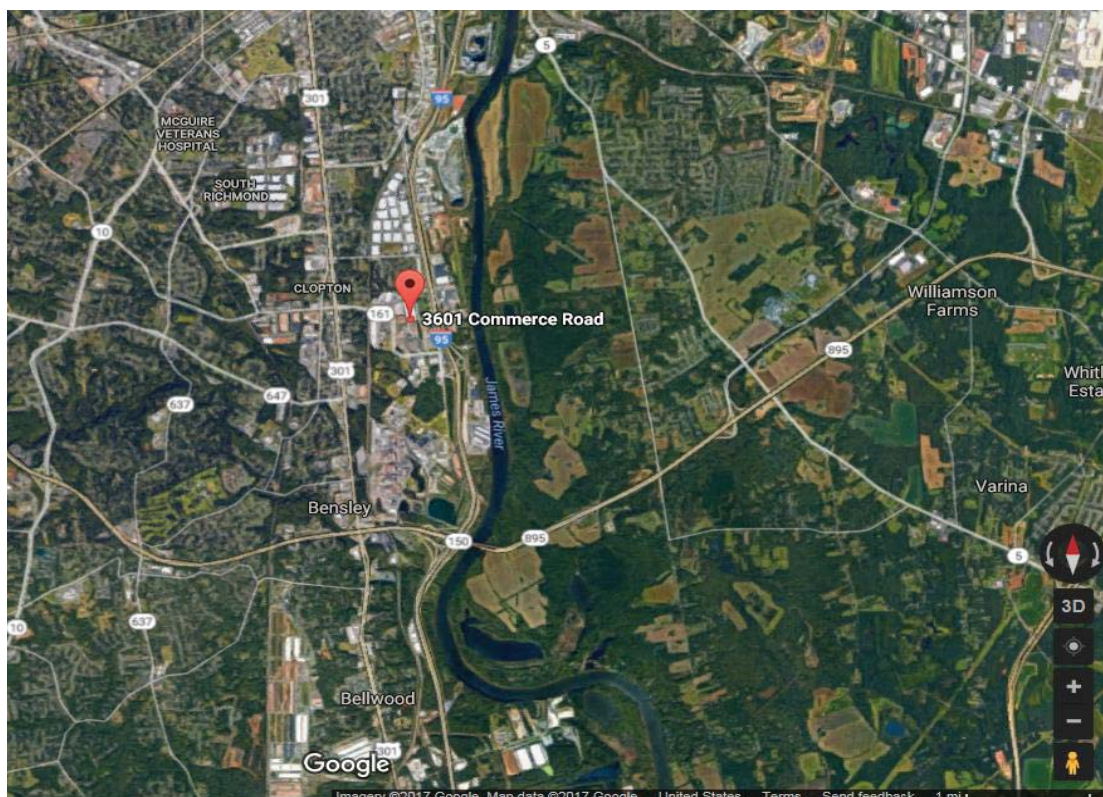
The Agency evaluates potential environmental impacts that may be caused by manufacturing the new product and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- The packaging materials, ingredients, and tobacco blend of the new product are commonly used in other cigarettes currently manufactured at the facility.
- The new product is intended to compete with or replace other tobacco products currently manufactured at the facility and in the United States.
- No facility expansion or new construction is expected due to manufacturing the new product.
- No increase in the facility production beyond current permitted production capacity is expected due to manufacturing the new product.

### 5.1 Affected Environment

The new product is manufactured at the address listed in section 1 of this document (Figure 1).

**Figure 1. Location of the Manufacturer**



The affected environment includes human and natural environments surrounding the 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.<sup>1</sup>

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).<sup>2 3</sup> Land use within the watershed is predominantly forest (65%). Agriculture and farming account for approximately 19% of the remaining land use, and 12% is urbanized area.<sup>4</sup>

## **5.2 Air Quality**

The Agency does not anticipate any new substances or new type of emissions would be released into the environment because of manufacturing the new product. 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; accordingly, the applicant concluded that manufacturing the new product 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, or land use and zoning. The applicant stated that facility expansion or new construction due to manufacturing the new product would not 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 expected.

## **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

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<sup>1</sup> Google. 2018. Map of 3601 Commerce Road, Richmond, VA 23234. Retrieved from Google Maps: [www.google.com/maps](http://www.google.com/maps). June 5, 2018.

<sup>2</sup> 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

<sup>3</sup> Virginia Department of Environmental Quality. Available at: <http://deg.state.va.us/Portals/0/DEQ/Water/SWRP/App%20B%20James%20River%20Basin%20Summary.pdf>. Accessed April 17, 2018

<sup>4</sup> See Virginia Department of Conservation and Recreation at: <http://www.dcr.virginia.gov/soil-and-water/wsheds>. Accessed April 17, 2018.

future plans to expand the facility production beyond 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).<sup>5,6</sup> 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:

- (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 EPA's Enforcement and Compliance History Online (ECHO) database did not reveal any violations of the environmental laws and regulations.<sup>7</sup>

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 products are 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 manufacturing facility is operating below its permitted capacity and the future year projections of cigarette production at the facility, including the new product, is 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 product. Thus, though 2010 U.S. Census and

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

<sup>6</sup> Critical habitat map available at: <https://datasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449>

<sup>7</sup> 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.

American Community Survey data show that 80% of the population within a three-mile radius of the manufacturing facility is minority,<sup>8</sup> no disproportionate 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 the introduction of the new product would 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 product 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 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 tobacco manufacturing. A search in EPA's 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 released no other hazardous air pollutants at reportable levels (Table 1).<sup>9</sup> Ammonia's health effects are ocular and respiratory; nicotine and nicotine salts have known developmental effects.<sup>10</sup> 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.

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<sup>8</sup> 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.

<sup>9</sup> 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](https://www3.epa.gov/enviro/facts/tri/form_ra_download.html). Searched on March 7, 2018.

<sup>10</sup> 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.



**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
Subtotal Waste Managed			227,680
On-site Release	Air	Ammonia	20,347
		Nicotine and Nicotine Salts	11,671
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-site Release			85,415
Subtotal Waste Released			117,433
Total Production-Related Waste			345,113

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 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 Action and Alternative – 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 was the projected market volume 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 order will 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 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.

Although there are changes in tobacco blend in the new product compared to the predicate product (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 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). The 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, 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).

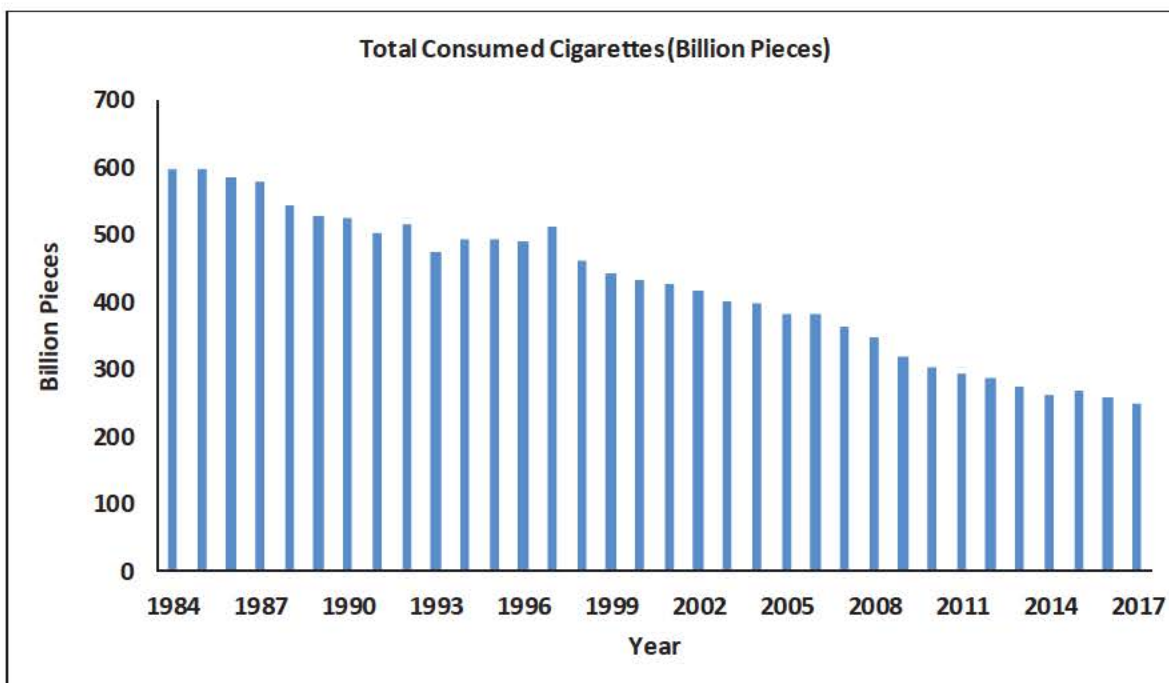
However, use of cigarettes in the United States is declining according to the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports (Figure 2).<sup>11</sup> This likely is responsible for the decline in SHS exposure observed in several studies that evaluated the levels of SHS 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. 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-

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<sup>11</sup> 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.

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).

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



As of December 2015, 26 states and the District of Columbia have implemented comprehensive smoke-free laws (Tynan, Holmes, Promoff, Hallett, Hopkins, & Frick, 2016). Such laws are 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 Action and Alternative – 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. 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 volume for the new product, the Agency found no significant impacts.

#### **7.1. Affected Environment**

The affected environment includes human and natural environments in the United States; the marketing order will 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 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 in the United States.

No changes in air quality from disposal of the packaging material of 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 new product 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 action is 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,<sup>12 13</sup> the disposal of the new product 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 product because the chemicals in the new product are the same as or similar to currently marketed cigarettes.

## **7.5. Socioeconomics and Environmental Justice**

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new 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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<sup>12</sup> 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.

<sup>13</sup> 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 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 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 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 butts, and the mass transfer behavior of combustion products along the cigarette.<sup>14</sup>

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 environmental assessment (EA):

### **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

### **Reviewer:**

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

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

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<sup>14</sup> NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed April 24, 2018.

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.

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. Sosnoff C.S., and 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.

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, P., Benowitz N, Winickoff JP, Rehan V, Talbot P, Schick SF, Samet J, Wang Y, Hang B, Martins-Green M, Pankow JF, and Hovell, M.E. (2011). Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*, 119(9), 1218-1226.

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 1 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., and 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.

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. Washington, DC: U.S. Environmental Protection Agency, Office of Land and Emergency Management. November 2016.

Wilson, N., J., Oliver, and G., Thomson. (2014). Smoking close to others and butt littering at stops: Pilot observational study. *PeerJ*. 2014;2:e272.

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.

## Confidential Appendix 1

### Comparison of the New Product to the Predicate Product

STN	Component	Change from Predicate Product
SE0013711	Cigarette paper	Decrease in weight Increase in (b) (4) Added (b) (4)
	Tipping paper	Added (b) (4)
	Filter plug wrap	Increase in (b) (4)
	Tobacco	Decrease in weight
	Tobacco Blend	Decreased: Tobacco leaf - (b) (4) Increased: (b) (4) – total

15 (b) (4)

16

## CONFIDENTIAL APPENDIX 2

### First- and Fifth-Year Market Volume Projection 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 projection for the new product was compared to the total forecasted use of cigarettes in the United States.<sup>17</sup> Although the projected use of the new product would account for (b) (4) % of the forecasted cigarette use in the United States, the applicant stated that the new product would compete with or replace other combusted cigarettes currently on the market.

STN	Market Volume			
	First-Year		Fifth-Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used <sup>18</sup>	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarette Used
SE0013711	(b) (4)			

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<sup>17</sup> 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<sup>2</sup> value of 0.9786, the forecasted number of cigarettes that will be used in the United States is estimated at (b) (4) billion cigarettes in the first year and (b) (4) billion cigarettes in the fifth year of marketing the new product.

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

# CONFIDENTIAL APPENDIX 3

## Projected Waste of Cigarette Butts in the First and Fifth-Year of Marketing the New Product

$\sum_{i=1}^I A_i = \sum_{i=1}^I (B_i * C_i) D_i$	<i>A<sub>i</sub></i> : Projected total waste generation of the product (metric tons) <i>B<sub>i</sub></i> : Market Volume (Pieces) <i>C<sub>i</sub></i> : Cigarette Butt Weight (grams) <i>D<sub>i</sub></i> : 1.0 x 10 <sup>-6</sup> metric tons/gram
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STN	Projected Year	Market Volume (Pieces) <i>B<sub>i</sub></i>	Cigarette Butt Weight (Grams) <i>C<sub>i</sub></i>	Cigarette Butt Waste (Tons) <i>A<sub>i</sub></i>
SE0013711	First-Year	(b) (4)	0.1277	(b) (4)
	Fifth-Year		0.1277	

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 in the first year and (b) (4) metric tons in the fifth year of marketing the new product would be negligible fractions of the 234.47 million metric tons of total waste reported in the United States in 2014 (U.S. Environmental Protection Agency, 2016).