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

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

August 8, 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 Names, Submission Tracking Numbers (STNs), and Predicate Product Names

New Product Name	STN	Predicate Product Name
Marlboro Special Select (Red Pack) Box	SE0015290	Marlboro Special Select (Red Pack) Box
Marlboro Special Select (Red Pack) 100's Box	SE0015291	Marlboro Special Select (Red Pack) 100's Box
Marlboro Red Label 100's Box	SE0015295	Marlboro Red Label 100's Box
Marlboro Red Label Box	SE0015297	Marlboro Red Label Box
Marlboro Menthol Smooth Ice Box	SE0015301	Marlboro Menthol Gold Pack Box
Marlboro Menthol Slate Box	SE0015303	Marlboro Menthol Slate Box
Marlboro Menthol Slate 100's Box	SE0015310	Marlboro Menthol Slate 100's Box
Marlboro Black Special Blend Box	SE0015317	Marlboro Soft Pack

Product Identification

Product Category	Cigarettes
Product Sub-Category	Combusted Filtered
Number of Products per Retail Unit	20 cigarettes per pack, 10 packs per paperboard carton, and 60 cartons per shipping case.
Product Package	The packaging materials consist of paperboard box, paper inner frame, foil inner liners, polypropylene outer film, polypropylene tear tape, paperboard carton, and corrugated paperboard shipping case.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act after finding the new tobacco products substantially equivalent to the corresponding predicate products. The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency eight substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue the marketing orders if the new products are found substantially equivalent to the corresponding predicate products. The predicate products were previously found by FDA to be substantially equivalent and received marketing orders.

The new products differ from the corresponding predicate products due to a change in the composition of the tipping adhesive (Confidential Appendix 1). The product package changed from soft pack in the predicate product to box in the new product in SE0015317.

4. Alternatives to the Proposed Actions

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

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

The Agency considered potential environmental impacts 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 new products are intended to replace the corresponding predicate products currently manufactured at the facility.
- No facility expansion is expected due to manufacturing the new products.
- No increase in the facility production beyond current permitted production capacity is expected due to manufacturing the new products.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the manufacturing facility. The new products are 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 commonwealth 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 products would lead to release of any new chemicals into the air. The applicant stated that manufacturing the new products is not expected to result in changes in air emissions. The applicant also stated that manufacturing the new products would not require new or revised 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 the corresponding predicate products currently manufactured at the facility. The applicant stated that manufacturing the new products is not expected to result in changes in wastewater discharge and, therefore, would not require new or revised wastewater permits.

5.4 Soil, Land Use, and Zoning

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

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[1] Google. 2019. Map of 3601 Commerce Road, Richmond, VA 23234. Retrieved from Google Maps: https://www.google.com/maps/place/3601+Commerce+Rd,+Richmond,+VA+23234/@37.4714484,-77.4281885,525m/data=!3m1!1e3!4m5!3m4!1s0x89b10e291d68474d:0x90a434f7ed13f9ed!8m2!3d37.4714229!4d-77.4328555. July 23, 2019.

[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 July 23, 2019

[4] Ibid.

5.5 Biological Resources

The Agency does not anticipate that manufacturing the new products 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 the current permitted level. The applicant reviewed the U.S. Fish and Wildlife Service's (U.S. FWS) critical habitat and endangered species maps. According to the maps, three threatened species (two flowering 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 the U.S. Environmental Protection Agency (EPA) ID# VAD000819466. The applicant provided detailed information for the following air emission and wastewater permits:

(1) Air permits: Title V air permit no. PRO50076 and Stationary Source permit issued by the Virginia Department of Environmental Quality (VA DEQ).

(2) Wastewater discharge permit number 2149 issued by the Division of Wastewater Treatment, City of Richmond. The permit requires compliance with the relevant effluent limitations (40 CFR 400 – 699) to ensure the wastewater is of a certain quality for effective treatment at the publicly owned treatment works (POTW) facility. The applicant stated that the facility complies with the requirements of this permit and 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.

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[5] U.S. Fish and Wildlife Services (U.S. FWS), available at: https://www.fws.gov/endangered/. Accessed July 23, 2019.

[6] Critical habitat maps available at: https://databasin.org/datasets/d579d87eb54f4374a77ea53e7ef66449 Accessed July 23, 2019.

[7] EPA ECHO Detailed Facility Report: Philip Morris USA Facility, Richmond, VA. Available at: https://echo.epa.gov/detailed-facility-report?fid=110000869793. Accessed July 23, 2019.

5.7 Socioeconomics and Environmental Justice

No changes in socioeconomics are anticipated due to manufacturing the new products. 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 manufacturing the new products would not require an increase in 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 products. Thus, though 2010 U.S. Census and American Community Survey data show that 80% of the population within three miles of the manufacturing facility is minority with 49% under the poverty line,[8] 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 Native American lands.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all combusted, filtered cigarettes. The Agency anticipates that the waste generated due to manufacturing the new products would be released to the environment, and disposed of in landfills 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 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 would 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 (PMUSA) manufacturing facility in Richmond, Virginia released 18,713 pounds of ammonia and 10,683 pounds of nicotine and nicotine salts to air (Table 1).[9] Ammonia's adverse health effects are ocular and respiratory; nicotine and nicotine salts have known adverse developmental effects.[10] The TRI database search did not show that the PMUSA 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

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[8] Ibid.

[9] U.S. Environmental Protection Agency (EPA) TRI Data https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/23234PHLLP3601C. Accessed July 23, 2019.

[10] EPA. myRight-to-Know, available at: https://myrtk.epa.gov/info. The site allows for searching the industrial facilities that manage toxic waste chemicals by entering the facility address and clicking on the facility location on the map. Accessed September 14, 2018.

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			126,020
Energy Recovery			0
Treated			104,427
Subtotal Waste Managed			*230,447*
On-Site Release	Air	Ammonia	18,713
		Nicotine and Nicotine Salts	10,683
Off-Site Release			60,822
Subtotal Waste Released			*90,218*
Total Production-Related Waste			**320,665**

The applicant stated that the manufacturer does not anticipate any future increased production beyond its current permitted capacity and, therefore, a new or revised air permit or waste water permit would not be required.

5.11 Impacts of the No-Action Alternative

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

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

The Agency evaluated potential impacts to resources in the environment that could 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 were the projected market volumes for the new products (Confidential Appendix 2) 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 orders would allow for the new tobacco products to be sold to consumers in the United States.

6.2 Air Quality

The Agency does not anticipate that new chemicals would be released into the environment as a result of use of the new products, 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 products would be

released in the same manner as the combustion products of any other marketed cigarettes; (2) the new products are expected to compete with or replace other currently marketed cigarettes, and (3) the ingredients in the new products are used in other currently marketed tobacco products.

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

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).

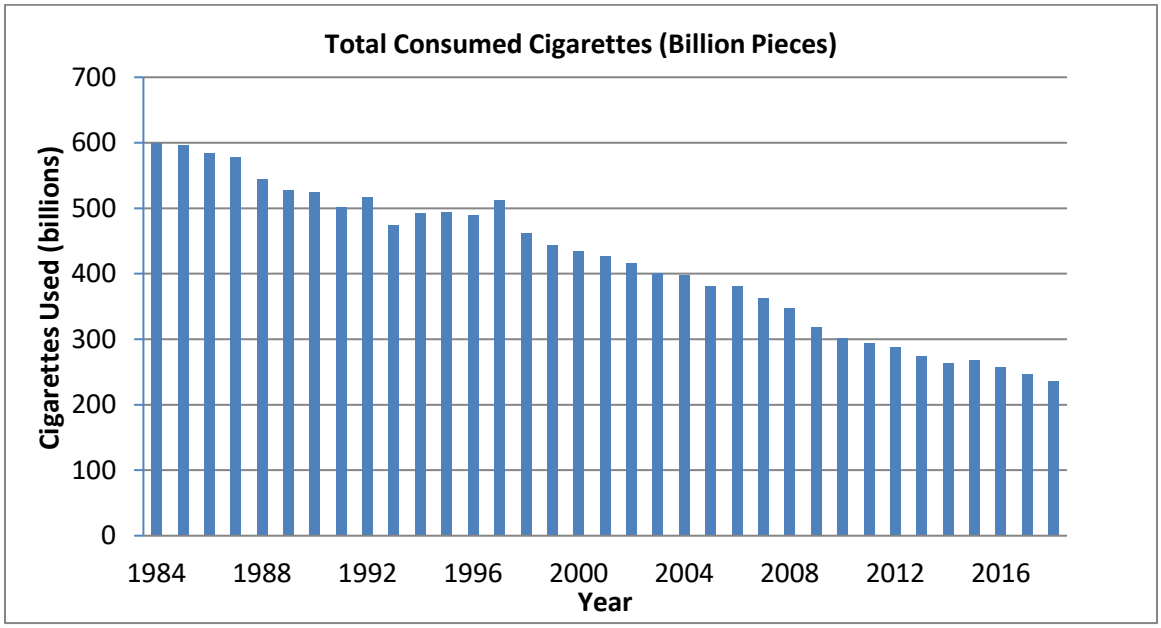
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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). 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 – 2018



As of March 2019, 28 states and the District of Columbia had implemented comprehensive smoke-free laws (American Lung Association, 2019). 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 no-action alternative would not change the existing condition of use of cigarettes, as similar tobacco products would continue to be marketed.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Products

The Agency evaluated potential 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 of cigarette use in the United States, and the applicant's submitted information, including market volume projections 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 because the marketing orders would allow for the applicant to distribute and sell the new tobacco products to consumers in the United States.

7.2 Air Quality

The Agency does not anticipate that disposal of the new 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 cigarette butts of the new products. The chemicals in the cigarette butts are commonly used in other currently marketed cigarettes. Because the new products are anticipated to compete with or replace other currently marketed cigarettes, the butt waste generated from the new products would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are 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 products 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 any impacts on water resources are expected due to disposal of the cigarette butts and packaging from the new products because the chemicals and packaging materials in the new products would be the same or similar to chemicals and packaging in currently marketed cigarettes. Furthermore, the new products would compete with or replace similar tobacco products currently on the market.

7.4 Biological Resources

The proposed actions are 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 products is not expected to change the fire frequency because (1) the disposal of the new products would be 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 products are anticipated to replace similar marketed cigarettes.

7.5 Solid Waste

The Agency does not foresee the introduction of the new products would notably affect the current cigarette butt and packaging waste generated from all combusted, filtered cigarettes. The waste generated due to disposal of the new products would be handled in the same manner as any other waste generated from any other combusted, filtered cigarettes in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2) and a portion of those would be littered.

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

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

7.6 Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products would 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 products; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7 Cumulative Impacts

The use of the new products may impact the environment through littering of discarded cigarette filters or butts, which can persist in the environment (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 aquatic and 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 filler, 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 no-action alternative would not change the existing condition of disposal of cigarettes and cigarette packaging, as similar tobacco products would continue to be disposed of in the United States.

8. List of Preparers

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

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

Preparer:

Susana Addo Ntim, Ph.D., Center for Tobacco Products

Education: Ph.D. in Environmental Science
Experience: Seven years in various scientific activities
Expertise: NEPA Analysis; fate, transport and ecotoxicology of new and emerging contaminants; applications and environmental implications of nanotechnology

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Education: Ph.D. in Plant Molecular Biology and Virology
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Expertise: NEPA analysis, environmental risk assessment, evidence-based assessment of health technologies, NEPA Implementation

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

American Lung Association. 2019. Smokefree Air Laws. www.lung.org/our-initiatives/tobacco/smokefree-environments/smokefree-air-laws.html (updated March 8, 2019). Accessed May 30, 2019.

Burton B. Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Environmental Health Perspectives*. 2011;119(2): A70-A74.

Becherucci ME, Pon JPS. 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*. 2014;34(8):1351-1355.

Claereboudt MR. Shore litter along sandy beaches of the Gulf of Oman. *Marine Pollution Bulletin*. 2004;49(9-10):770-777.

Healton CG., Cummings KM, O'Connor RJ, Novotny TE. Butt really? The environmental impact of cigarettes. *Tobacco Control*. 2011;20(suppl. 1): i1.

Homa DM, Neff LJ, King BA, Caraballo RS, Bunnell RE, Babb SD, Garrett BE, Sosnoff CS, Wang L. Vital signs: disparities in nonsmokers' exposure to secondhand smoke — United States, 1999–2012. *Morbidity Mortality Weekly Report*. 2015;*64*(4), 103-108.

Kadir AA, Sarani NA. Cigarette butts pollution and environmental impact – a review. *Applied Mechanics and Materials*. 2015;773-774:1106-1110.

Matt GE, Quintana PJE, Destaillats H, Gundel LA, Sleiman M, Singer BC, Jacob P, Benowitz N, Winickoff JP, Rehan V, Talbot P, Schick SF, Samet J, Wang Y, Hang B, Martins-Green M, Pankow JF, Hovell ME.

Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environmental Health Perspectives*. 2011;119(9):1218-1226.

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

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

Seco Pon JP, Becherucci ME. Spatial and temporal variations of urban litter in Mar del Plata, the major coastal city of Argentina. *Waste Management*. 2102;32(2):343-348.

Smith CJ, Livingston SD, Doolittle DJ. An international literature survey of "IARC Group 1 carcinogens" reported in mainstream cigarette smoke. *Food and Chemical Toxicology*. 1997;35(10-11):1107-1130.

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. 2018. *Advancing Sustainable Materials Management: 2015 Fact Sheet*. Washington, DC: U.S. Environmental Protection Agency, Office of Land and Emergency Management. July 2018.

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

Yao T, Sun HY, Wang Y, Lightwood J, Max W. Sociodemographic differences among U.S. children and adults exposed to secondhand smoke at home: National Health Interview Surveys 2000 and 2010. *Public Health Reports*. 2016;131:357-366.

CONFIDENTIAL APPENDIX 1

Comparison of the New Products to the Corresponding Predicate Products

STN	Component	Change from the Predicate Product
SE0015290 SE0015291 SE0015295 SE0015297 SE0015301 SE0015303 SE0015310 SE0015317	Tipping adhesive	Addition of (b)(4)

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.[15] The projected use of the new products in the first and fifth years of marketing after marketing orders are issued account for about (b) (4) and (b) (4) of the forecasted cigarette use in the United States, respectively. In addition, the applicant stated that the new products would replace the corresponding predicate 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]
SE0015290	(b) (4)	(b) (4)	(b) (4)	(b) (4)
SE0015291				
SE0015295				
SE0015297				
SE0015301				
SE0015303				
SE0015310				
SE0015317				
Total				

[15] The Agency used historical data regarding total use of cigarettes from 1984 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R^2 value of 0.98, the forecasted number of cigarettes that would be used in the United States is estimated at 233.43 billion cigarettes in the first year and 189.99 billion cigarettes in the fifth year of marketing the new products.

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

[17] Ibid.