

**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**

March 19, 2020

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1. Applicant and Manufacturer Information

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

2. Product Information

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

STN	New Product Name	Predicate Product Name
SE0015426	Marlboro Red Label 100's Box	Marlboro Red Label 100's Box
SE0015427	Benson & Hedges 100's Box	Benson & Hedges 100's Box

Product Identification

Product Category	Cigarettes
Product Subcategory	Combusted filtered
Product Number per Retail Unit	Twenty cigarettes per pack with ten packs per carton and 60 cartons per shipping case.
Product Package	The packaging materials consist of a foil inner liner, paperboard inner frame, paperboard hard pack, polypropylene outer wrap 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 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 nine 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 predicate products.

The new products differ from the corresponding predicate products in cigarette paper, tipping adhesive, cigarette seam adhesive, and filter seam adhesive. (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

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

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Philip Morris USA Facility in 2018

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			122,530
Energy Recovery			0
Treated			94,266
<i>Subtotal Waste Managed</i>			<i>216,796</i>
On-Site Release	Air	Nicotine and Salts	10,313
Off-Site Disposal/Release			35,528
<i>Subtotal Waste Released</i>			<i>45,841</i>
Total Production-Related Waste			262,637

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

5.11 Impacts of the No-Action Alternative

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

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 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 were the projected market volumes (Confidential Appendix 2) 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 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 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 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).

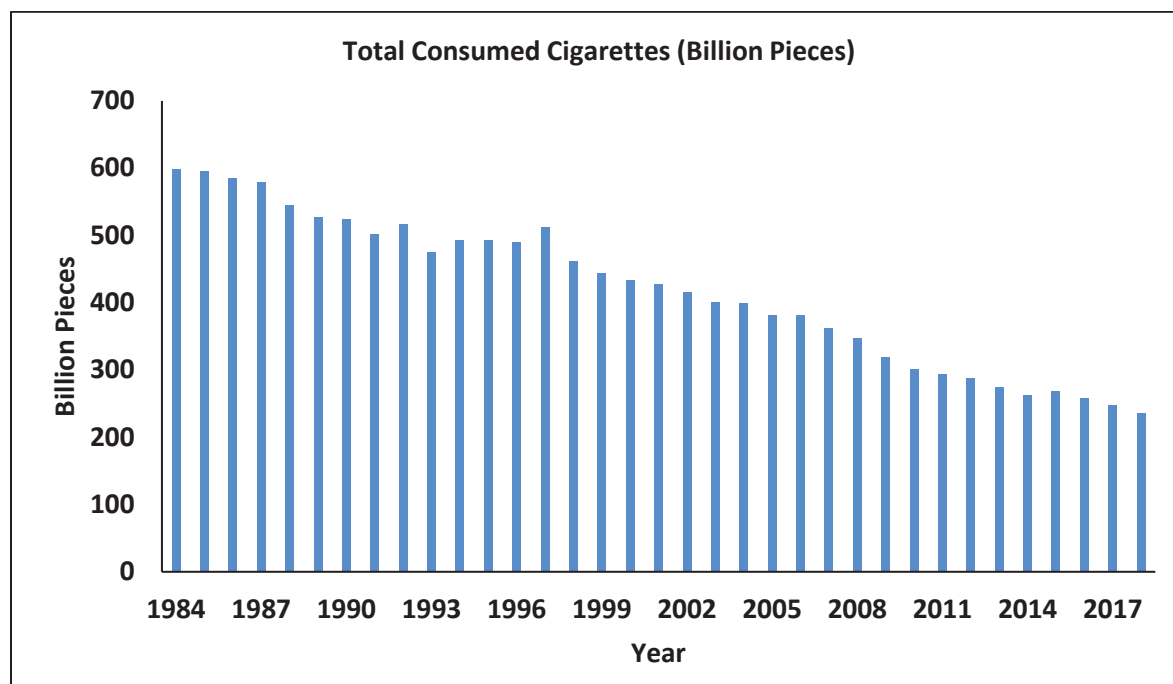
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- 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).¹² 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).

¹² U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: <https://www.ttb.gov/tobacco/tobacco-stats.shtml>. Accessed July 18, 2019.

Figure 2. Use of Cigarettes in the United States, 1984 – 2018



As of March 2019, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2019). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

6.5 Impacts of the No-Action Alternative

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

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

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. The Agency found no significant impacts based on publicly available information such as the documented continuous decline in use of cigarettes in the United States, and the applicant’s submitted information, including the projected market volumes for the new products.

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 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 is anticipated to be the same as any materials from other cigarettes disposed of in the United States.

No changes in air quality from disposal of the packaging materials in the new 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 tobacco products.

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 in the new products are like chemicals in currently marketed cigarettes and the new products would compete with or replace other cigarettes 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,^{13, 14} the disposal of the new products is not expected to change the fire frequency because (1) the disposal of the new products would be the same as 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 that the introduction of the new products would noticeably 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 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

¹³ 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 July 18, 2019.

¹⁴ UC Davis Health News. Available at: <https://www.ucdmc.ucdavis.edu/publish/news/newsroom/2763>. Accessed July 18, 2019.

combusted, filtered cigarettes in the United States. The number of cigarette butts generated is equivalent to the market projections (Confidential Appendix 2); a portion of those would be littered.

7.6 Socioeconomics and Environmental Justice

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

7.7 Cumulative Impacts

A major existing environmental consequence of the use of the new products as well as other conventional cigarettes is littering of discarded cigarette filters or butts (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 (Pon and Becherucci, 2012).

Compounds in cigarette butts can leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigarette butts due to air emissions is not well studied. The chemicals in cigarette butts can be the original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the cigarette butts. Airborne emissions from cigarette butts after disposal depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco fillers, number of puffs, and the mass transfer behavior of combustion products along the cigarette.¹⁵

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

7.8 Impacts of the No-Action Alternative

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

8. List of Preparers

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

¹⁵ NIST Technical Report 8147 available at: <http://dx.doi.org/10.6028/NIST.IR.8147>. Accessed July 18, 2019.

Preparer:

William E. Brenner, B.S., Center for Tobacco Products

Education: B.S. in Biology

Experience: Five years in various scientific activities

Expertise: NEPA analysis, environmental risk assessment, air quality analysis, archaeological and archival preservation

Reviewer:

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

Education: M.S. in Environmental Science and PhD in Biochemistry

Experience: Ten years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

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CONFIDENTIAL APPENDIX 1

Comparison of the New Products to the Predicate Products

STN	Component	Change from Predicate Product
SE0015426	Cigarette Paper	<ul style="list-style-type: none"> • Addition of (b) (4) • Addition of (b) (4) • Decrease in (b) (4) • Increase in (b) (4) • Addition of (b) (4) • Addition of (b) (4) • Removal of (b) (4) • Removal of (b) (4)
	Tipping Adhesive	<ul style="list-style-type: none"> • Addition of (b) (4)
SE0015427	Cigarette Seam Adhesive	<ul style="list-style-type: none"> • Addition of (b) (4) • Removal of (b) (4) • Removal of (b) (4) • Addition of (b) (4) • Addition of (b) (4) • Addition of (b) (4) • Addition of (b) (4) • Addition of (b) (4)
	Filter Seam Adhesive	<ul style="list-style-type: none"> • Removal of (b) (4)
	Tipping Adhesive	<ul style="list-style-type: none"> • 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.¹⁶ The projected use of the new products in the first- and fifth-year of marketing account for about (b) (4) respectively, of the forecasted cigarette use in the United States. The applicant stated the predicate products would not be marketed simultaneously if marketing orders were issued for the new products. In addition, the applicant stated that the new products would compete with or replace similar tobacco products currently on the market.

STN	Projected Market Volume			
	First-Year		Fifth-Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁷	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁸
SE0015426	(b) (4)	(b) (4)	(b) (4)	(b) (4)
SE0015427	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Total	(b) (4)	(b) (4)	(b) (4)	(b) (4)

¹⁶ The Agency used historical data regarding total use of cigarettes from 2002 to 2018 to mathematically estimate the total number of cigarettes used in the United States. Using the best-fit trend line with an R² value of 0.9814, the forecasted number of cigarettes that would be used in the United States is estimated at 228.657 billion cigarettes in the first year and 205.021 billion cigarettes in the fifth year of marketing the new products.

¹⁷ Projected Market Occupation of the New Product in the United States (%) = $\frac{\text{Projected Market Volume of the New Product (cigarette pieces)}}{\text{Projected Use of Cigarettes in United States (cigarette pieces)}} \times 100$

¹⁸ Ibid