

**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**

December 9, 2019

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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

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

STN	New Product Name	Predicate Product Name
SE0015507	Marlboro Special Select (Red Pack) 100's Box	Marlboro Special Select (Red Pack) 100's Box
SE0015508	Chesterfield Blue Pack 100's Box	Chesterfield Blue Pack 100's Box
SE0015509	Marlboro Red Label Box	Marlboro Red Label Box

Product Identification

Product Category	Cigarettes
Product Sub-Category	Combusted Filtered
Number of Products per Retail Unit	Twenty cigarettes per pack with ten packs per paperboard carton and 60 cartons per shipping case.
Product Package	The packaging materials consist of paperboard hard packs with inner frames. The hard packs have inner foils, polypropylene outer wraps, polypropylene tear tapes, paperboard cartons and corrugated paperboard shipping cases.

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 three 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 substantially equivalent and received marketing orders.

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

4. Alternative to the Proposed Actions

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

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

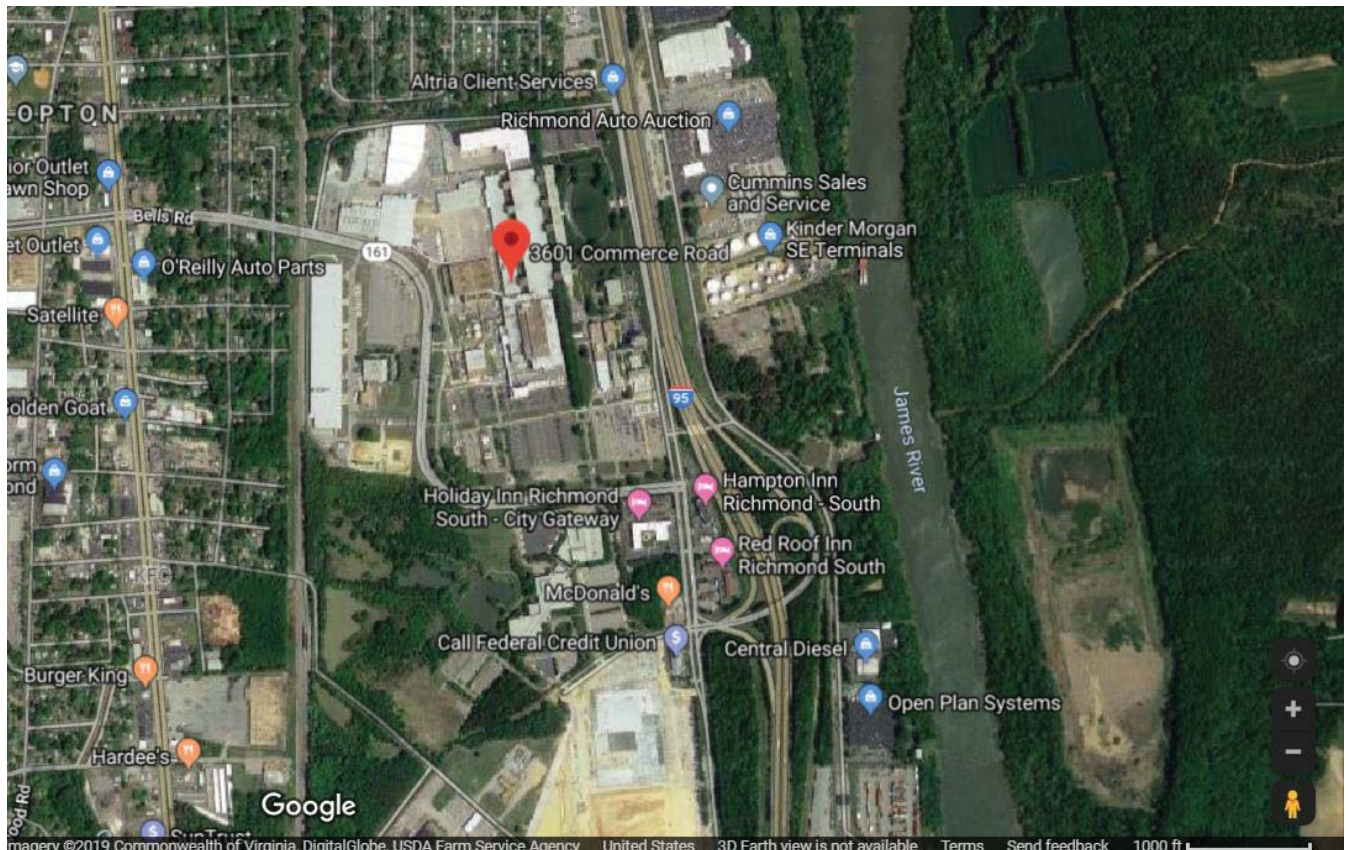
The Agency considered potential impacts that may be affected by manufacturing the new products and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

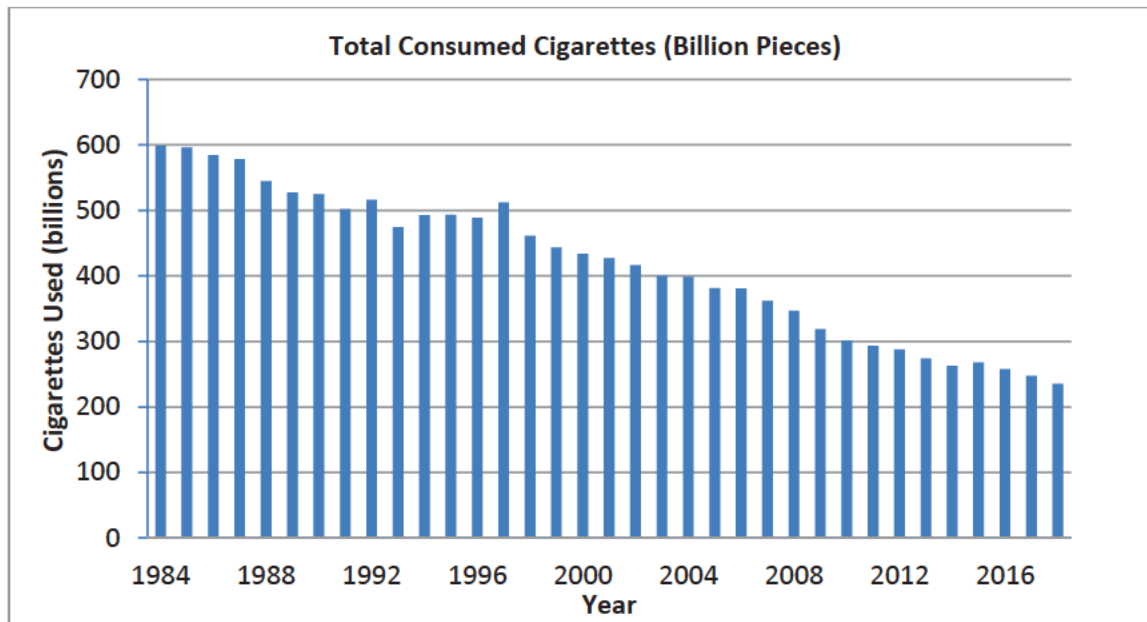
- The production of the new products will replace production of other cigarettes currently being manufactured at the same facility.
- The applicant stated that the new and predicate products would not be simultaneously manufactured if the new products receive marketing orders.
- No facility expansion or new construction is expected due to manufacturing the new products.
- No net increase in the facility production is expected due to manufacturing the new products.

5.1 Affected Environment

The new and predicate products are manufactured at 3601 Commerce Road, Richmond, VA (Figure 1).

Figure 1. Location of the Manufacturing Facility





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 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 Alternative – 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. 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; the marketing orders would allow for the new tobacco products to be sold to consumers nationwide.

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

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, 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 marine ecosystems (Kadir and Sarani, 2015). The environmental toxicity of cigarette butts due to air emissions is not well studied. The chemicals in cigarette butts can be the original chemicals in the unsmoked cigarettes or the pyrolysis and distillation products deposited in the cigarette butts. Airborne emissions from cigarette butts after disposal depend on the environmental conditions and the chemicals in the butts. These emissions can be influenced by several factors, such as the cigarette brand, cigarette length, filter material, types of tobacco, ingredients in the cigarette and tobacco fillers, number of puffs, and the mass transfer behavior of combustion products along the cigarette.¹⁴

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

7.8 Impacts of the No-Action Alternative

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

8. List of Preparers

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

Preparer:

Dilip Venugopal, Ph.D., Center for Tobacco Products

Education: M.S. in Ecology and Ph.D. in Entomology

Experience: Seventeen years in various scientific activities

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

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

Reviewer:

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

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

Experience: 11 years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

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 August 7, 2019

Burton B. Does the smoke ever really clear? Thirdhand smoke exposure raises new concerns. *Enviro 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. *MMWR Morb Mortal Wkly Rep*. 2015;64(4), 103-108.

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

Matt GE, Quintana PJE, Destailats 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. *Enviro 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 Chem Toxicol*. 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*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2014. Printed with corrections, January, 2014.

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

U.S. Department of Health and Human Services. 2006b. The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General: What it Means to You. *Consumer Booklet*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 2006.

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	Change from Predicate Product
SE0015507 SE0015508 SE0015509	<p data-bbox="418 373 1308 443">Cigarette paper - Minor changes in the material composition of the cigarette paper with an increase in total cigarette paper levels of (b) (4)</p> <p data-bbox="418 443 1308 548">[REDACTED] Decreased total cigarette paper levels of (b) (4)</p> <p data-bbox="418 583 1057 621">Tipping adhesive - Addition of (b) (4)</p> <p data-bbox="418 657 1300 756">As a result of the cigarette paper change, the total cigarette weight in the new product is slightly increased (SE15507, SE15508) or decreased (SE15509).</p>

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 account for about (b) (4) of the forecasted cigarette use in the United States, respectively. In addition, the applicant stated that the new products would replace similar tobacco products currently on the market.

STN	Projected Market Volume			
	First-Year		Fifth-Year	
	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁶	New Product (# of Cigarettes)	New Product as a Percent of Total Cigarettes Used ¹⁷
SE0015507	(b) (4)			
SE0015508				
SE0015509				
Total				

¹⁵ 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 228.66 billion cigarettes in the first year and 205.02 billion cigarettes in the fifth year of marketing the new products.

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

¹⁷ Ibid.