

**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**

July 22, 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 Name, Submission Tracking Numbers (STNs), and Predicate Product Names

STN	New Product	Predicate Product
SE0015260	Marlboro Gold Pack 100's Soft Pack	Marlboro Gold Pack 100's Box
SE0015261	Marlboro Silver Pack Box	Marlboro Silver Pack Box
SE0015262	Marlboro Silver Pack 100's Box	Marlboro Silver Pack 100's Box
SE0015263	Marlboro Gold Pack 100's Box	Marlboro Gold Pack 100's Box

Product Identification

Product Category	Cigarette
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, inner foils, polypropylene outer wraps, polypropylene tear tapes, paperboard cartons and corrugated board 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.

The applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency substantial equivalence (SE) reports to obtain marketing orders. The Agency shall issue marketing orders if the new products are found substantially equivalent to the corresponding predicate products. The predicate products are grandfathered products commercially marketed in the United States as of February 15, 2007.

The new products differ from the corresponding predicate products in the product characteristics (Confidential Appendix 1). The applicant provided first- and fifth-year market volume projections for the new products (Confidential Appendix 2).

4. Alternatives to the Proposed Actions

The no-action alternative is the Agency 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

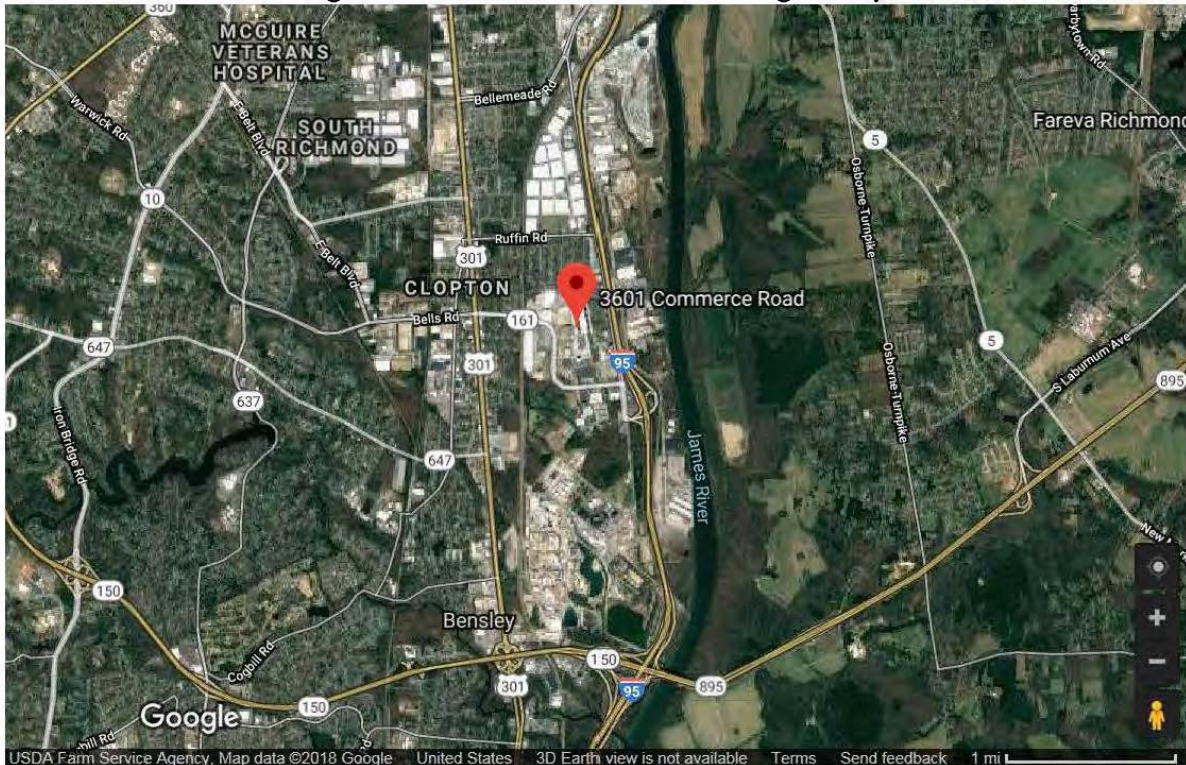
The Agency considered potential environmental impacts that may be affected by manufacturing the new products and found no significant impacts, based on Agency-gathered information and the following information submitted by the applicant:

- The ingredients in the new products are commonly used in other products currently manufactured at the facility.
- The new products are intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.
- No facility expansion or new construction is expected due to manufacturing the new products.

5.1 Affected Environment

The new products would be manufactured at 3601 Commerce Road, Richmond, VA (Figure 1).

Figure 1. Location of the Manufacturing Facility



No changes in impacts on environmental justice are anticipated. The applicant stated that the future year projections of cigarette production at the facility, including the new products, are within 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 a three-mile radius of the manufacturing facility is minority,⁸ no disproportionate impacts to environmental justice populations would occur as a result of manufacturing the new products.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee 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 the waste generated due to manufacturing the new products would be handled in the same process 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 to 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 manufacturing facility in Richmond, Virginia released 18,713 pounds of ammonia and 10,683 pounds of nicotine and nicotine salts to air (totaling 29,396 pounds), but released no other hazardous air pollutants at reportable levels (Table 1).⁹ Ammonia adversely affects ocular and respiratory systems; nicotine and nicotine salts have known adverse developmental effects.¹⁰ 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 reportable 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.

⁸ EPA ECHO Detailed Facility Report: Demographic profile of surrounding area (3 miles). Available at: <https://echo.epa.gov/detailed-facility-report?fid=110000869793>. Accessed July 10, 2019.

⁹ U.S. Environmental Protection Agency (EPA) TRI Data <https://www3.epa.gov/enviro/facts/tri/ef-facilities/#/Facility/23234PHLLP3601C>. Accessed November 28, 2018.

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.

Table 1 Management of Chemical Waste Associated with Manufacturing Tobacco Products at Philip Morris USA Facility in 2017

Production-Related Waste Managed or Released			Chemical Mass (Pounds)
Recycled			126,020
Energy Recovery			0
Treated			104,427
<i>Subtotal Waste Managed</i>			<i>230,447</i>
On-Site Release	Air	Ammonia	18,713
		Nicotine and Nicotine Salts	10,683
	Water	Ammonia	0
		Nicotine and Nicotine Salts	0
	Land	Ammonia	0
		Nicotine and Nicotine Salts	0
Off-Site Release			60,822
<i>Subtotal Waste Released</i>			<i>90,218</i>
Total Production-Related Waste			320,665

The applicant does not anticipate manufacturing the new products would require a revised or new wastewater 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 listed 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 for the new products and the documented decline in cigarette use in the United States.

6.1 Affected Environment

The affected environment includes human and natural environments in the United States; the marketing orders would allow for the new tobacco products 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 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; and (2) the new products are expected to compete with or replace other currently marketed cigarettes (Confidential Appendix 2).

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

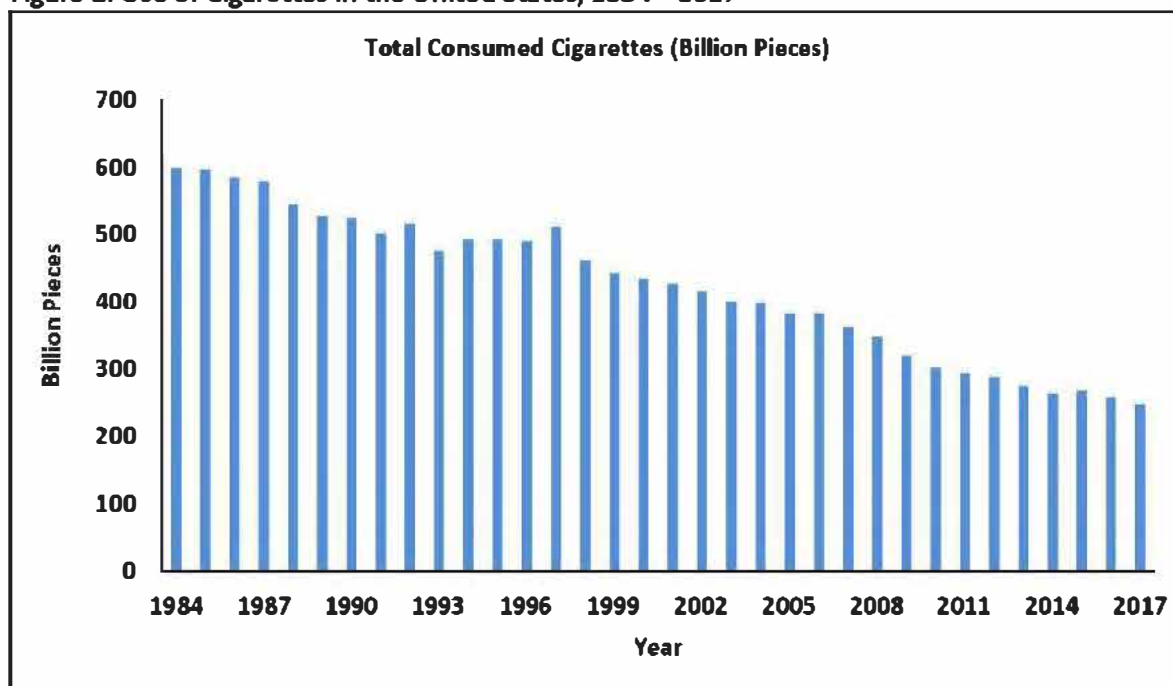
The impacts from use of combusted tobacco products include exposure to secondhand smoke (SHS) produced from burned cigarettes. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, 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; 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-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 – 2017



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 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. 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.

Reviewer:

Gregory G. Gagliano, M.S., Center for Tobacco Products

Education: M.S. in Environmental Science

Experience: Thirty-six years in environmental compliance and analysis

Expertise: Environmental toxicology, risk assessment, regulatory compliance, NEPA analysis

9. A Listing of Agencies and Persons Consulted

Not applicable.

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CONFIDENTIAL APPENDIX 1

Comparison of the New Products to the Corresponding Predicate Products

STN	Component	Change from Predicate Product
SE0015260 SE0015262 SE0015263	Ingredients	Addition of (b) (4) mg/cig Addition of (b) (4) mg/cig Addition of (b) (4) mg/cig Addition of (b) (4) in tipping paper (b) (4) mg/cig 67% increase in (b) (4) and (b) (4) 233% increase in (b) (4) in cigarette paper
SE0015261	Ingredients	Addition of (b) (4) (b) (4) mg/cig Addition of (b) (4) (b) (4) mg/cig 70% increase in (b) (4) and (b) (4) 250% increase in (b) (4)

