

**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**

January 28, 2020

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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 Inc.
<b>Product Manufacturing Address:</b>	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
SE0015605	Marlboro Edge Box	Marlboro Edge Box
SE0015606	Marlboro Menthol Smooth Ice Box	Marlboro Menthol Gold Pack Box

**Product Identification**

<b>Product Category</b>	Cigarettes
<b>Product Subcategory</b>	Combusted filtered
<b>Number of Products per Retail Unit</b>	Twenty cigarettes per box with ten packs per carton.
<b>Product Package</b>	The packaging materials consist of a foil inner liner with laminated paper, inner frame paperboard box, polypropylene film overwrap, polypropylene tear tape, and paperboard carton.

**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 two new tobacco products into interstate commerce for commercial distribution in the United States and submitted to the Agency two 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 by FDA and received marketing orders.

The new products differ from the corresponding predicate products due to changes in cigarette paper, ink, plug wrap, and tipping 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 in the United States.

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

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

- The new and predicate products would not be marketed simultaneously after marketing orders are issued.
- Components of the new products are commonly used in other products 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 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 and predicate products are manufactured at 3601 Commerce Road, Richmond, VA (Figure 1).

**Figure 1. Location of the Manufacturing Facility**

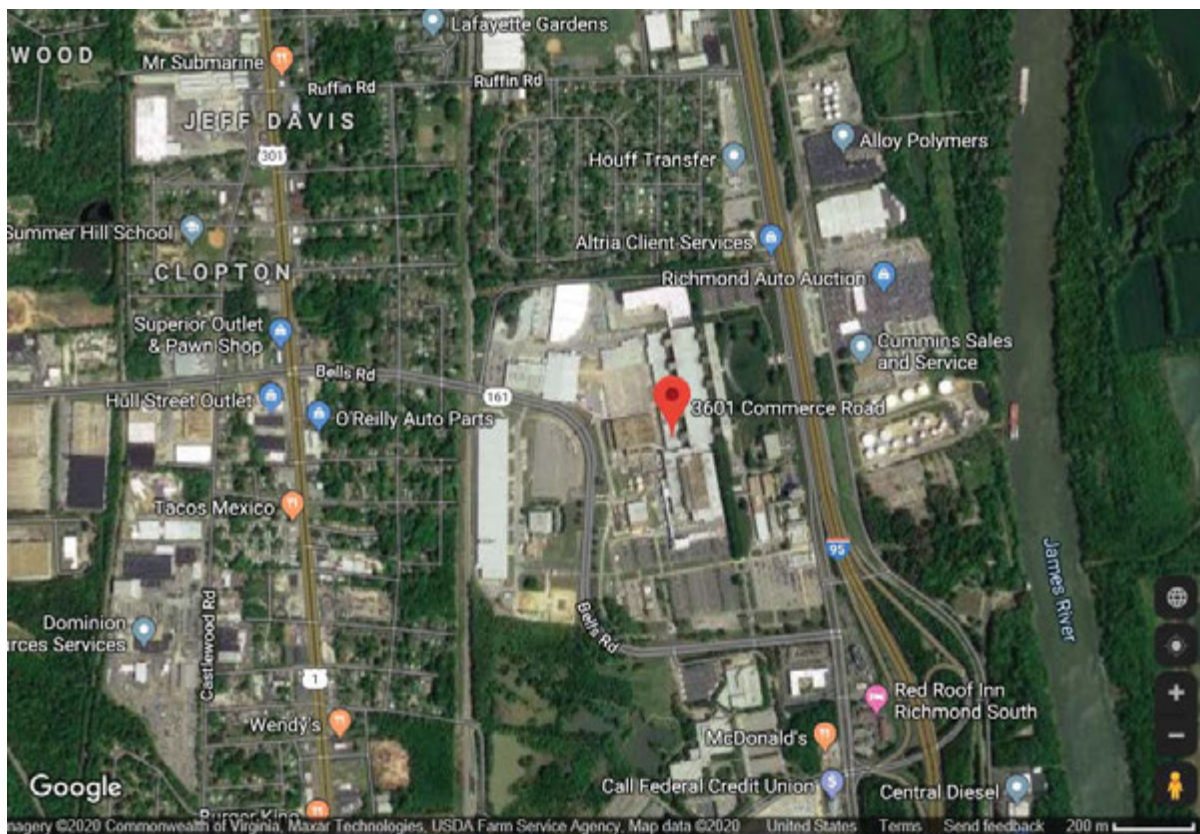






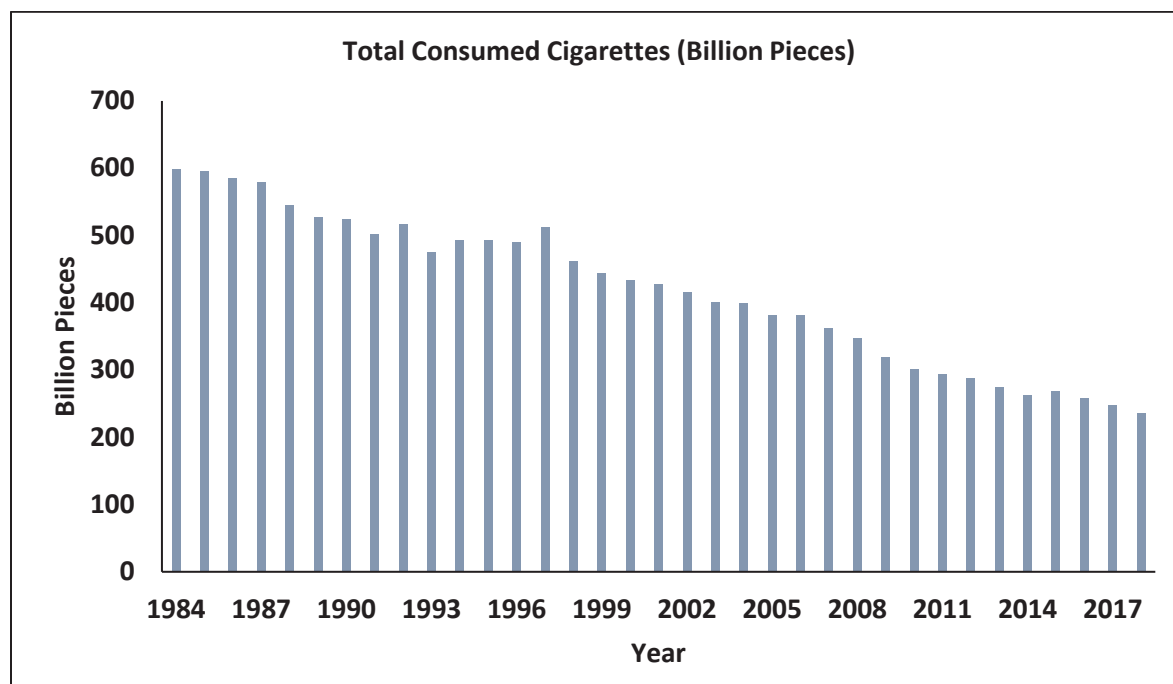








Figure 2. Use of Cigarettes in the United States, 1984 – 2018



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 from 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 used in the United States.

## 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. 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 new tobacco products to be sold to consumers and be disposed of in the United States.





**Preparer:**

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Education: B.S. in Biology

Experience: Six years in various scientific activities

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

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

Experience: Eleven 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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