



U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

March 03, 2020

## **SUBSTANTIALLY EQUIVALENT**

Philip Morris USA Inc.  
Attention: Rebecca A. Rivas, Senior Director, Regulatory Submissions  
Altria Client Services LLC  
2325 Bells Road  
Richmond, VA 23234

**FDA Submission Tracking Numbers (STNs):** Multiple STNs, see Appendix A

Dear Ms. Rivas:

We completed our review of your SE Reports<sup>1</sup> and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A<sup>2</sup> and are in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter.

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

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<sup>1</sup> Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

<sup>2</sup> In addition to comparing the new tobacco products to the predicate tobacco products named by the applicant, FDA also compared the new tobacco products in these SE Reports to the grandfathered tobacco products in SE0014887 and SE0014203. Although the new products have different characteristics than the grandfathered tobacco products in SE0014887 and SE0014203, FDA found that those differences do not cause the new tobacco products to raise different questions of public health, and thus the new tobacco products are also substantially equivalent to the grandfathered products in SE0014887 and SE0014203.

If you have any questions, please contact Pin Zhang, Ph.D., Regulatory Health Project Manager, at (240) 402 – 0997 or [Pin.Zhang@fda.hhs.gov](mailto:Pin.Zhang@fda.hhs.gov).

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2020.03.03 16:35:48 -05'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

**Enclosures:**

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter

Appendix B – Health Information Summary

**Appendix A**  
New and Corresponding Predicate Tobacco Products Subject of This Letter

<b>Common Attributes of SE Reports</b>		
<b>Date of Submission:</b>	December 10, 2019	
<b>Date of Receipt:</b>	December 10, 2019	
<b>Product Manufacturer:</b>	Philip Morris USA Inc.	
<b>Product Category:</b>	Cigarettes	
<b>Product Sub-Category:</b>	Combusted, Filtered	
	<b>New Tobacco Product</b>	<b>Predicate Tobacco Product</b>
	SE0015605: Marlboro Edge Box <sup>3,4</sup>	SE0014887: Marlboro Edge Box <sup>3,4</sup>
<b>Package Type:</b>	Hard Pack	Hard Pack
<b>Package Quantity:</b>	20 Cigarettes	20 Cigarettes
<b>Characterizing Flavor:</b>	None	None
<b>Eligibility Status:</b>	N/A	Previously Found SE
<b>Length:</b>	83 millimeters (mm)	83 mm
<b>Diameter:</b>	7.89 mm	7.89 mm
<b>Ventilation:</b>	17%	17%
	<b>New Tobacco Product</b>	<b>Predicate Tobacco Product</b>
	SE0015606: Marlboro Menthol Smooth Ice Box <sup>3,4</sup>	SE0014203: Marlboro Menthol Gold Pack Box <sup>3,4</sup>
<b>Package Type:</b>	Hard Pack	Hard Pack
<b>Package Quantity:</b>	20 Cigarettes	20 Cigarettes
<b>Characterizing Flavor:</b>	Menthol	Menthol
<b>Eligibility Status:</b>	N/A	Previously Found SE
<b>Length:</b>	83 mm	83 mm
<b>Diameter:</b>	7.89 mm	7.89 mm
<b>Ventilation:</b>	34%	34%

<sup>3</sup> Brand/sub-brand or other commercial name used in commercial distribution.

<sup>4</sup> The applicant submitted the circumference which allowed for a calculation of diameter.

## **Appendix B**

### Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

Description of the new tobacco products

Description of the predicate tobacco products

List of all differences in characteristics between the new and predicate tobacco products

Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health

Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us.