



September 19, 2022

## **SUBSTANTIALLY EQUIVALENT**

Philip Morris USA Inc.  
Attention: Rebecca A. Rivas, Senior Director, Regulatory Submissions  
Altria Client Services LLC  
601 East Jackson Street  
Richmond, VA 23219

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

Dear Rebecca A. 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 pre-existing tobacco products in SE0018021.PD1, SE0018022.PD1, SE0016688.PD1, SE0016996.PD1-SE0016999.PD1, SE0016964.PD1, SE0017241.PD1, and SE0016868.PD1. Although the new products have different characteristics than the pre-existing tobacco products in SE0018021.PD1, SE0018022.PD1, SE0016688.PD1, SE0016996.PD1-SE0016999.PD1, SE0016964.PD1, SE0017241.PD1, and SE0016868.PD1, 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 pre-existing products in SE0018021.PD1, SE0018022.PD1, SE0016688.PD1, SE0016996.PD1-SE0016999.PD1, SE0016964.PD1, SE0017241.PD1, and SE0016868.PD1.

If you have any questions, please contact Rida Tariq, M.H.A, Regulatory Health Project Manager, at (301) 348-1830 or [Rida.Tariq@fda.hhs.gov](mailto:Rida.Tariq@fda.hhs.gov).

Sincerely,

**Todd L. Cecil -S**

Digitally signed by Todd L. Cecil

-S

Date: 2022.09.19 11:52:14

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Todd L. Cecil, Ph.D.  
Acting Director  
Office of Science  
Center for Tobacco Products

**Enclosures (if provided electronically, the Appendix is not included in physical mail):**

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

Appendix B – Health Information Summary

**Appendix A<sup>3,4,5</sup>**

## New and Corresponding Predicate Tobacco Products Subject of This Letter

<b>Common Attributes of SE Reports</b>		
Submission date	June 15, 2020 <sup>6</sup> , July 17, 2020 <sup>7</sup> , July 31, 2020 <sup>8</sup> , August 3, 2020 <sup>9</sup> , August 14, 2020 <sup>10</sup> , September 3, 2020 <sup>11</sup>	
Receipt date	June 15, 2020 <sup>5</sup> , July 17, 2020 <sup>6</sup> , July 31, 2020 <sup>7</sup> , August 3, 2020 <sup>8</sup> , August 14, 2020 <sup>9</sup> , September 3, 2020 <sup>10</sup>	
Product manufacturer	Philip Morris USA Inc.	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
<b>Attributes</b>	<b>New Tobacco Product</b>	<b>Predicate Tobacco Product</b>
STN	SE0016688	GF1200269
Static Product ID	PD1	Not Applicable
Product Name	Marlboro Blend No. 27 100's Box	Chesterfield 100's Lights Box
Eligibility Status	Not Applicable (N/A)	Grandfathered
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.89 millimeters (mm)	7.89 mm
Product Length	98.5 mm	98.5 mm
Ventilation	28%	28%
Nicotine Source	Tobacco	Tobacco
STN	SE0016868	SE0015500
Static Product ID	PD1	Not Applicable
Product Name	L&M Turkish Blend Box	L&M Turkish Blend Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.89 mm	7.89 mm
Product Length	83 mm	83 mm
Ventilation	23%	23%
Nicotine Source	Tobacco	Tobacco

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

<sup>4</sup> Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. As such, nicotine source is considered a required property for unique identification.

<https://www.congress.gov/bill/117th-congress/house-bill/2471>

<sup>5</sup> Previously, FDA used the term "grandfathered product" to describe a product that was commercially marketed in the United States (other than in a test market) on or before February 15, 2007. However, since the publication of the SE rule that became effective November 4, 2021, FDA shifted product terminology from "grandfathered" to "pre-existing" for tobacco products.

<sup>6</sup> For SE0016688.PD1

<sup>7</sup> For SE0016868.PD1

<sup>8</sup> For SE0016964.PD1

<sup>9</sup> For SE0016996.PD1-SE0016999.PD1

<sup>10</sup> For SE0017241.PD1

<sup>11</sup> For SE0018021.PD1 and SE0018022.PD1

Attributes	New Tobacco Product	Predicate Tobacco Product
STN	SE0016964	SE0015306
Static Product ID	PD1	N/A
Product Name	Marlboro Menthol Smooth 100's Box	Marlboro Menthol Black Special Blend 100's Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Product Length	98.5 mm	98 mm
Ventilation	15%	16%
Nicotine Source	Tobacco	Tobacco
Additional Property	N/A	Tipping Paper 2
STN	SE0016996	SE0015316
Static Product ID	PD1	N/A
Product Name	Marlboro Edge Box	Marlboro Edge Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.89 mm	7.89 mm
Product Length	83 mm	83 mm
Ventilation	17%	17%
Nicotine Source	Tobacco	Tobacco
STN	SE0016997	SE0015309
Static Product ID	PD1	N/A
Product Name	Marlboro Menthol 100's Box	Marlboro Menthol Black Special Blend 100's Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Product Length	98 mm	98 mm
Ventilation	18%	16%
Additional Property	Tipping Paper 1	Tipping Paper 1
Nicotine Source	Tobacco	Tobacco

<b>Attributes</b>	<b>New Tobacco Product</b>	<b>Predicate Tobacco Product</b>
STN	SE0016998	SE0015306
Static Product ID	PD1	N/A
Product Name	Marlboro Menthol 100's Box	Marlboro Menthol Black Special Blend 100's Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Product Length	98 mm	98 mm
Ventilation	18%	16%
Additional Property	Tipping Paper 2	Tipping Paper 2
Nicotine Source	Tobacco	Tobacco
STN	SE0016999	SE0015305
Static Product ID	PD1	N/A
Product Name	Marlboro Menthol 100's Box	Marlboro Menthol Black Special Blend 100's Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Product Length	98 mm	98 mm
Ventilation	18%	16%
Additional Property	Tipping Paper 3	Tipping Paper 3
Nicotine Source	Tobacco	Tobacco
STN	SE0017241	SE0014444
Static Product ID	PD1	N/A
Product Name	Marlboro Menthol Special Blend 100's Box	Marlboro Menthol Gold Pack 100's Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Product Length	98.5 mm	98.5 mm
Ventilation	26%	33%
Nicotine Source	Tobacco	Tobacco

<b>Attributes</b>	<b>New Tobacco Product</b>	<b>Predicate Tobacco Product</b>
STN	SE0018021	SE0015665
Static Product ID	PD1	N/A
Product Name	Marlboro Special Select (Gold Pack) Box	Marlboro Special Select (Gold Pack) Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	None	None
Diameter	7.89 mm	7.89 mm
Product Length	83 mm	84 mm
Ventilation	23%	23%
Nicotine Source	Tobacco	Tobacco
STN	SE0018022	SE0015727
Static Product ID	PD1	N/A
Product Name	Chesterfield Menthol 100's Box	Chesterfield Menthol 100's Box
Eligibility Status	N/A	Previously found SE
Package Type	Hard Pack	Hard Pack
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing Flavor	Menthol	Menthol
Diameter	7.89 mm	7.89 mm
Product Length	98 mm	99 mm
Ventilation	None	None
Nicotine Source	Tobacco	Tobacco

## **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.