U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

June 19, 2020

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 Number (STN): SE0015781**,** see Appendix A

Dear Ms. Rivas:

We completed our review of your SE Report[1] and determined that the new tobacco product is substantially equivalent to the predicate tobacco product listed in Appendix A[2] and is 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 product subject of this letter.

Our finding does not mean we "approved" the new product specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco product 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 product 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 product specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

[1] Substantially Equivalent (SE) Report submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
[2] In addition to comparing the new tobacco product to the predicate tobacco product named by the applicant, FDA also compared the new tobacco product in SE0015781 to the grandfathered tobacco product in SE0015059. Although the new product has different characteristics than the grandfathered tobacco product SE0015059, FDA found that those differences do not cause the new tobacco product to raise different questions of public health, and thus the new tobacco product are also substantially equivalent to the grandfathered product in SE0015059.

If you have any questions, please contact Ryan Nguy, Regulatory Health Project Manager, at (301) 796 – 7079 or Ryan.Nguy@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2020.06.19 12:03:37 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

Enclosures:

Appendix A – New and Predicate Tobacco Products Subject of This Letter
Appendix B – Health Information Summary

Appendix A

New and Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Report		
Date of Submission:	March 20, 2020	
Date of Receipt:	March 20, 2020	
Product Manufacturer:	Philip Morris USA Inc.	
Product Category:	Cigarettes	
Product Sub-Category:	Combusted, Filtered	
	New Tobacco Product	**Predicate Tobacco Product**
	SE0015781: Chesterfield Blue Pack Box[3]	**SE0015059: Chesterfield Blue Pack Box[3]**
Package Type:	Hard Pack	Hard Pack
Package Quantity:	20 cigarettes	20 cigarettes
Characterizing Flavor:	None	None
Eligibility Status:	N/A	Previously Found SE
Length:	83 millimeters (mm)	83 mm
Diameter:[4]	7.89 mm	7.89 mm
Ventilation:	18%	18%

[3] Brand/sub-brand or other commercial name used in commercial distribution.

[4] The applicant submitted the circumference which allowed for a calculation of diameter.

Appendix B

Health Information Summary

Your SE Report did not provide a summary of any health information related to the new tobacco product, required by section 910(a)(4) of the FD&C Act; however, your SE Report 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 Report 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 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]."

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.