

May 14, 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 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 <u>not</u> 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.

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

<sup>&</sup>lt;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 SE0014859 and SE0014914. Although the new products have different characteristics than the grandfathered tobacco products in SE0014859 and SE0014914, 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 SE0014859 and SE0014914.

If you have any questions, please contact Ryan Nguy, Regulatory Health Project Manager, at (301) 796 - 7079 or <a href="mailto:Ryan Nguy@fda.hhs.gov">Ryan Nguy@fda.hhs.gov</a>.

Sincerely,

Digitally signed by Matthew R. Holman -S Date: 2020.05.14 08:37:04 -04'00'

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

Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Quantity: Characterizing Flavor: Eligibility Status: Length: Biameter: Ventilation:  SE0015501: Virginia Slims Box  Package Quantity: Characterizing Flavor: Eligibility Status: None Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Quantity: Characterizing Flavor: And	Common Attributes of SE Reports			
Product Manufacturer: Product Category: Product Sub-Category: Cigarettes Combusted, Filtered    New Tobacco Product   Predicate Tobacco Product	Date of Submission:	September 19, 2019		
Product Category: Product Sub-Category:    New Tobacco Product	Date of Receipt:	September 19, 2019		
Product Sub-Category: Combusted, Filtered    New Tobacco Product   Predicate Tobacco Product	Product Manufacturer:	Philip Morris USA Inc.		
Product Sub-Category: Combusted, Filtered    New Tobacco Product   Predicate Tobacco Product	Product Category:	Cigarettes		
New Tobacco Product   Predicate Tobacco Product   SE0015500: L&M Turkish Blend Box   SE0014914: L&M Turkish Blend Box   SE001431: L&M Turkish Box   SE001431: L&M				
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Package Quantity: Diameter: Ventilation:  Package Type: Package Quantity: Characterizing Flavor:  Hard Pack Package Quantity: Characterizing Flavor:  Hard Pack Package Quantity: Characterizing Flavor:  Hard Pack Package Quantity: Characterizing Flavor:  Menthol  Hard Pack Package Quantity: Characterizing Flavor:  Menthol	-		Predicate Tobacco Product	
Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation: Package Quantity: Characterizing Flavor: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  SE0015501: Virginia Slims Box  SE0015501: Virginia Slims Box  GF1200173: Virginia Slims 100's Box  Fackage Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Package Type: Package Quantity: Characterizing Flavor: Menthol  Diameter: Menthol  Diameter: Menthol		SE0015500: L&M Turkish Blend Box <sup>3</sup>	SE0014914: L&M Turkish Blend Box <sup>3</sup>	
Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Type: Hard Pack Length: Diameter:  None  N/A  83 millimeters (mm)  7.89 mm  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: 98 mm  Diameter: 7.32 mm  7.32 mm  Ventilation: 23%  SE0015502: Marlboro Menthol Slate Box³  Package Type: Package Quantity: Characterizing Flavor: Menthol  None  SE0014859: Marlboro Menthol Slate Box³  Package Quantity: Characterizing Flavor: Menthol  None  Regrandfathered 98 mm  7.32 mm  80°  80°  80°  80°  Package Type: Package Quantity: Characterizing Flavor: Menthol	Package Type:	Hard Pack	Hard Pack	
Eligibility Status: Length: Diameter: Ventilation:  Package Type: Hard Pack Package Quantity: Characterizing Flavor: Eligibility Status: Length:  98 mm  N/A  Previously Found SE  83 mm  7.89 mm  7.80 mm  7.89 mm  Package Type: Hard Pack Package Quantity: Characterizing Flavor: Eligibility Status: Length: 98 mm  7.32 mm  Package Type: Package Type: Box3  Package Type: Hard Pack Package Quantity: Characterizing Flavor: Menthol  Previously Found SE  83 mm  7.89 mm  7.89 mm  Package Type: Package Quantity: Previously Found SE  83 mm  7.89 mm  7.89 mm  7.89 mm  Package Type: Package Quantity: Pa	Package Quantity:	20 Cigarettes	20 Cigarettes	
Length: Diameter: <sup>4</sup> Ventilation:  SE0015501: Virginia Slims Box <sup>3</sup> Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: <sup>4</sup> Ventilation:  SE0015502: Marlboro Menthol Slate Box <sup>3</sup> Package Quantity: Characterizing Flavor:  SE0015502: Marlboro Menthol  Package Quantity: Characterizing Flavor:  SE0014859: Marlboro Menthol Slate Box <sup>3</sup> Package Quantity: Characterizing Flavor:  Menthol  SE0014859: Marlboro Menthol Slate Box <sup>3</sup> Menthol  Menthol	Characterizing Flavor:	None	None	
Diameter:4 Ventilation:  7.89 mm 23%  SE0015501: Virginia Slims Box³  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter:4 Ventilation:  Package Type: Hard Pack 20 Cigarettes None N/A Grandfathered 98 mm 98 mm 98 mm 7.32 mm 7.32 mm 7.32 mm Ventilation:  SE0015502: Marlboro Menthol Slate Box³  Package Type: Package Quantity: Characterizing Flavor: Menthol  N/A Grandfathered 98 mm 7.32 mm 98 mm 7.32 mm 7.32 mm 7.32 mm 98 mm 7.32 mm 7.3	Eligibility Status:	N/A	Previously Found SE	
Ventilation:23%23%SE0015501: Virginia Slims Box³GF1200173: Virginia Slims 100's BoxPackage Type:Hard PackHard PackPackage Quantity:20 Cigarettes20 CigarettesCharacterizing Flavor:NoneNoneEligibility Status:N/AGrandfatheredLength:98 mm98 mmDiameter:47.32 mm7.32 mmVentilation:23%SE0014859: Marlboro Menthol Slate Box³Box³Box³Box³Package Type:Hard Pack 20 CigarettesHard Pack 20 CigarettesPackage Quantity:Characterizing Flavor:Menthol	Length:	83 millimeters (mm)	83 mm	
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Type: Package Quantity: Characterizing Flavor:  Mariboro Menthol Slate Box3  Package Quantity: Characterizing Flavor:  Menthol  Package Quantity: Characterizing Flavor:  Menthol  Package Type: Package Quantity: Characterizing Flavor:  Menthol  Package Type: Package Type: Package Quantity: Characterizing Flavor:  Menthol  Menthol	Diameter:4	7.89 mm	7.89 mm	
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  Package Type: Package Quantity:  SE0015502: Marlboro Menthol Slate Box³  Package Type: Package Quantity: Characterizing Flavor:  Menthol  Hard Pack 20 Cigarettes None None Grandfathered 98 mm 7.32 mm 7.32 mm 7.32 mm 7.32 mm SE0014859: Marlboro Menthol Slate Box³  Package Type: Package Quantity: Characterizing Flavor:  Menthol	Ventilation:	23%	23%	
Package Quantity: Characterizing Flavor: Eligibility Status: Length: Diameter: Ventilation:  SE0015502: Marlboro Menthol Slate Box³  Package Quantity: Characterizing Flavor:  Menthol  20 Cigarettes None None Grandfathered 98 mm 7.32 mm 7.32 mm 7.32 mm 23%  SE0014859: Marlboro Menthol Slate Box³  Package Type: Package Quantity: Characterizing Flavor: Menthol  Menthol		SE0015501: Virginia Slims Box <sup>3</sup>	GF1200173: Virginia Slims 100's Box <sup>3</sup>	
Characterizing Flavor: Eligibility Status: Length: Diameter: 98 mm 7.32 mm 7.32 mm 7.32 mm Ventilation:  SE0015502: Marlboro Menthol Slate Box³  Package Type: Package Quantity: Characterizing Flavor:  None Grandfathered 98 mm 7.32 mm 7.32 mm 550014859: Marlboro Menthol Slate Box³  Hard Pack 20 Cigarettes Menthol Menthol	Package Type:	Hard Pack	Hard Pack	
Eligibility Status: Length: 98 mm 98 mm 7.32 mm 7.32 mm 7.32 mm 7.32 mm Ventilation:  SE0015502: Marlboro Menthol Slate Box³  Package Type: Package Quantity: Characterizing Flavor:  N/A 98 mm 7.32 mm 7.32 mm 5E0014859: Marlboro Menthol Slate Box³  For increase of the pack of the pa	Package Quantity:	20 Cigarettes	20 Cigarettes	
Length: 98 mm 98 mm 7.32 mm 7.32 mm 23%  SE0015502: Marlboro Menthol Slate Box³  Package Type: Hard Pack Package Quantity: Characterizing Flavor: Menthol  Menthol  98 mm 7.32 mm 8.00 mathol Slate 8.00 mathol Sl	Characterizing Flavor:	None	None	
Diameter: <sup>4</sup> Ventilation:  23%  SE0015502: Marlboro Menthol Slate Box <sup>3</sup> Package Type: Package Quantity: Characterizing Flavor:  7.32 mm 23%  SE0014859: Marlboro Menthol Slate Box <sup>3</sup> Hard Pack 20 Cigarettes Menthol  Menthol	Eligibility Status:	N/A	Grandfathered	
Ventilation:     23%       SE0015502: Marlboro Menthol Slate Box³       Package Type:     Hard Pack       Package Quantity:     20 Cigarettes       Characterizing Flavor:     Menthol	Length:	98 mm	98 mm	
SE0015502: Marlboro Menthol Slate Box³  Package Type: Hard Pack Package Quantity: 20 Cigarettes Characterizing Flavor: Menthol Slate Box³  Hard Pack 20 Cigarettes Menthol	Diameter:4	7.32 mm	7.32 mm	
Box³     Box³       Package Type:     Hard Pack     Hard Pack       Package Quantity:     20 Cigarettes     20 Cigarettes       Characterizing Flavor:     Menthol     Menthol	Ventilation:	23%	23%	
Package Type:     Hard Pack       Package Quantity:     20 Cigarettes       Characterizing Flavor:     Menthol   Hard Pack 20 Cigarettes Menthol		SE0015502: Marlboro Menthol Slate	SE0014859: Marlboro Menthol Slate	
Package Quantity: 20 Cigarettes 20 Cigarettes Characterizing Flavor: Menthol Menthol		Box <sup>3</sup>	Box <sup>3</sup>	
Characterizing Flavor: Menthol Menthol	Package Type:	Hard Pack	Hard Pack	
	Package Quantity:	20 Cigarettes	20 Cigarettes	
Fligibility Status: N/A Previously Found SF	Characterizing Flavor:	Menthol	Menthol	
	Eligibility Status:	N/A	Previously Found SE	
Length: 83 mm 83 mm	Length:	83 mm	83 mm	
Diameter: 4 7.89 mm 7.89 mm	Diameter:4	7.89 mm	7.89 mm	
Ventilation: 23% 23%	Ventilation:	23%	23%	
SE0015503: Benson & Hedges 100's GF1200128: Benson & Hedges 100's		SE0015503: Benson & Hedges 100's	GF1200128: Benson & Hedges 100's	
Menthol Box <sup>3</sup> Menthol Box <sup>3</sup>		Menthol Box <sup>3</sup>	Menthol Box <sup>3</sup>	
Package Type: Hard Pack Hard Pack	Package Type:	Hard Pack	Hard Pack	
Package Quantity: 20 Cigarettes 20 Cigarettes	Package Quantity:	20 Cigarettes	20 Cigarettes	
Characterizing Flavor: Menthol Menthol	Characterizing Flavor:	Menthol	Menthol	
Eligibility Status: N/A Grandfathered	Eligibility Status:	N/A	Grandfathered	
Length: 98 mm 98 mm	Length:	98 mm	98 mm	
Diameter: <sup>4</sup> 7.89 mm 7.89 mm	Diameter:4	7.89 mm	7.89 mm	
Ventilation: 26% 26%	Ventilation:	26%	26%	

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

<sup>&</sup>lt;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.