



January 19, 2022

EXEMPT

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

FDA Submission Tracking Numbers (STNs): EX0001634.PD1 - EX0001637.PD1

Dear Rebecca Rivas:

We completed review of your EX REQ¹s and determined that the new tobacco products listed in Appendix A are exempt from the requirements of Substantial Equivalence.²

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).

To market the new tobacco products that are the subject of these EX REQs, the following must be met:

- 1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and**
- 2. Ninety days have passed since FDA receipt of your Abbreviated Report.**

See Appendix B for FDA’s recommended format for submitting of an Abbreviated Report.

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 comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Requests for Exemption from Substantial Equivalence (EX REQs) submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

² See section 910(a)(3)(a) of the FD&C Act

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{3,4} using eSubmitter.⁵ Alternatively, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA's Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date⁶; if the due date falls on a weekend or holiday, the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, please contact Rida Tariq, Regulatory Health Project Manager, at (301) 348 - 1830 or Rida.Tariq@fda.hhs.gov.

Sincerely,

Digitally signed by Todd L. Cecil -S
Date: 2022.01.19 11:51:14 -05'00'

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

Enclosures:

Appendix A – New and Corresponding Original Tobacco Products Subject of This Letter
Appendix B – FDA's Recommended Format for Submitting an Abbreviated Report

³ For more information about CTP Portal, see <https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

⁴ FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

⁵ For more information about eSubmitter, see <http://www.fda.gov/ForIndustry/FDAeSubmitter>

⁶ <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

Appendix A⁷

New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes of EX REQs		
Submission date	February 26, 2021	
Receipt date	February 26, 2021	
Applicant	Philip Morris USA Inc.	
Product manufacturer	Philip Morris USA Inc.	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Product	Original Product
STN	EX0001634	SE0015757
Product name	Virginia Slims Superslims Menthol Box	Virginia Slims Superslims Menthol Box
Eligibility status	Not Applicable (N/A)	Previously found SE
Marketing authorization date	N/A	June 3, 2020
Abbreviated report date	N/A	N/A
Package type	Hard Pack	Hard Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Ventilation	70.0 %	70.0 %
Diameter ^{8,9}	5.41 millimeters (mm)	5.41 mm
Length	98.0 mm	98.0 mm
Additional Property	Tipping Paper 1	N/A
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of a tipping paper¹⁰ (32 mm) • Addition of a tipping paper¹⁰ (32 mm) 	

⁷ Brand/sub-brand or other commercial name used in commercial distribution.

⁸ The applicant submitted the circumference which allowed for a calculation for diameter.

⁹ The diameter = [circumference]/ π where $\pi = 3.14$

¹⁰ Supplier of the tipping papers or their target masses were not provided

Attributes	New Product	Original Product
STN	EX0001635	SE0015483
Product name	Virginia Slims Superslims Box	Virginia Slims Superslims Box
Eligibility status	N/A	Previously found SE
Marketing authorization date	N/A	May 22, 2020
Abbreviated report date	N/A	N/A
Package type	Hard Pack	Hard Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Ventilation	68.0 %	68.0 %
Diameter ^{8,9}	5.41 mm	5.41 mm
Length	98.0 mm	98.0 mm
Additional Property	Tipping Paper 2	N/A
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of a tipping paper¹⁰ (32 mm) • Addition of a tipping paper¹⁰ (32 mm) 	
Attributes	New Product	Original Product
STN	EX0001636	SE0015757
Product name	Virginia Slims Superslims Menthol Box	Virginia Slims Superslims Menthol Box
Eligibility status	N/A	Previously found SE
Marketing authorization date	N/A	June 3, 2020
Abbreviated report date	N/A	N/A
Package type	Hard Pack	Hard Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Ventilation	70.0 %	70.0 %
Diameter ^{8,9}	5.41 mm	5.41 mm
Length	98.0 mm	98.0 mm
Additional Property	Tipping Paper 2	N/A
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of a tipping paper¹⁰ (32 mm) • Addition of a tipping paper¹⁰ (32 mm) 	

Attributes	New Product	Original Product
STN	EX0001637	SE0015483
Product name	Virginia Slims Superslims Box	Virginia Slims Superslims Box
Eligibility status	N/A	Previously found SE
Marketing authorization date	N/A	May 22, 2020
Abbreviated report date	N/A	N/A
Package type	Hard Pack	Hard Pack
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Ventilation	68.0 %	68.0 %
Diameter ^{8,9}	5.41 mm	5.41 mm
Length	98.0 mm	98.0 mm
Additional Property	Tipping Paper 1	N/A
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of a tipping paper¹⁰ (32 mm) • Addition of a tipping paper¹⁰ (32 mm) 	

Appendix B

FDA's Recommended Format for Submitting an Abbreviated Report

Mock-up Tobacco Company

April 3, 2015

US Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Abbreviated Report

To Whom It May Concern:

Mock-Up Tobacco Company provides this Abbreviated Report at least 90 days prior to the introduction or delivery for introduction into interstate commerce for commercial distribution of the new product, Cigarette Brand A. We submitted an Exemption Request (EX0000XXX) under section 905(j)(3) for the new product on February 1, 2015, and received a found exempt order from FDA on March 20, 2015.

I, John Doe, on behalf of Mock-Up Tobacco Company, certify that Cigarette Brand A is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, all the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3), and I have taken actions to comply with the requirements under section 907 that are applicable to the product. I certify that this information is true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Sincerely,
John Doe **[ink or digital signature]**
Vice President
Mock-Up Tobacco Company