

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001634.PD1 - EX0001637.PD1
Common Attributes	
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
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

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Date: 2022.01.18 18:40:49 -05'00'

Delshanee Kotandeniya, Ph.D.
Chemistry Team Supervisor
Office of Science/ Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2022.01.19 08:50:23 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

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1. BACKGROUND

1.1. NEW AND ORIGINAL PRODUCTS

The applicant submitted information for the new and original products listed in detail in Appendix A.

1.2. REGULATORY ACTIVITY

On February 26, 2021, FDA received Exemption Requests (EX REQs) from Philip Morris USA Inc. On May 19, 2021, FDA issued an Acceptance letter.

See appendix for products.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1	
	Reviewer(s)	Review Date
Regulatory	Grace Kaiyuan	5/19/2021
Chemistry	Norman Fraley	1/14/2022
Environmental science	Chad H. Baisden	7/8/2021

2. COMPLIANCE REVIEW

The original products in EX0001634.PD1, EX0001635.PD1, EX0001636.PD1, and EX0001637.PD1 were determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA. Therefore, the original products are eligible for modification under the Exemption Request pathway.¹

3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modifications of the original products compared to the corresponding new products are the result of:

- deleting an additive (tipping paper) in all the EX Requests
- adding an additive (tipping paper) in all the EX Requests

¹ Any product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

4. SCIENTIFIC REVIEW

The review finds these modified ingredients (see Section 3) are additives because their intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the products. The review concludes that the modifications are minor modifications of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on January 14, 2022. The FONSI was supported by an environmental assessment prepared by FDA on January 14, 2022.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are a minor modification of a product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are “additives” as defined in section 900(1) of the FD&C Act. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new products to be marketed would be appropriate for the protection of the public health.

The original products were previously determined to be substantially equivalent under section 910(a)(2)(A)(i) of the FD&C Act (SE0015757 for EX0001634.PD1 and EX0001636.PD1; SE0015483 for EX0001635.PD1 and EX0001637.PD1). The information in these SE Reports show that the tipping paper component of the previously found SE products have base paper, tipping ink, extender and lip release. This means that the tipping paper component of the original products in EX0001634.PD1, EX0001635.PD1, EX0001636.PD1, and EX0001637.PD1 should also contain base paper, tipping ink, extender and lip release. All EX Reports are lacking information on the lip release. EX0001634.PD1 and EX0001637 both lack information on the base paper and EX0001634.PD1 and EX0001636.PD1 lack information on the tipping extender. However, in Section 5 of the EX Requests, the applicant states “...all other characteristics of the Modified Product remain the same as the Market Order Product”. Since section 910(B) of the FD&C Act defines the term “characteristic” as “any materials, ingredients, design composition, heating source, or other features of a tobacco product”, we interpret the applicant’s statements to mean only certain components of the original products were being modified and all other components remain identical to their corresponding original products. In EX0001634.PD1 - EX0001637.PD1, the differences between the ingredients of tipping inks (e.g., ethyl alcohol, ethyl acetate, butyl acetate, isopropyl alcohol, N-propanol, isopropyl acetate, titanium dioxide, polyvinyl acetate, triacetin, talc, nitrocellulose, Pigment blue 15, Pigment yellow 17, aluminum, copper, zinc, polystyrene, octadecanoic acid, aromatic hydrocarbon resin and hydrogenated methyl esters of resin and rosin acids) in the new products and those in the corresponding original products are less than 0.032 mg/cigarette and therefore considered small. Therefore, the changes in tipping ink would not result in a measurable change in HPHC smoke yields. The applicant provided information on the base paper modification for EX0001635.PD1 and EX0001636.PD1. The difference between the ingredients (e.g., calcium carbonate, cellulose pulp, titanium dioxide) of the base paper is less than 0.85 mg/cigarette. For EX0001635.PD1 and EX0001636.PD1, the weight of the base paper in the new and corresponding original products have identical target specifications of (b) (4) mg/cigarette. Therefore, any small changes in base paper ingredients as described above is not expected to result in measurable changes in HPHC yields. The

applicant provided information on the extender for the new and original products for EX0001635.PD1 and EX0001637.PD1, where the extender is deleted. Removal of extender ingredients from the tipping paper is not expected to result in changes in HPHC yields.

As TPL, I agree that the differences in the ingredients of tipping inks in EX0001634.PD1, EX0001635.PD1, EX0001636.PD1, and EX0001637.PD1; differences in ingredients of base paper in EX0001635.PD1 and EX0001636.PD1; and the deletion of the extender in EX0001635.PD1 and EX0001637.PD1 are considered minor modifications in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I find that an exemption for these modifications are otherwise appropriate as required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products were previously found SE and in compliance with the FD&C Act by FDA.

FDA has examined the environmental effects of finding the new products exempt and made a finding of no significant impact.

An exempt order should be issued for the new products, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original products

Common Attributes		
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.PD1	SE0015757
Product name	Virginia Slims Superslims Menthol Box ²	Virginia Slims Superslims Menthol Box ²
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 ^{3, 4}	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 tipping paper⁵, (32 mm) • Addition of tipping paper⁵, (32 mm) 	

² Brand/sub-brand or other commercial name used in commercial distribution.

³ The applicant submitted the circumference which allowed for a calculation of diameter.

⁴ The diameter = [circumference]/ π where $\pi = 3.14$

⁵ Supplier of the tipping papers or their target masses were not provided

Attributes	New Product	Original Product
STN	EX0001635.PD1	SE0015483
Product name	Virginia Slims Superslims Box ²	Virginia Slims Superslims Box ²
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 ^{3,4}	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 tipping paper⁵, (32 mm) • Addition of tipping paper⁵, (32 mm) 	
Attributes	New Product	Original Product
STN	EX0001636.PD1	SE0015757
Product name	Virginia Slims Superslims Menthol Box ²	Virginia Slims Superslims Menthol Box ²
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 ^{3,4}	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 tipping paper⁵, (32 mm) • Addition of tipping paper⁵, (32 mm) 	

Attributes	New Product	Original Product
STN	EX0001637.PD1	SE0015483
Product name	Virginia Slims Superslims Box ²	Virginia Slims Superslims Box ²
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 ^{3,4}	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 tipping paper⁵, (32 mm) • Addition of tipping paper⁵, (32 mm) 	