

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001393-PD1, EX0001394-PD1 and EX0001396-PD1
Common Attributes	
Submission date	December 21, 2020
Receipt date	December 21, 2020
Applicant	R.J. Reynolds Tobacco Company
Product manufacturer	R.J. Reynolds Tobacco Company
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):

Digitally signed by Matthew J. Walters -S3
Date: 2021.05.28 11:41:10 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Division Director
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Matthew R. Holman -S
Date: 2021.05.28 12:50:32 -04'00'

For 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 the Appendix.

1.2. REGULATORY ACTIVITY

See appendices for products and amendments.

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	
	Reviewers	Review Date
regulatory	Camille Hayslett	12/31/2020
chemistry	Mona Shrestha	3/31/2021
environmental science	Thomas Creaven	3/8/2021

2. COMPLIANCE REVIEW

For EX0001393-PD1, the original product was determined to be exempt from the requirements of section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to the demonstration of substantial equivalence by FDA. A report under section 905(j)(1)(A)(ii) (Abbreviated Report) was submitted, and at least 90 days have elapsed since receipt of the Abbreviated Report by FDA. For EX0001394-PD1 and EX0001396-PD1, the original products 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 (menthol capsule) in EX0001394-PD1 and EX0001396-PD1
- adding an additive (menthol capsule) in EX0001394-PD1 and EX0001396-PD1
- increasing the quantity of an existing additive (b) (4) in EX0001394-PD1 and EX0001396-PD1
- deleting an additive (tipping paper adhesive) in EX0001393-PD1
- adding an additive (tipping paper adhesive) in EX0001393-PD1

¹ Any tobacco 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.

- deleting an additive (b) (4) in EX0001393-PD1
- adding an additive (b) (4) in EX0001393-PD1
- increasing the quantities of existing additives (b) (4) in EX0001393-PD1

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 April 5, 2021. The FONSI was supported by an environmental assessment prepared by FDA on April 5, 2021.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications 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. For EX0001393-PD1, the applicant intends to delete tipping paper adhesive in the original product and add an alternate tipping paper adhesive in the new products which is a minor modification. These adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase in content between these adhesives of the new and original product is not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original product. In addition, the deletion of the flavor ingredient of (b) (4) and addition of (b) (4) with an increase of the existing additives of (b) (4) and (b) (4) in the tobacco casing are minor modifications that are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. For EX0001394-PD1 and EX0001396-PD1, the applicant proposes to delete a menthol capsule in the filter and add an alternate menthol capsule which is not expected to have any significant effects on product chemistry or a change in characterizing flavor. This modification resulted in a decrease in (b) (4) and the menthol capsule in the filter is not combusted or volatilized; and the modification of this ingredient in the non-combusted materials is not expected to significantly alter the HPHC smoke chemistry. Additionally, for these EX Requests, the applicant proposes to increase the quantity of (b) (4) (b) (4) of the new tobacco products. However, the total menthol inclusion level in the new tobacco products is (b) (4) of the total weight and remains comparable between the two sets of products (i.e., new and original) and does not raise a concern from a chemistry perspective. The increase in the quantity of (b) (4) (b) (4) is not expected to materially affect any other characteristics (e.g., materials, ingredients, design, composition, heating source, or other features) of the new tobacco products. Lastly, I find that an exemption for these modifications is otherwise appropriate as

required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new tobacco 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 previously found Exempt by FDA, a report under section 905(j)(1)(A)(ii) (Abbreviated Reports) was submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Reports or 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. APPENDIX

Appendix A. New and original products

Common Attributes of EX REQs		
Submission date	December 21, 2020	
Receipt date	December 21, 2020	
Applicant	R.J. Reynolds Tobacco Company	
Product manufacturer	R.J. Reynolds Tobacco Company	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Product	Original Product
STN	EX0001393-PD1	EX0000665
Product name	Camel Royal Box	Camel Royal
Eligibility status	Not Applicable	Previously found EX
Marketing authorization date	Not Applicable	February 13, 2020
Abbreviated report date	Not Applicable	March 31, 2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	24%	24%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) • Deletion of (b) (4) • Addition of (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) and (b)(4) 	

Attributes	New Product	Original Product
STN	EX0001394 - PD1	SE0014763
Product name	Camel Crush Smooth Menthol Box	Camel Crush Smooth Menthol
Eligibility status	Not Applicable	Previously found SE
Marketing authorization date	Not Applicable	December 21, 2018
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor ¹	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Additional Property	Crushable Menthol Capsule in Filter	Crushable Menthol Capsule in Filter
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of menthol capsule from the filter (b) (4) • Addition of menthol capsule in the filter (b) (4) Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) 	
STN	EX0001396-PD1	SE0014764
Product name	Camel Crush Smooth Menthol Silver Box	Camel Crush Smooth Menthol Silver
Eligibility status	Not Applicable	Previously found SE
Marketing authorization date	Not Applicable	December 21, 2018
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor ¹	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Additional Property	Crushable Menthol Capsule in Filter	Crushable Menthol Capsule in Filter
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of menthol capsule from the filter (b) (4) • Addition of menthol capsule in the filter (b) (4) Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) (b) (4) 	

¹ Characterizing flavor as indicated by the applicant