

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001299-PD1, EX0001300-PD1, EX0001306-PD1, EX0001307-PD1, EX0001313-PD1, and EX0001314-PD1
Common Attributes	
Submission date	September 24, 2020, ¹ October 12, 2020, ² and October 27, 2020 ³
Receipt date	September 24, 2020, ¹ October 12, 2020, ² and October 27, 2020 ³
Applicant	R.J. Reynolds Tobacco Company
Product manufacturer	R.J. Reynolds Tobacco Company
Product category	Cigarettes
Product subcategory	Combusted, Filtered
Cross-Referenced Submissions	
All EX Requests	None
Supporting FDA Memoranda Relied Upon in this Review	
All EX Requests	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: 2021.01.04 13:54:05 -05'00'

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 Todd L. Cecil -S
Date: 2021.01.04 14:23:21 -05'00'

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

¹ EX0001299-PD1 and EX0001300-PD1

² EX0001306-PD1 and EX0001307-PD1

³ EX0001313-PD1 and EX0001314-PD1

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1. BACKGROUND

1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

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

1.2. REGULATORY ACTIVITY

See appendices for tobacco products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1: Reviewers	Review Date
regulatory	Fatima Sow	10/16/2020 ¹
	Kekeli Messan	11/6/2020 ²
	Sarah Amyot	11/18/2020 ³
chemistry	Sandra Salido	12/7/2020
environmental science	Thomas Creaven	12/4/2020

2. COMPLIANCE REVIEW

The original tobacco products in EX0001299-PD1, EX0001300-PD1, EX0001306-PD1, and EX0001307-PD1 were 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. Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted, and at least 90 days have elapsed since receipt of the Abbreviated Reports by FDA. The original tobacco products in EX0001313-PD1 and EX0001314-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 tobacco products are eligible for modification under the Exemption Request pathway.⁴

3. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive (menthol capsule in filter) in all EX Requests
- adding an additive (alternative menthol capsule in filter) in all EX Requests
- increasing the quantity of an existing additive (b)(4) applied to the filter tow) in EX0001313-PD1 and EX0001314-PD1

⁴ 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.

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 tobacco products. The review concludes that the modifications are minor modifications of a tobacco 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 December 4, 2020. The FONSI was supported by an environmental assessment prepared by FDA on December 4, 2020.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications of a tobacco 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 tobacco products to be marketed would be appropriate for the protection of the public health. The applicant proposes for all EX Requests to delete a menthol capsule in the filler 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 menthol 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 EX0001313-PD1 and EX0001314-PD1 only, the applicant proposes to increase the quantity of (b)(4) in the filter tow of the new tobacco products. However, the total menthol inclusion level in the new tobacco products is 0.5% 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) in the filter tow 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 tobacco products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original tobacco products are previously found Exempt by FDA, reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Reports or are previously found SE and in compliance with the FD&C Act by FDA.

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

An exempt order should be issued for the new tobacco products in EX0001299-PD1, EX0001300-PD1, EX0001306-PD1, EX0001307-PD1, EX0001313-PD1, and EX0001314-PD1, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes of EX REQs		
Submission date	September 24, 2020, ¹ October 12, 2020, ² and October 27, 2020 ³	
Receipt date	September 24, 2020, ¹ October 12, 2020, ² and October 27, 2020 ³	
Applicant	R.J. Reynolds Tobacco Company	
Product manufacturer	R.J. Reynolds Tobacco Company	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001299-PD1	EX0000907
Product name	Camel Crush Switch Blue Box	Camel Crush Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	2/14/2020
Abbreviated report date	Not Applicable	4/22/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of menthol capsule from the filter (b)(4) • Addition of alternative menthol capsule in the filter (b)(4) (b)(4)	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001300-PD1	EX0001016
Product name	Camel Crush Switch Red Box	Camel Crush Rich Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	4/23/2020
Abbreviated report date	Not Applicable	7/1/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of menthol capsule from the filter (b)(4) • Addition of alternative menthol capsule in the filter (b)(4) 	
STN	EX0001306-PD1	EX0001016
Product name	Camel Crush Switch Red Box	Camel Crush Rich Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	4/23/2020
Abbreviated report date	Not Applicable	7/1/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of menthol capsule from the filter (b)(4) • Addition of alternative menthol capsule in the filter (b)(4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001307-PD1	EX0000907
Product name	Camel Crush Switch Blue Box	Camel Crush Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	2/14/2020
Abbreviated report date	Not Applicable	4/22/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of menthol capsule from the filter (b)(4) • Addition of alternative menthol capsule in the filter (b)(4) 	
STN	EX0001313-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	12/21/2018
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of menthol capsule from the filter (b)(4) • Addition of alternative menthol capsule in the filter (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase the quantity of (b)(4) applied to the filter tow 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001314-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	12/21/2018
Abbreviated report date	Not Applicable	Not Applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 mm
Ventilation	32%	32%
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of menthol capsule from the filter (b)(4) • Addition of alternative menthol capsule in the filter (b)(4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase the quantity of (b)(4) applied to the filter tow 	