

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001392-PD1 and EX0001395-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):

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

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 ¹
environmental science	Thomas Creaven	3/8/2021

Table 2. Consultations

Discipline	Reviewer	Review Date
social science	Lisa Lagasse	3/29/2021 ²

2. COMPLIANCE REVIEW

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.³

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 (white tipping paper) in all EX Requests
- adding an additive (white tipping paper) in in all EX Requests
- deleting an additive (menthol capsule) in all EX Requests
- adding an additive (menthol capsule) in all EX Requests
- adding an additive ((b) (4)) in all EX Requests

¹ A chemistry addendum to the review was completed on July 6, 2021 to update the chemistry findings.

² A social science addendum to the consult was completed on July 6, 2021 to update the social science findings.

³ 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.

- increasing the quantity of an existing additive (tipping paper adhesive) in all EX Requests

4. SCIENTIFIC REVIEW¹

The chemistry review (March 31, 2021) with addendum (July 6, 2021) 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 chemistry review (March 31, 2021) 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 May 21, 2021. The FONSI was supported by an environmental assessment prepared by FDA on May 21, 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. The applicant proposes the deletion of white tipping paper and the addition of an alternate white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. The applicant also intends to increase the quantity of the tipping paper adhesive in the new product compared to the original product. The tipping paper 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 products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original product. 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 menthol. The menthol capsule in the filter is not combusted or volatilized and as a result, 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 intends to (b) (4)

[REDACTED], which is not expected to materially affect any other characteristics (e.g., materials, ingredients, design, composition, heating source, or other features) of the new 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 products

¹ When referring to reviews in this TPL, I am referring to the chemistry review (dated March 31, 2021) and the social science consult (dated March 29, 2021), with their respective addenda (dated July 6, 2021).

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 are 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	EX0001392-PD1	SE0006134
Product name	Camel Crush Smooth Menthol Silver Box	Camel Crush
Eligibility status	Not Applicable	Previously found SE
Marketing authorization date	Not Applicable	August 7, 2019
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%
Additional Property	Crushable Menthol Capsule in Filter	Crushable Menthol Capsule in Filter
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper ((b) (4) [REDACTED]; [REDACTED] MM]; target: ((b) (4) mg/cigarette) • Addition of white tipping paper ((b) (4) [REDACTED] [REDACTED] MM]; target: ((b) (4) mg/cigarette) • Deletion of menthol capsule from the filter ((b) (4) [REDACTED]) • Addition of menthol capsule in the filter ((b) (4) [REDACTED]) • ((b) (4) [REDACTED]) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of tipping paper adhesive ((b) (4) [REDACTED]) 	

Attributes	New Product	Original Product
STN	EX0001395 - PD1	SE0006134
Product name	Camel Crush Smooth Menthol Silver Box	Camel Crush
Eligibility status	Not Applicable	Previously found SE
Marketing authorization date	Not Applicable	August 7, 2019
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%
Additional Property	Crushable Menthol Capsule in Filter	Crushable Menthol Capsule in Filter
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper ((b) (4) MM]; target: (b) (4) mg/cigarette) • Addition of white tipping paper ((b) (4) MM]; target: (b) (4) mg/cigarette) • Deletion of menthol capsule from the filter ((b) (4) .) • Addition of menthol capsule in the filter ((b) (4)) • ((b) (4)) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increasing the quantity of tipping paper adhesive ((b) (4)) 	