

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review ¹	
Submission tracking numbers (STNs)	EX0002025.PD1 and EX0002026.PD1, see Appendix A
Common Attributes	
Submission date	June 3, 2021
Receipt date	June 3, 2021
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 Delshanee Kotandeniya -S
Date: 2022.06.13 11:34:37 -04'00'

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

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Todd L. Cecil -S Digitally signed by Todd L. Cecil -S
Date: 2022.06.13 13:57:16 -04'00'

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

¹ Product details, amendments, and dates provided in the Appendix. EX means exemption (request) from substantial equivalence. STN means submission tracking number.

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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

	Cycle 1	
Discipline	Reviewer(s)	Review Date
Regulatory	Marieme Ba	6/14/2021
Chemistry	Ethan Englund	5/19/2022
Environmental Science	Bria Martin	5/17/2022

2. COMPLIANCE REVIEW

The original product in EX0002025.PD1 and EX0002026.PD1 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 Reports) was submitted, and at least 90 days have elapsed since receipt of the Abbreviated Report by FDA.

Therefore, the original product is eligible for modification under the Exemption Request pathway.²

3. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive (FSC cigarette paper) in all the EX Requests
- adding an additive (an alternate FSC cigarette paper) in all the EX Requests
- increasing the quantity of an existing additive (tipping adhesive) in all the EX Requests

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

² 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.

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 May 17, 2022. The FONSI was supported by an environmental assessment prepared by FDA on May 17, 2022.

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 to modify both EX Requests by deleting Fire Standard Compliant (FSC) cigarette paper (b) (4) FSC paper) purchased from (b) (4) and adding an alternate FSC cigarette paper ((b) (4) FSC paper) purchased from (b) (4) (EX0002025.PD1), or (b) (4) (EX0002026.PD1). All new products are modified by increasing the quantity of an already existing component, tipping paper adhesive purchased from (b) (4). The purpose of modifying the quantity of tipping paper adhesive in the new products is to improve manufacturing efficiency. The purpose of modifications of FSC cigarette paper in the new products is to provide alternate FSC cigarette papers.

The scientific review determined that the modifications to the FSC cigarette paper in the new product of EX0002025.PD1 results in a small decrease in target mass of (b) (4) mg/cigarette (5.5%) from (b) (4) mg/cigarette in the original product to (b) (4) mg/cigarette in the new product.³ In EX0002026.PD1, the target weight of the FSC cigarette paper is increase (b) (4) mg/cigarette (↑ 12.6%) from (b) (4) mg/cigarette in the original product to (b) (4) mg/cigarette in the new product.⁴ In EX0002025.PD1, the addition of the alternate FSC cigarette paper resulted in chemical ingredient quantity changes such as decreases in (b) (4) (b) (4) mg/cigarette, ↓,19.5%), (b) (4) (b) (4) mg/cigarette, ↓,61.7%), (b) (4) (b) (4) mg/cigarette, ↓,57.9%), and (b) (4) (b) (4) mg/cigarette, ↓,20.6%), and the removal of chemical ingredients such as (b) (4) (b) (4) mg/cigarette), and (b) (4) (b) (4) mg/cigarette) from the original product. In EX0002025.PD1, chemical ingredients such as (b) (4) (b) (4) mg/cigarette), (b) (4) (b) (4) mg/cigarette), (b) (4) (b) (4) mg/cigarette), (b) (4) (b) (4) mg/cigarette), (b) (4) (b) (4) mg/cigarette), and (b) (4) (b) (4) mg/cigarette) are added to the new product. In EX0002026.PD1, the quantities of (b) (4) (b) (4) mg/cigarette, ↓,4%), (b) (4) (b) (4) mg/cigarette,

³ These totals are based on the sum of the ingredient masses the applicant provided and do not match the target mass estimates provided in Table 3 of applicant’s EX Request submission (b) (4) mg/cigarette and (b) (4) mg/cigarette, respectively).

⁴ These totals are based on the sum of the ingredient masses the applicant provided and do not match the target mass estimates provided in Table 3 of applicant’s EX Request submission (b) (4) mg/cigarette and (b) (4) mg/cigarette, respectively).

↓,3%)(b) (4) (b) (4) mg/cigarette, ↓,3%),(b) (4) (b) (4) (b) (4) mg/cigarette, ↓,3%), are reduced, while (b) (4) (b) (4) (b) (4) mg/cigarette) is removed from the original product. In EX0002026.PD1, the quantity of (b) (4) mg/cigarette, ↑3%) is increased while (b) (4) mg/cigarette), (b) (4) mg/cigarette), (b) (4) mg/cigarette), and (b) (4) mg/cigarette) are added to the new product. Therefore, the overall differences between the original FSC cigarette papers and the alternate FSC cigarette papers show very small differences (i.e., ingredient additions and increases were less than 1% of the total mass of the new products) and these differences are not expected to have a significant impact on the product performance or HPHC yields.

The scientific review determined that the modifications to the tipping paper adhesive of both the new products in EX0002025.PD1 and EX0002026.PD1 resulted in (b) (4) mg/cigarette higher (↑1.63% - ↑ 4.2% higher) amounts of total chemical ingredients. The new products contain a buffering agent (b) (4) that remains identical between the new and their corresponding original products and ingredients such as (b) (4) increased in the new products compared to their respective original products. Also, the differences in the tipping paper adhesive quantities between the new and corresponding original products are very small (less than 0.0002% of the total mass of the products) and are not expected to significantly alter the tobacco smoke chemistry. Overall, the increased amount of the tipping paper adhesive is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. Specifically, these modifications are made to the non-combusted component of the cigarette; the tipping paper adhesive is not combusted, volatilized or otherwise released during normal cigarette consumption and consumer exposure to chemical constituents from the tipping paper adhesive is not expected.

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 should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original product (EX0001015) is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original product was 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 Report.

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	June 3, 2021	
Receipt date	June 3, 2021	
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	EX0002025.PD1	EX0001015
Product name	Camel Crush Box ⁵	Camel Crush Box ⁵
Eligibility status	Not applicable (N/A)	Previously found Exempt
Marketing authorization date	N/A	4/23/2020
Abbreviated report date	N/A	7/15/2020
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%
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 Fire Standard Compliant (FSC) cigarette paper (b) (4) FSC]; target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper ((b) (4) (b) (4) FSC]; target: (b) (4) mg/cigarette) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of tipping adhesive (b) (4) target: (b) (4) mg/cigarette) 	
Attributes	New Product	Original Product
STN	EX0002026.PD1	EX0001015
Product name	Camel Crush Box ⁵	Camel Crush Box ⁵
Eligibility status	N/A	Previously found Exempt
Marketing authorization date	N/A	4/23/2020
Abbreviated report date	N/A	7/15/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm

⁵ Brand/sub-brand or other commercial name used in commercial distribution.

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 FSC cigarette paper ((b) (4) (b) (4) FSC]; target: (b) (4) mg/cigarette)• Addition of FSC cigarette paper ((b) (4) FSC]; target (b) (4) mg/cigarette) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none">• Increase in the quantity of tipping adhesive (b) (4) ; target (b) (4) mg/cigarette)	

Appendix B. Amendments

Submission Date	Receipt Date	Applications being amended	Reviewed	Brief Description
April 28, 2022	April 28, 2022	EX0002025.PD1	Yes	Correction or clarification to ingredient amount errors in EX0002025.PD1
April 28, 2022	April 28, 2022	EX0002026.PD1	Yes	Correction or clarification to ingredient amount errors in EX0002026.PD1