FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review[1]	
STNs	EX0002401.PD1 and EX0002401.PD3
Common Attributes	
Submission date	September 16, 2021
Receipt date	September 16, 2021
Applicant	R.J. Reynolds Tobacco Company
Product manufacturer	R.J. Reynolds Tobacco Company
Product category	Cigarette
Product subcategory	Filtered
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	Social Science Evaluation of the Design of Cigarette Tipping Paper (May 16, 2017)
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jikun Liu -S
Date: 2022.10.06 13:14:39 -04'00'

Jikun Liu, 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: 2022.10.14 13:54:34 -04'00'

Todd L. Cecil, Ph.D.
Acting 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.

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	Sequoia Bacon	9/22/2021
Chemistry	Olufisayo Salako	8/26/2022
Environmental Science	Alexander Lowe	8/19/2022

2. COMPLIANCE REVIEW

The original products in EX0002401.PD1 and EX0002401.PD3 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. 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 (white/cork tipping paper) in all the EX Requests
- adding an additive (white tipping paper) in all the EX Requests
- deleting an additive (tipping adhesive) in EX0002401.PD1
- adding an additive (tipping adhesive) in EX0002401.PD1
- deleting an additive ((b) (4)) in EX0002401.PD1
- deleting additives ((b) (4) [redacted] in EX0002401.PD3
- adding an additive ((b) (4) [redacted]) in all the EX Requests
- increasing the quantity of an existing additive ((b) (4) [redacted]) 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.

- decreasing the quantity of an existing additive ((b) (4)) in all the EX Requests
- increasing the quantity of an existing additive ((b) (4)) in EX0002401.PD3

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 August 22, 2022. The FONSI was supported by an environmental assessment prepared by FDA on August 19, 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.

For EX0002401.PD1, the modification to the white tipping paper results in the deletion of [redacted] mg/cigarette) in the new product and a [redacted] mg/cigarette) higher quantity in [redacted] base paper in the new product compared to the original product. For EX0002401.PD3, the modification to the tipping paper results in the deletion of [redacted] ([redacted] mg/cigarette) from the original product and causes the new product to contain [redacted] mg/cigarette) higher level of [redacted] base paper than the original product. Additionally, [redacted] mg/cigarette of [redacted] release will be added to the new product. Lip release agents (e.g., [redacted]) possess hydrophobic characteristics and serve as a moisture barrier to reduce the stickiness and provide a comfortable sensation during cigarette consumption.[2,3] Since the tipping paper does not combust during normal cigarette use and does not release harmful or potentially harmful constituents (HPHCs) to mainstream smoke (MSS), the modifications to the tipping papers for EX0002401.PD1 and EX0002401.PD3 are not expected to significantly alter the smoke chemistry and consumer exposure to HPHCs via the inhalation, oral and dermal routes. Additionally, an internal memorandum from Social Science indicates that consumer behavior such as increased initiation or use solely due to cigarette design are likely to be minimal.[4] Therefore, the proposed modification to the tipping paper is acceptable with respect to social science.

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[2] Lindner M and Schopper E. The power of tactility: tipping paper in interaction with the consumer. *TSRC, Tob Sci Res Conf, 2017, 71, abstr 076 (accessed July 28, 2022)*

[3] Salonen H and Kanervo H, Inventors. Method of Producing a Filter Cigarette with Tipping Paper Having Lip Release Properties. 1995.

[4] Internal Memorandum: Social Science Evaluation of the Design of Cigarette Tipping Paper. May 16, 2017.

The proposed modification to the tipping paper adhesive for EX0002401.PD1 causes the new product to contain (b) (4) mg/cigarette) higher amount of (b) (4) in the new product compared to the corresponding original product. The tipping paper adhesive is not combusted, volatilized, or otherwise released during normal cigarette consumption. Therefore, the modification to the tipping paper adhesive for EX0002401.PD1 is not expected to significantly alter the MSS yields of HPHCs from a chemistry perspective.

For EX0002401.PD1, the applicant proposed to modify the original product by deleting (b) (4) (b) (4) mg/cigarette) and adding (b) (4) (b) (4) mg/cigarette) to the new product. For EX0002401.PD3, the applicant proposed to modify the original product by deleting (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), (b) (4) (b) (4) mg/cigarette), and (b) (4) (b) (4) mg/cigarette) and adding (b) (4) (b) (4) mg/cigarette) to the new product. (b) (4) is a (b) (4) stronger than (b) (4) and has been in common use since 1975.[7] The proposed modifications involving the flavor ingredients and (b) (4) are not expected to significantly affect the MSS yields of HPHCs from the new products compared to the original products and introduce any characterizing flavor to the new products. Furthermore, the applicant proposed to increase (b) (4) (b) (4) and decrease (b) (4) in the new products of both EX REQs and increase (b) (4) in the new product of EX0002401.PD1. Most cigarette (b) (4) and (b) (4) are transferred to smoke intact when heated under the conditions of a burning cigarette; only a small portion of the humectants may be decomposed to acrolein.[8,9] The proposed modification results in a decrease in total nonaqueous humectants (i.e., (b) (4)) up to (b) (4) mg/cigarette for the new products compared to the original products, which is not anticipated to lead to higher levels of smoke HPHC yields in the new products compared to the original products.

Lastly, I find that an exemption for this modification 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 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 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.

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[5] (b) (4)

[6] (b) (4)

[7] (b) (4) .

(b) (4)

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[10,11]

Common Attributes		
Submission date	September 16, 2021	
Receipt date	September 16, 2021	
Applicant	R.J. Reynolds Tobacco Company	
Product manufacturer	R.J. Reynolds Tobacco Company	
Product category	Cigarette	
Product subcategory	Filtered	
Attributes	**New Product**	**Original Product**
STN	EX0002401.PD1	EX0000772
Product Name	Camel Classic Gold Box	Camel Classic Gold Box
Eligibility status	Not Applicable (N/A)	Previously found exempt
Marketing Authorization date	N/A	October 28, 2019
Abbreviated report	N/A	January 10, 2020
Package Type	Box	Box
Package Quantity	20 cigarettes	20 cigarettes
Characterizing Flavor (CF)	Tobacco	Tobacco
Nicotine Source	Tobacco	Tobacco
Diameter	7.8 mm	7.8 mm
Product Length	83 mm	83 mm
Ventilation	29%	29%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of white tipping paper (b) (4) ; target: (b) (4) • mg/cigarette) • Addition of white tipping paper (b) (4) ; target: (b) (4) • mg/cigarette) • Deletion of tipping adhesive ((b) (4) ; target: (b) (4) • mg/cigarette) • Addition of tipping adhesive (b) (4) ; target: (b) (4) • mg/cigarette) • Deletion of (b) (4) (target: (b) (4) mg/cigarette) • Addition of (b) (4) (target: (b) (4) • mg/cigarette) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4) • Decrease in the quantity of (b) (4)	

[10] Brand/sub-brand or other commercial name used in commercial distribution.
[11] Effective April 14, 2022, FDA's authority to regulate tobacco products was extended to include tobacco products containing nicotine from any source. As such, nicotine source is considered a required property for unique identification. https://www.congress.gov/bill/117th-congress/house-bill/2471

STN	EX0002401.PD3	EX0001065
Product Name	Camel Classic Blue Box	Camel Classic Blue Box
Eligibility status	N/A	Previously found exempt
Marketing Authorization date	N/A	November 4, 2020
Abbreviated report	N/A	December 10, 2020
Package Type	Box	Box
Package Quantity	20 cigarettes	20 cigarettes
Characterizing Flavor (CF)	Tobacco	Tobacco
Nicotine Source	Tobacco	Tobacco
Diameter	7.8 mm	7.8 mm
Product Length	83 mm	83 mm
Ventilation	25%	25%
Product modifications	Addition/Deletion of tobacco additives: • Deletion of cork tipping paper (b) (4) ; target: (b) (4) • mg/cigarette) • Addition of white tipping paper (b) (4) ; target: (b) (4) • mg/cigarette) • Deletion of (b) (4) (target: (b) (4) mg/cigarette) • Deletion of (b) (4) (target: (b) (4) mg/cigarette) • Deletion of (b) (4) (target: (b) (4) mg/cigarette) • Deletion of (b) (4) (target: (b) (4) mg/cigarette) • Deletion of (b) (4) (target: (b) (4) mg/cigarette) • Deletion of (b) (4) (target: (b) (4) mg/cigarette) • Deletion of (b) (4) (target: (b) (4) mg/cigarette) • Addition of (b) (4) (target: (b) (4) • mg/cigarette) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4) • Increase in the quantity of (b) (4) • Decrease in the quantity of (b) (4)	