

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001492-PD1 – EX0001501-PD1
Common Attributes	
Submission date	January 27, 2021
Receipt date	January 27, 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 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 Jenna F. Dumond -S
Date: 2021.06.23 15:43:48 -04'00'

Jenna DuMond, Ph.D.
Chemistry Team Supervisor
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.06.29 08:23:55 -04'00'

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

	Cycle 1	
Discipline	Reviewer(s)	Review Date
regulatory	Camille D. Hayslett	2/11/2021
chemistry	Mona Shrestha	6/3/2021
environmental science	Thomas Creaven	6/2/2021

2. COMPLIANCE REVIEW

The original products in EX0001492-PD1 – EX0001501-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. Therefore, the original products are eligible for modification under the Exemption Request pathway.¹

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.

3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modification of the original products compared to the corresponding new products is the result of:

- deleting an additive (filter tow) in all the EX Requests
- adding an additive (filter tow) in all the EX Requests

4. SCIENTIFIC REVIEW

The review finds this modified ingredient (see Section 3) is an additive 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 modification is a minor modification 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 June 8, 2021. The FONSI was supported by an environmental assessment prepared by FDA on June 8, 2021.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that this modification (see Section 3) is 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 ingredient is an “additive” 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 all the EX Requests, the applicant proposes to replace the filter tow with an alternate filter tow in the new products. Although the filter tows are purchased from different suppliers, the applicant states that the filter tows present in the new and corresponding original products are compositionally similar and functionally identical. In the filter tow, the quantity of (b) (4) decreases by 2% in the new products in EX0001492-PD1 and EX0001501-PD1 while the quantity of (b) (4) decreases by 1% in the remaining EX Requests, which may yield higher volatile and semi volatile smoke constituents, however, this would be a minor 1 – 2% difference. Therefore, the nominal change in the quantity of (b) (4) is not a chemistry concern. (b) (4) increases by 20% in the new products compared to corresponding original products in all the EX Requests, however, (b) (4) is used for appearance and does not impact filter efficiency. Therefore, the 20% higher (b) (4) in the filter tows of the new products is not a concern from a chemistry perspective. The applicant provided certificate of analysis (COA) for the filter for all the EX Requests, which included the measured average values of DPF and TD along with the calculated density values of the filter tows that fall within the manufacturer’s specifications. The measured DPF values for new and corresponding original products are identical for EX0001492-PD1. The measured DPF values of the new products are 3 – 14% higher than the corresponding original products for the remaining EX Requests. The measured TD values of the new products are 0.4 – 7% lower compared to the corresponding original products for all the EX Requests. The calculated densities are identical

between the new and corresponding original products. The physical parameters of filter tow such as DPF and TD may influence the filtration efficiency and therefore may affect the mainstream smoke composition, however, the calculated percent changes in DPF and TD for these EX Requests are not expected to significantly impact mainstream smoke composition. Moreover, the overall ventilation is reported to be the same for new and corresponding original products in all the EX Requests. Furthermore, the filter tow is not combusted, volatilized, or otherwise released during normal cigarette consumption. 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 were previously found Exempt by FDA, a report under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Reports.

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	January 27, 2021	
Receipt date	January 27, 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	EX0001492-PD1	EX0000907
Product name	Camel Crush Box	Camel Crush Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	2/14/2020
Abbreviated report date	Not applicable	4/27/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Diameter	7.8 mm	7.8 mm
Length	83 mm	83 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 filter tow ((b) (4) /cigarette) Target: (b) (4) • Addition of filter tow ((b) (4) ; Target: (b) (4) cigarette) 	
Attributes	New Product	Original Product
STN	EX0001493-PD1	EX0000291
Product name	Camel Classic Filters 99 Box	Camel Classic Filters 99
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	5/22/2019
Abbreviated report date	Not applicable	7/10/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.8 mm	7.8 mm
Length	98 mm	98 mm
Ventilation	12%	12%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) /cigarette) Target: (b) (4) • Addition of filter tow ((b) (4) ; Target: 138 mg/cigarette) 	
Attributes	New Product	Original Product
STN	EX0001494-PD1	EX0000276
Product name	Camel Classic Blue Box	Camel Classic Blue
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	12/3/2018
Abbreviated report date	Not applicable	7/10/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.8 mm	7.8 mm
Length	83 mm	83 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) /cigarette) Target: (b) (4) • Addition of filter tow ((b) (4) ; Target: (b) (4) /cigarette) 	
Attributes	New Product	Original Product
STN	EX0001495-PD1	EX0000273
Product name	Camel Classic Blue 99 Box	Camel Classic Blue 99
Eligibility status	Not Applicable	Previously Found Exempt

Marketing authorization date	Not Applicable	12/3/2018
Abbreviated report date	Not applicable	7/10/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.8 mm	7.8 mm
Length	98 mm	98 mm
Ventilation	39%	39%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) ██████████); Target: ((b) (4) ██████████) /cigarette) • Addition of filter tow ((b) (4) ██████████); Target: ((b) (4) ██████████) /cigarette) 	
Attributes	New Product	Original Product
STN	EX0001496-PD1	EX0000701
Product name	Pall Mall Blue Filter Box	Pall Mall Blue Filter Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	9/27/2019
Abbreviated report date	Not applicable	1/28/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.8 mm	7.8 mm
Length	83 mm	83 mm
Ventilation	34%	34%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4) ██████████); Target: ((b) (4) ██████████) /cigarette) • Addition of filter tow ((b) (4) ██████████); Target: ((b) (4) ██████████) /cigarette) 	
Attributes	New Product	Original Product
STN	EX0001497-PD1	EX0000305
Product name	Camel Classic Filters Box	Camel Classic Filters
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	3/28/2019
Abbreviated report date	Not applicable	7/10/2019
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.8 mm	7.8 mm
Length	83 mm	83 mm
Ventilation	23%	23%
Product modifications	Addition/Deletion of tobacco additives:	

	<ul style="list-style-type: none"> • Deletion of filter tow (b) (4) ; Target: (b) (4) /cigarette) • Addition of filter tow (b) (4) ; Target: (b) (4) /cigarette) 	
Attributes	New Product	Original Product
STN	EX0001498-PD1	EX0000709
Product name	Pall Mall Red Filter Box	Pall Mall Red Filter Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	9/27/2019
Abbreviated report date	Not applicable	1/28/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.8 mm	7.8 mm
Length	83 mm	83 mm
Ventilation	33%	33%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) ; Target: (b) (4) /cigarette) • Addition of filter tow (b) (4) ; Target: (b) (4) /cigarette) 	
Attributes	New Product	Original Product
STN	EX0001499-PD1	EX0001010
Product name	Pall Mall Orange Filter 100 Box	Pall Mall Orange Filter 100 Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	4/22/2020
Abbreviated report date	Not applicable	6/26/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.8 mm	7.8 mm
Length	98 mm	98 mm
Ventilation	60%	60%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) ; Target: (b) (4) /cigarette) • Addition of filter tow (b) (4) ; Target: (b) (4) /cigarette) 	
Attributes	New Product	Original Product
STN	EX0001500-PD1	EX0000977
Product name	Pall Mall Red Filter 100 Box	Pall Mall Red Filter 100 Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	3/17/2020

Abbreviated report date	Not applicable	6/8/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.9 mm	7.9 mm
Length	97 mm	97 mm
Ventilation	32%	32%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) ; Target: (b) (4) /cigarette) • Addition of filter tow (b) (4) ; Target: (b) (4) /cigarette) 	
Attributes	New Product	Original Product
STN	EX0001501-PD1	EX0000704
Product name	Pall Mall Orange Filter Box	Pall Mall Orange Filter Box
Eligibility status	Not Applicable	Previously Found Exempt
Marketing authorization date	Not Applicable	9/27/2019
Abbreviated report date	Not applicable	1/28/2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Diameter	7.8 mm	7.8 mm
Length	83 mm	83 mm
Ventilation	58%	58%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) ; Target: (b) (4) /cigarette) • Addition of filter tow (b) (4) ; Target: (b) (4) /cigarette) 	