

Technical Project Lead (TPL) Review of Exemption Requests: EX0001006 – EX0001011

Common Attributes of EX Requests		
Applicant	R.J. Reynolds Tobacco Company	
Product category	Cigarettes	
Product subcategory	Combusted, Filtered	
EX Requests Included in this Review		
Tobacco Product	New	Original
Submission tracking number	EX0001006	EX0000705
Product name	Pall Mall Blue Filter 100 Box	Pall Mall Blue Filter 100 Box
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	September 27, 2019
Abbreviated report date	Not applicable	January 10, 2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	44%	44%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) target: (b) (4) mg/cig) • Addition of white tipping paper (b) (4) target: (b) (4) mg/cig) • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001007	EX0000700
Product name	Pall Mall Orange Filter 100 Box	Pall Mall Orange Filter 100 Box
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	September 27, 2019
Abbreviated report date	Not applicable	January 10, 2020
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	60%	60%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) target: (b) (4) mg/cig) • Addition of white tipping paper (b) (4) target: (b) (4) mg/cig) 	
Tobacco Product	New	Original
Submission tracking number	EX0001008	EX0000705
Product name	Pall Mall Blue Filter 100 Box	Pall Mall Blue Filter 100 Box
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	September 27, 2019
Abbreviated report date	Not applicable	January 10, 2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	44%	44%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) target: (b) (4) mg/cig) • Addition of white tipping paper (b) (4) target: (b) (4) mg/cig) 	

Tobacco Product	New	Original
Submission tracking number	EX0001009	EX0000705
Product name	Pall Mall Blue Filter 100 Box	Pall Mall Blue Filter 100 Box
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	September 27, 2019
Abbreviated report date	Not applicable	January 10, 2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	44%	44%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of tipping paper adhesive (b) (4) • Addition of tipping paper adhesive (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001010	EX0000700
Product name	Pall Mall Orange Filter 100 Box	Pall Mall Orange Filter 100 Box
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	September 27, 2019
Abbreviated report date	Not applicable	January 10, 2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	60%	60%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) target: (b) (4) mg/cig • Addition of white tipping paper (b) (4) target: (b) (4) mg/cig • Deletion of tipping adhesive (b) (4) • Addition of tipping adhesive (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001011	EX0000700
Product name	Pall Mall Orange Filter 100 Box	Pall Mall Orange Filter 100 Box
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	September 27, 2019
Abbreviated report date	Not applicable	January 10, 2020
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	None	None
Length	98 mm	98 mm
Diameter	7.8 mm	7.8 mm
Ventilation	60%	60%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none">• Deletion of tipping paper adhesive (b) (4)• Addition of tipping paper adhesive (b) (4)	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

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Date: 2020.04.22 15:07:11 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Director
Division of Product Science

Signatory Decision:

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2020.04.22 15:26:20 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The original tobacco products are combusted, filtered cigarettes manufactured by the applicant as indicated on the cover page of this review.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 3, 2020, FDA received Exemption Requests EX0001016 - EX0001011 from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued an Acceptance letter on March 16, 2020.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco products contain the following modification compared to the corresponding original tobacco products:

- deleting an additive (white tipping paper) in EX0001006 – EX0001008 and EX0001010
- adding an additive (white tipping paper) in EX0001006 – EX0001008 and EX0001010
- deleting an additive (tipping paper adhesive) in EX0001006 and EX0001009 - EX0001011
- adding an additive (tipping paper adhesive) in EX0001006 and EX0001009 - EX0001011

2. REGULATORY REVIEW

Regulatory reviews were completed by Antonio Thornton on March 13, 2020. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco products in EX0001016 - EX0001011 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 under EX0000700 or EX0000705 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 tobacco products are eligible for modification under the Exemption Request pathway.¹

¹ 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

A chemistry review was completed by DeLauren McCauley on March 24, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. White tipping paper² and tipping paper adhesive³ is used in the manufacturing of the original tobacco products, and 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 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. For EX0001006 – EX0001008 and EX0001010 only, the applicant proposed the deletion of white tipping paper and the addition of white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception as outlined in the May 16, 2017 social science memo. For EX0001006 and EX0001009 - EX0001011 only, the review concludes that the deletion of tipping paper adhesive in the original products and the addition of an alternate tipping paper adhesive in the new products is a minor modification. 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 the tipping paper adhesive 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 products relative to the original products. The scientific review has found these modifications to be minor.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Bria Martin on March 24, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 13, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 13, 2020.

6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

- deleting an additive (white tipping paper) in EX0001006 – EX0001008 and EX0001010
- adding an additive (white tipping paper) in EX0001006 – EX0001008 and EX0001010
- deleting an additive (tipping paper adhesive) in EX0001006 and EX0001009 - EX0001011
- adding an additive (tipping paper adhesive) in EX0001006 and EX0001009 - EX0001011

I concur with the conclusion of the scientific review that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines “additive” as “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing,

² EX0001006 – EX0001008 and EX0001010 only

³ EX0001006 and EX0001009 - EX0001011 only

treating, packaging, transporting, or holding), . . .” I concur with the scientific review that the white tipping paper² and tipping paper adhesive³ is an addition/deletion of tobacco additives. 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. For EX0001006 – EX0001008 and EX0001010 only, the addition of white tipping paper and the deletion of white tipping paper is not expected to have any significant effects on product chemistry or consumer perception. In addition, for EX0001006 and EX0001009 - EX0001011 only, the deletion of the tipping paper adhesive in the original products and the addition of an alternate tipping paper adhesive in the new products is a minor modification. 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 the tipping paper adhesive 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 products relative to the original products. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP’s scientific understanding, 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.

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 EX0001006 – EX0001011, as identified on the cover page of this review.