

**Technical Project Lead (TPL) Review:
Exemption Request EX0000157, EX0000158,
EX0000160**

EX0000157: Pall Mall Menthol 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	44%
Characterizing Flavor	Menthol
Modification	Substitution and removal of tobacco additives: deletion of a tobacco additive (white tipping paper) and addition of a tobacco additive (cork-on-white tipping paper).
EX0000158: Pall Mall Menthol Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	34%
Characterizing Flavor	Menthol
Modification	Substitution and removal of tobacco additives: deletion of a tobacco additive (white tipping paper) and addition of a tobacco additive (cork-on-white tipping paper).
EX0000160: Camel Classic Menthol Silver	
Length	83 mm
Diameter	7.79 mm
Ventilation	38%
Characterizing Flavor	Menthol
Modification	Substitution and removal of tobacco additives: deletion of a tobacco additive (cork-printed tipping paper) and addition of a tobacco additive (white tipping paper).
Common Attributes of Exemption Requests	
Applicant	R.J. Reynolds Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 cigarettes
Package Type	Hard Pack
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
Date: 2017.08.31 10:32:35 -04'00'

For Matthew J. Walters, Ph.D., MPH
CDR, U.S. 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: 2017.08.31 13:01:40 -04'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Product

EX0000157	
Product Name	Pall Mall Light Menthol 100s Box
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	98 mm
Diameter	7.79 mm
Ventilation	44%
Characterizing Flavor	Menthol
EX0000158	
Product Name	Pall Mall Light Menthol King Box
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	34%
Characterizing Flavor	Menthol
EX0000160	
Product Name	Camel Lights Menthol Hard Pack
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	38%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco products and claims that they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original Exemption Requests EX0000157, EX0000158, and EX0000160 on February 16, 2017. FDA issued the applicant Acknowledgement letters for the Exemption Requests on March 6, 2017 and an Advice and Information Request (A/I) letter for these Exemption Requests on June 29, 2017. In response, the applicant submitted an amendment (EX0000187) to these Exemption Requests.

1.3. SCOPE OF MEMO

This memo captures all administrative, 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 tobacco product:

- EX0000157 & EX0000158: Deletion of a tobacco additive (white tipping paper) and addition of a tobacco additive (cork-on-white tipping paper)
- EX0000160: Deletion of a tobacco additive (cork-printed tipping paper) and addition of a tobacco additive (white tipping paper)

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Jennifer Schmitz on March 6, 2017. The review concludes that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the original tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated March 31, 2017, conclude that the original tobacco products are grandfathered products. Therefore the original products are eligible for modification under the Exemption pathway.¹

4. SCIENTIFIC REVIEW

A scientific review was completed by Caroline Agarabi on August 28, 2017. The review concludes that the modifications are a minor modification of tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The applicant proposed the substitution of cork-on-white tipping paper with white tipping paper or substitution of white tipping paper with cork-on-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. The chemistry review has found this modification to be minor.

¹ Any tobacco product that can be sold under the FD&C Act (i.e., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 30, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 22, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- EX0000157 & EX0000158: Deletion of a tobacco additive (white tipping paper) and addition of a tobacco additive (cork-on-white tipping paper)
- EX0000160: Deletion of a tobacco additive (cork-printed tipping paper) and addition of a tobacco additive (white tipping paper)

I concur with the conclusion of the chemistry review that these modifications are minor modifications involving tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Tipping paper is an additive because it is a substance that is a component of a tobacco product. In addition, it is my conclusion and consistent with section 905(j)(3)(A)(ii) of the FD&C Act, SE Reports are not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for protection of the public health. Although the modification results in different characteristics for the original and new tobacco products, the substitution of cork-on-white tipping paper with white tipping paper or substitution of white tipping paper with cork-on-white tipping paper is not expected to have any significant effects on product chemistry or consumer perception. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP's scientific understanding, 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 tobacco product 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 meet statutory requirements because they are legally marketed in the United States. The original products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

Exempt order letters should be issued for the new tobacco products in EX0000157, EX0000158, and EX0000160 as identified on the cover page of this review.