



## Technical Project Lead (TPL) Review: Exemption Request EX0000176

<b>EX0000176: Camel Crush</b>	
Length	83 mm
Diameter	7.8 mm
Filter Ventilation	32%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Deletion of tobacco additives: <ul style="list-style-type: none"><li>• Substitution of non-FSC<sup>1</sup> cigarette paper with FSC cigarette paper</li><li>• Deletion of printed monogram ink on the barrel</li></ul>
<b>Common Attributes of Exemption Requests</b>	
Applicant	R.J. Reynolds Tobacco Company
Product Category	Cigarette
Product Sub-Category	Combusted Filtered
Package Quantity	20 cigarettes
Package Type	Hard Pack
Additional Property	Crushable menthol capsule in filter
<b>Recommendation</b>	
Issue an Exempt order letter.	

<sup>1</sup> Fire Standards Compliant

**Technical Project Lead (TPL):**

Matthew J. Walters -S  
2017.08.18 13:41:15 -04'00'

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: 2017.08.18 13:56:53 -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**

EX0000176	
Product Name	Camel Light Box with Menthol Capsule
Package Quantity	20 cigarettes
Package Type	Hard Pack
Length	83 mm
Diameter	7.8 mm
Filter Ventilation	32%
Characterizing Flavor	Menthol
Additional Property	Crushable menthol capsule in filter

The applicant manufactures the original tobacco products and claims that it is grandfathered.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original Exemption Request EX0000176, on April 4, 2017. FDA issued the applicant an Acknowledgement letter for the Exemption Request on April 10, 2017 and an Advice/ Information Request (A/I) letter for this Exemption Request on May 26, 2017. In response, the applicant submitted an amendment (EX0000178) to the Exemption Request.

### 1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for this Exemption Request.

### 1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modification compared to the corresponding tobacco product:

- Substitution of non-FSC cigarette paper with FSC cigarette paper
- Deletion of a tobacco additive (monograph ink on the barrel of the cigarette)

## 2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Melis Coraggio on April 10, 2017. The review concludes that the Exemption Request is administratively complete.

### **3. COMPLIANCE REVIEW**

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated May 5, 2017, concludes that the original tobacco product is a grandfathered product. Therefore the original product is eligible for modification under the Exemption Request pathway.<sup>2</sup>

### **4. SCIENTIFIC REVIEW**

A scientific review was completed by Caroline Agarabi on August 18, 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 review concludes the substitution of non-FSC cigarette paper to FSC cigarette paper is a minor modification. The change from non-FSC to FSC cigarette paper may result in increased HPHC yields; however, the reduction in household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of the FSC cigarette paper, as outlined in the July 14, 2017 toxicology memo. Additionally, the chemistry review states that the removal of monogram ink on the barrel of the cigarette is a minor modification. Furthermore, the removal of the monogram is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product and may potentially decrease HPHC yields.

### **5. ENVIRONMENTAL DECISION**

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 17, 2017. The FONSI was supported by an environmental assessment prepared by FDA on August 17, 2017.

### **6. CONCLUSION AND RECOMMENDATION**

The new tobacco product contains the following modification compared to the original tobacco product:

- Substitution of non-FSC cigarette paper with FSC cigarette paper
- Deletion of a tobacco additive (monograph ink on the barrel of the cigarette)

I concur with the conclusion of the chemistry review that these modifications are minor modifications of tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. In addition, it is my conclusion and consistent with section

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<sup>2</sup> 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.

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. At this time, based on the information available and CTP's scientific understanding and experience with non-FSC to FSC modifications that are limited to changes in tobacco additives and do not result in other changes to the product (i.e., no changes to blend, filter, design parameters such as ventilation, etc.), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. Additionally, the removal of the monogram ink is not expected have any toxicological or other concerns. 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 product meets statutory requirements because it is legally marketed in the United States. The original product is a grandfathered product (i.e., was commercially marketed in the United States as of February 15, 2007).

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

An Exempt order letter should be issued for the new tobacco product in EX0000176 as identified on the cover page of this review.