

## Technical Project Lead (TPL) Review of Exemption Requests: EX0001015 – EX0001017

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	EX0001015	SE0006134
Product name	Camel Crush Box	Camel Crush
Eligibility status	Not applicable	Previously found SE
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 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"> <li>• Deletion of white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> </ul>	

Tobacco Product	New	Original
Submission tracking number	EX0001016	EX0000203
Product name	Camel Crush Rich Box	Camel Crush Rich <sup>1</sup>
Eligibility status	Not applicable	Previously found EX
Marketing order date	Not applicable	December 22, 2017
Abbreviated report date	Not applicable	January 30, 2018
Package Type	Box	Box
Package Quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 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"> <li>• Deletion of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> </ul>	
Tobacco Product	New	Original
Submission tracking number	EX0001017	SE0006134
Product name	Camel Crush Rich Box	Camel Crush
Eligibility status	Not applicable	Previously found SE
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	20 Cigarettes	20 Cigarettes
Characterizing flavor	Menthol	Menthol
Length	83 mm	83 mm
Diameter	7.8 mm	7.8 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"> <li>• Deletion of white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of cork tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> </ul>	

<sup>1</sup> Product identified as Camel Crush Filter in the October 25, 2017 EX Request

**Recommendation**

Issue Exempt (EX) order.

**Technical Project Lead (TPL):**

Digitally signed by Matthew J. Walters -S  
Date: 2020.04.21 11:37:51 -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: 2020.04.21 11:49:53 -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 12, 2020, FDA received Exemption Requests EX0001015 - EX0001017 from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On March 16, 2020, FDA issued an Acceptance letter.

### **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 modifications compared to the corresponding original tobacco products:

- deleting an additive (white or cork tipping paper) in all EX Requests
- adding an additive (white or cork tipping paper) in all EX Requests
- deleting an additive (filter tow) in EX0001016
- adding an additive (filter tow) in EX0001016

## **2. REGULATORY REVIEW**

Regulatory reviews were completed by Pin Zhang on March 16, 2020. The reviews conclude that the Exemption Requests are administratively complete.

## **3. COMPLIANCE REVIEW**

The original tobacco product in EX0001015 and EX0001017 was determined by FDA under SE0006134 to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act). The original tobacco product in EX0001016 was determined by FDA under EX0000203 to be exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration of substantial equivalence; and a report under section 905(j)(1)(A)(ii) (Abbreviated Report) was received on January 30, 2018. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.<sup>2</sup>

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<sup>2</sup> 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 Salome Bhagan on March 31, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. White or cork tipping paper and filter tow<sup>3</sup> are used in the manufacturing of the original tobacco products, and is an additive because the intended use may reasonably be expected to result, directly or indirectly, in the becoming of 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. The review concludes that the deletion of white or cork tipping paper and the addition of an alternate white or cork tipping paper is a minor modification. This change is not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo. For EX0001016 only, the review concludes that the deletion of filter tow and the addition of an alternate filter tow is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. The filter tow of the new product includes a 17% decrease in (b) (4) compared to the original product and possess the same amounts of (b) (4). Because the filter tows are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of ingredients in the filter tow are not expected to significantly alter the smoke chemistry and consumer exposure to chemical constituents from the filter tow while smoking. The filter tow can influence the ventilation and filter efficiency of a product; however, the ventilation remains the same when comparing the new and corresponding original tobacco products.

#### 5. ENVIRONMENTAL DECISION

An environmental review was completed by Ronald Edwards on March 31, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 15, 2020. The FONSI was supported by an environmental assessment prepared by FDA on April 15, 2020.

#### 6. CONCLUSION AND RECOMMENDATION

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

- deleting an additive (white or cork tipping paper) in all EX Requests
- adding an additive (white or cork tipping paper) in all EX Requests
- deleting an additive (filter tow) in EX0001016
- adding an additive (filter tow) in EX0001016

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,

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<sup>3</sup> EX0001016 only

treating, packaging, transporting, or holding), . . .” I concur with the scientific review that the white or cork tipping paper and filter tow<sup>3</sup> are 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. The applicant proposes the deletion of white, cork, or white-on-cork tipping paper and the addition of an alternate white or cork tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. For EX00001016, the applicant proposes to delete the filter tow and add an alternate filter tow which is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco product. The filter tow in the new product includes a 17% decrease in <sup>(b) (4)</sup> compared to the original product and possess the same amounts of <sup>(b) (4)</sup>. Because the filter tows are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of ingredients in the filter tow are not expected to significantly alter the smoke chemistry and consumer exposure to chemical constituents from the filter tow while smoking. The filter tow can influence the ventilation and filter efficiency of a product; however, the ventilation of the new and corresponding original tobacco products remains the same. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP’s scientific understanding, that an exemption for these modifications are 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 product for EX0001015 and EX00001017 was previously found SE and in compliance with the FD&C Act by FDA. The original product for EX0001016 was previously found Exempt by FDA, and a report under section 905(j)(1)(A)(ii) (Abbreviated Report) was received on January 30, 2018.

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 EX0001015 – EX0001017, as identified on the cover page of this review.