

**Technical Project Lead (TPL) Review:  
Exemption Requests EX0000783 – EX0000784**

EX0000783: Camel No. 9 Smooth Menthe	
Length	83 mm
Diameter	7.9 mm
Ventilation	40%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of filter center line adhesive (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter center line adhesive (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of white tipping paper (b) (4) MM]; target: (b) (4) mg/cigarette)</li> <li>• Addition of white tipping paper (b) (4) MM]; 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> <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> <li>• Increase in the quantity of filter sideseam adhesive (b) (4) target: (b) (4) mg/cigarette)</li> </ul>
EX0000784: Camel No.9 Smooth Taste	
Length	83 mm
Diameter	7.9 mm
Ventilation	40%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of filter center line adhesive (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter center line adhesive (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of white tipping paper (b) (4) MM]; target: (b) (4) /cigarette)</li> <li>• Addition of white tipping paper (b) (4) MM]; 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> <li>• Deletion of single flavor ingredient (b) (4) (target: (b) (4) mg/cigarette)</li> </ul> <p>Increasing/Decreasing the quantity of existing tobacco additives:</p>

	<ul style="list-style-type: none"> <li>• Increase in the quantity of filter sideseam adhesive (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Increase in the quantity of (b) (4) (target: (b) (4) mg/cigarette)</li> </ul>
<b>Common Attributes of Exemption Requests</b>	
<b>Applicant</b>	R.J. Reynolds Tobacco Company
<b>Product Category</b>	Cigarette
<b>Product Sub-Category</b>	Combusted, Filtered
<b>Package Quantity</b>	20 cigarettes
<b>Package Type</b>	Box
<b>Supporting Memo Included in the EX Request Review</b>	
EX0000783 and EX0000784	Internal Memorandum: Social Science Evaluation of the Design of Cigarette Tipping Paper (May 16, 2017)
<b>Conclusion</b>	
Issue Exempt order letter.	

**Technical Project Lead (TPL):**

**Todd L. Cecil -S** Digitally signed by Todd L. Cecil  
 -S  
 Date: 2020.05.18 16:47:21 -04'00'

Todd L. Cecil, Ph.D.  
 Associate 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: 2020.05.19 07:47:39 -04'00'

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

TABLE OF CONTENTS

- 1. BACKGROUND ..... 4
  - 1.1. ORIGINAL TOBACCO PRODUCTS..... 4
  - 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW ..... 4
  - 1.3. SCOPE OF REVIEW ..... 4
  - 1.4. TOBACCO ADDITIVE MODIFICATIONS ..... 5
- 2. ADMINISTRATIVE REVIEW ..... 5
- 3. COMPLIANCE REVIEW ..... 5
- 4. SCIENTIFIC REVIEW..... 5
- 5. ENVIRONMENTAL DECISION ..... 6
- 6. CONCLUSION AND RECOMMENDATION..... 6

## 1. BACKGROUND

### 1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

**Table 1. Original Tobacco Products**

<b>EX0000783: Camel No. 9 Smooth Menthe</b>	
<b>Product Name</b>	Camel No. 9 Menthe
<b>Package Type</b>	Box
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	40%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000784: Camel No.9 Smooth Taste</b>	
<b>Product Name</b>	Camel No. 9
<b>Package Type</b>	Box
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	40%
<b>Characterizing Flavor</b>	None

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

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On September 25, 2019, FDA received the Exemption Requests EX0000783-EX0000784 from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. FDA issued the applicant an Acceptance letter for these Exemption Requests on October 2, 2019.

### 1.3. SCOPE OF REVIEW

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

#### 1.4. TOBACCO ADDITIVE MODIFICATIONS

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

- Deletion of white tipping paper (b) (4) (EX0000783-EX0000784)
- Addition of white tipping paper (b) (4) (EX0000783-EX0000784)
- Deletion of filter tow (b) (4) (EX0000783-EX0000784)
- Addition of filter tow (b) (4) (EX0000783-EX0000784)
- Increase in the quantity of filter sideseam adhesive (EX0000783-EX0000784)
- Deletion of filter center line adhesive (b) (4) (EX0000783-EX0000784)
- Addition of filter center line adhesive (b) (4) (EX0000783-EX0000784)
- Increase in the quantity of (b) (4) in the tobacco (EX0000784)
- Deletion of (b) (4) in the tobacco (EX0000784)

#### 2. ADMINISTRATIVE REVIEW

Regulatory reviews were completed by Barbara Banchemo on October 2, 2019. The reviews conclude 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 in the United States, other than exclusively in test markets, as of February 15, 2007). The OCE reviews dated October 31, 2019, conclude that the original tobacco products are grandfathered products.

Therefore, the original products are eligible for modification under the Exemption Request pathway.<sup>1</sup>

#### 4. SCIENTIFIC REVIEW

A scientific review was completed by Youbang Liu on February 19, 2020.

The scientific review concludes that the new tobacco products have been modified by adding or deleting tobacco additives and increasing or decreasing tobacco additives. Tipping paper, filter tow, filter sideseam adhesive, filter center line adhesive, (b) (4), and (b) (4)<sup>2</sup> are used in the manufacturing of the original tobacco products and are additives 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 tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review also concludes the deletion of white tipping paper and the addition of

---

<sup>1</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.

<sup>2</sup> EX0000784 Only

an alternate white tipping paper is a minor modification. These changes are not expected to have any significant effects on consumer perception as outlined in the May 16, 2017, social science memo. Furthermore, 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 products. The filter tow can influence the filter efficiency of a product; however, the filter efficiency remains the same when comparing the new and corresponding original tobacco products. The deletion of filter center line adhesive, the addition of an alternate center line adhesive, and the increase in the quantity of the filter sideseam adhesive in the new tobacco products are unlikely to have any measurable differences in HPHC yields between the new and corresponding original tobacco products. Therefore, the proposed changes are considered as minor modifications. In addition, for EX0000784, the deletion of the flavor ingredient (b) (4) along with the increase of existing additives of (b) (4) in the tobacco casing are minor modifications and are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by Rudaina Alrefai-Kirkpatrick on October 21, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 05, 2019. The FONSI was supported by an environmental assessment prepared by FDA on December 05, 2019.

## 6. CONCLUSION AND RECOMMENDATION

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

- Deletion of white tipping paper (b) (4) (EX0000783-EX0000784)
- Addition of white tipping paper (b) (4) (EX0000783-EX0000784)
- Deletion of filter tow (b) (4) (EX0000783-EX0000784)
- Addition of filter tow (b) (4) (EX0000783-EX0000784)
- Increase in the quantity of filter sideseam adhesive (EX0000783-EX0000784)
- Deletion of filter center line adhesive (b) (4) (EX0000783-EX0000784)
- Addition of filter center line adhesive (b) (4) (EX0000783-EX0000784)
- Increase in the quantity of (b) (4) in the tobacco (EX0000784)
- Deletion of (b) (4) in the tobacco (EX0000784)

I concur with the conclusion of the scientific review that these modifications are minor modification involving tobacco additives 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, treating, packaging, transporting, or holding), . . ." I agree with the scientific review that the new tobacco

products have been modified by adding or deleting tobacco additives and increasing or decreasing tobacco additives. Tipping paper, filter tow, filter center line adhesive, filter sideseam adhesive, (b) (4), and (b) (4) are used in the manufacturing of the original tobacco products and are additives 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. In addition, it is my conclusion that 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 protection of the public health. I also agree with the scientific review which concludes the deletion of white tipping paper and the addition of white tipping paper in EX0000783-EX0000784 is a minor modification. This change is not expected to have any significant effect on consumer perception as outlined in the May 16, 2017, social science memo. Furthermore, 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 products. The filter tow can influence the filter efficiency of a product; however, the filter efficiency remains the same when comparing the new and corresponding original tobacco products. I agree with the scientific conclusion that the deletion of filter center line adhesive, the addition of an alternate filter center line adhesive, and the increase in the quantity of the filter sidestream adhesive in the new tobacco products are unlikely to have any measurable differences in HPHC yields between the new and corresponding original tobacco products. Therefore, the proposed change is considered a minor modification. In addition, for EX0000784, the deletion of the flavor ingredient (b) (4) along with the increase of existing additives of (b) (4) in the tobacco casing are minor modifications and are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Lastly, FDA finds, based on the information contained in the Exemption Requests 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 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 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, other than exclusively in test markets, 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.

An Exempt order letter should be issued for the new tobacco products in EX0000783-EX0000784 as identified on the cover page of this review.