

**Technical Project Lead (TPL) Review:  
Exemption Requests EX0000289 – EX0000293**

EX0000289: Camel Classic Wides Blue	
Length	79 mm
Diameter	8.6 mm
Ventilation	37 %
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of filter tow (b)(4)</li> <li>• Addition of filter tow (b)(4)</li> <li>• Deletion of cork tipping paper ((b) (4) ; (b)(4) ; Target: (b)(4)</li> <li>• Addition of cork-on-white tipping paper (b) (4) ; (b)(4) ; Target: (b)(4)</li> </ul>
EX0000290: Camel Classic Menthol Silver Box	
Length	83 mm
Diameter	7.8 mm
Ventilation	38 %
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of filter tow (b)(4)</li> <li>• Addition of filter tow (b)(4)</li> <li>• Deletion of cork-on-white tipping paper (b)(4) ; (b)(4) ; Target: (b)(4)</li> <li>• Addition of white tipping paper (Mundet Inc.; (b)(4) ; Target: (b)(4)</li> </ul>
EX0000291: Camel Classic Filters 99	
Length	98 mm
Diameter	7.8 mm
Ventilation	12 %
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of filter tow (b)(4)</li> <li>• Addition of filter tow (b)(4)</li> <li>• Deletion of cork-on-white tipping paper (b) (4) ; (b) (4) ; Target: (b)(4)</li> <li>• Addition of cork-on-white tipping paper (b) (4) ; (b)(4) ; Target: (b)(4)</li> <li>• Deletion of printed monogram ink on barrel (gold)</li> </ul>

EX0000292: Camel Classic Wides Filters	
Length	79 mm
Diameter	8.6 mm
Ventilation	0 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of filter tow (b)(4)</li> <li>• Addition of filter tow (b)(4)</li> <li>• Deletion of cork tipping paper (b) (4) (b)(4) ; Target: (b)(4)</li> <li>• Addition of cork-on-white tipping paper (b) (4) ; (b)(4) Target: (b)(4)</li> </ul>
EX0000293: Camel Classic Platinum	
Length	83 mm
Diameter	7.8 mm
Ventilation	59 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of filter tow (b)(4)</li> <li>• Addition of filter tow (b)(4)</li> <li>• Deletion of white tipping paper ((b) (4) (b)(4) ; Target: (b)(4)</li> <li>• Addition of white tipping paper (b) (4) (b)(4) Target: (b)(4)</li> </ul>
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	Box
Recommendation	
Issue Exempt order letters	

**Technical Project Lead (TPL):**

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Date: 2019.03.04 15:50:39 -05'00'

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: 2019.03.05 06:51:42 -05'00'

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 Products**

<b>EX0000289: Camel Classic Wides Blue</b>	
Product Name	Camel Wides Lights Hard Pack
Package Type	Box
Package Quantity	20 cigarettes
Length	79 mm
Diameter	8.6 mm
Ventilation	37%
Characterizing Flavor	None
<b>EX0000290: Camel Classic Menthol Silver Box</b>	
Product Name	Camel Lights Menthol Hard Pack
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	38%
Characterizing Flavor	Menthol
<b>EX0000291: Camel Classic Filters 99</b>	
Product Name	Camel Filters 99s Hard Pack
Package Type	Box
Package Quantity	20 cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	12%
Characterizing Flavor	None
<b>EX0000292: Camel Classic Wides Filters</b>	
Product Name	Camel Wides Filters Hard Pack
Package Type	Box
Package Quantity	20 cigarettes
Length	79 mm
Diameter	8.6 mm
Ventilation	0%
Characterizing Flavor	None

EX0000293: Camel Classic Platinum	
Product Name	Doral Ultra Light Box
Package Type	Box
Package Quantity	20 cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	59%
Characterizing Flavor	None

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

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 19, 2018, FDA received Exemption Requests (EX0000289 – EX0000293) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On October 25, 2018, FDA issued Acknowledgement letters to the applicant. On December 11, 2018, FDA issued a Deficiency letter. In response, the applicant submitted an amendment (EX0000406) to the Exemption Requests, received by FDA on January 4, 2019.

### 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:

- Deletion of white or cork-on-white tipping paper (b) (4) or cork tipping paper (b) (4)
- Addition of white or cork-on-white tipping paper (b) (4)
- Deletion of filter tow (b)(4)
- Addition of filter tow (b)(4)
- Deletion of printed monogram ink on barrel (gold) for EX0000291 only

## 2. REGULATORY REVIEW

Regulatory reviews were completed by Camille Hayslett on October 25, 2018. 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 November 15, 2018, for EX0000289 - EX0000292 and November 19, 2018 for EX0000293, conclude that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modifications under the Exemption Request pathway.<sup>1</sup>

#### 4. SCIENTIFIC REVIEW

The first scientific review was completed by Salome Bhagan on November 16, 2018 and a second scientific review was completed by Megan Mekoli on February 15, 2019.

The reviews state that the new tobacco products have been modified by adding or deleting tobacco additives and increasing or decreasing the quantities of existing tobacco additives. Tipping paper, filter tow, and monogram ink<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 reviews conclude 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 reviews conclude that the deletion of cork, white, or cork-on-white tipping paper with the addition of white or cork-on-white 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. The new products include a 17% decrease in (b)(4) compared to the original products 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 of a product; however, the ventilation remains the same when comparing the new and corresponding original tobacco products. For EX0000291 only, the reviews conclude that the deletion of monogram ink on the cigarette barrel is a minor modification and this removal of the monogram ink is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products and may potentially decrease HPHC yields.

#### 5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Dilip Venugopal on November 30, 2018 and February 27, 2019.

The final environmental review found that the applicant did not provide current-year market volume of the original products and detailed measurements of all product components. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

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<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> EX0000291 only

## 6. CONCLUSION AND RECOMMENDATION

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

- Deletion of white or cork-on-white tipping paper (b) (4) or cork tipping paper (b) (4)
- Addition of white or cork-on-white tipping paper (b) (4)
- Deletion of filter tow (b)(4)
- Addition of filter tow (b)(4)
- Deletion of printed monogram ink on barrel (gold) for EX0000291 only

I concur with the conclusion of the scientific reviews 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, treating, packaging, transporting, or holding), . . .” I concur with the scientific reviews that the changes represent deletion of tobacco additives (cork, white, or cork-on-white tipping paper, filter tow, and monogram ink on barrel<sup>3</sup>), and the addition of tobacco additives (filter tow and white or cork-on-white tipping paper). 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 protection of the public health. The applicant proposed the deletion of cork, white, or cork-on-white tipping paper followed by the addition of white or cork-on-white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. The new products include a 17% decrease in (b)(4) compared to the original products 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 of a product; however, the ventilation of the new and corresponding original tobacco products remains the same. Also, for EX0000291 only, the review concludes that the deletion of monogram ink on the cigarette barrel is a minor modification and this removal of the monogram ink 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. 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 modifications through Exemption Requests 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).

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<sup>3</sup> EX0000291 only



FDA has examined the environmental effects of finding these new tobacco products exempt from substantially equivalent and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing EX orders.

An Advice/Information Request letter should be issued requesting the following information:

1. All of your EX Requests and the response you provided to the deficiency letter dated December 11, 2018 lack information on the current marketing status of the original products. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new products. In Table 1, provide the marketing status of the original products and, if currently marketed, provide the current market volumes for the original products. Identify any confidential information so that it can be placed in a confidential appendix to the public EA document.

STN	Original Product		Current Marketing Status	Current Market Volume
	Name	STN		
EX0000289	Camel Wides Lights Hard Pack	GF1702229		
EX0000290	Camel Lights Menthol Hard Pack	GF1501181		
EX0000291	Camel Filters 99s Hard Pack	GF1200554		
EX0000292	Camel Wides Filters Hard Pack	GF1501093		
EX0000293	Doral Ultra Light Box	GF1501254		

2. All of your EX Requests and the response you provided to the deficiency letter dated December 11, 2018 lack detailed measurements of all product components. Product component details for combusted cigarettes are used to quantitatively assess the environmental impact of cigarette butt waste. In Table 2, for each new product, provide the length of the tipping paper (filter overwrap), the length of the tobacco rod, and the mass of the tobacco rod (including tobacco filler, cigarette paper, and adhesive). Confirm the cigarette length and mass data in Table 2 as provided in your submissions.

STN	New Product	Length of cigarette (mm)	Mass of one cigarette (g)	Length of tipping paper (filter overwrap) (mm)	Length of tobacco rod (mm)	Mass of tobacco rod including filler, paper, and adhesive (g)
EX0000289	Camel Classic Wides Blue	79	██████			
EX0000290	Camel Classic Menthol Silver Box	83	██████			
EX0000291	Camel Classic Filters 99	98	██████			

Table 2: Product Component Measurements						
STN	New Product	Length of cigarette (mm)	Mass of one cigarette (g)	Length of tipping paper (filter overwrap) (mm)	Length of tobacco rod (mm)	Mass of tobacco rod including filler, paper, and adhesive (g)
EX0000292	Camel Classic Wides Filters	79	██████			
EX0000293	Camel Classic Platinum	83	██████			

If the applicant adequately responds to the request and an EIS or FONSI is completed, EX order letters should be issued for the new tobacco products in EX0000289-EX0000293, as identified on the cover page of this review.