

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000303 – EX0000307**

EX0000303: Camel Classic Menthol	
Length	83 mm
Diameter	7.8 mm
Ventilation	10%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4)) • Addition of filter tow ((b) (4)) • Deletion of cork tipping paper ((b) (4)); Target: ((b) (4) mg/cig) • Addition of cork-on-white tipping paper ((b) (4)); Target: ((b) (4) mg/cig) • Deletion of printed monogram ink (green) on barrel ((b) (4)) • Addition of printed monogram ink (blue) on barrel ((b) (4))
EX0000304: Camel Classic Filters Soft Pack	
Length	83 mm
Diameter	7.9 mm
Ventilation	22%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4)) • Addition of filter tow ((b) (4)) • Deletion of cork tipping paper ((b) (4)); Target: ((b) (4) mg/cig) • Addition of cork-on-white tipping paper ((b) (4)); Target: ((b) (4) mg/cig) • Deletion of printed monogram ink (gold) on barrel ((b) (4)) • Addition of printed monogram ink (blue) on barrel ((b) (4))
EX0000305: Camel Classic Filters	
Length	83 mm
Diameter	7.8 mm
Ventilation	23%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter tow ((b) (4)) • Addition of filter tow ((b) (4)) • Deletion of cork tipping paper ((b) (4)); Target: ((b) (4) mg/cig) • Addition of cork-on-white tipping paper ((b) (4)); Target: ((b) (4) mg/cig) • Deletion of printed monogram ink (gold) on barrel ((b) (4)) • Addition of printed monogram ink (blue) on barrel ((b) (4))

EX0000306: Camel Classic Wides Menthol	
Length	79 mm
Diameter	8.6 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) • Deletion of cork tipping paper (b) (4); Target: (b) (4) mg/cig • Addition of cork-on-white tipping paper (b) (4); Target: (b) (4) mg/cig • Deletion of printed monogram ink (green) on barrel (b) (4) • Addition of printed monogram ink (blue) on barrel (b) (4)
EX0000307: Camel Classic Wides Menthol Silver	
Length	79 mm
Diameter	8.6 mm
Ventilation	37%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) • Deletion of cork tipping paper (b) (4); Target: (b) (4) mg/cig • Addition of cork-on-white tipping paper (b) (4); Target: (b) (4) mg/cig • Deletion of printed monogram ink (green) on barrel (b) (4) • Addition of printed monogram ink (blue) on barrel (b) (4)
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: EX0000303 and EX0000305 – EX0000307 Soft Pack: EX0000304
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

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Date: 2019.03.27 16:27:06 -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: 2019.03.28 07:28:52 -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 Products

EX0000303: Camel Classic Menthol	
Product Name	Camel Filters Menthol Hard Pack
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	10%
Characterizing Flavor	Menthol
EX0000304: Camel Classic Filters Soft Pack	
Product Name	Camel Filters King Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.9 mm
Ventilation	22%
Characterizing Flavor	None
EX0000305: Camel Classic Filters	
Product Name	Camel Filters Hard Pack
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	23%
Characterizing Flavor	None
EX0000306: Camel Classic Wides Menthol	
Product Name	Camel Wides Menthol Filters Hard Pack
Package Type	Box
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	8.6 mm
Ventilation	0%
Characterizing Flavor	Menthol

EX0000307: Camel Classic Wides Menthol Silver	
Product Name	Camel Wides Lights Menthol Hard Pack
Package Type	Box
Package Quantity	20 Cigarettes
Length	79 mm
Diameter	8.6 mm
Ventilation	37%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On November 7, 2018, FDA received five Exemption Requests (EX0000303 – EX0000307) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On November 14, 2018, FDA issued Acknowledgement letter to the applicant. On December 31, 2018, an Advice/Information Request (A/I) letter was issued. In response, the applicant submitted an amendment (EX0000438) to the Exemption Request, received by FDA on January 30, 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 cork tipping paper ((b) (4))
- Addition of cork-on-white tipping paper ((b) (4))
- Deletion of filter tow ((b) (4))
- Addition of filter tow ((b) (4))
- Deletion of printed monogram ink (green or gold) on barrel ((b) (4))
- Addition of printed monogram ink (blue) on barrel ((b) (4))

2. REGULATORY REVIEW

Regulatory reviews were completed by Kaylene Charles on November 14, 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 December 2, 2018, conclude that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modifications under the Exemption Request pathway.¹

4. SCIENTIFIC REVIEW

Scientific reviews were completed by Jeffrey Ammann on December 12, 2018 and Megan Mekoli on February 20, 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 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 tipping paper and the addition of cork-on-white tipping paper for all Exemption Requests 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. Additionally, for all Exemption Requests, the reviews conclude that the deletion of monogram ink (green or gold) on the cigarette barrel and the addition of monogram ink (blue) on the cigarette barrel is a minor modification and this is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products and are not expected to alter the HPHC yields of the new tobacco products. A toxicology consult dated December 12, 2018, examined if there were any toxicology concerns when the ink color is changed yet the quantity of ink remains the same. The toxicology consult concluded the quantities of these ingredients are very low and therefore, do not expect an appreciable risk from exposures to these ingredients at these levels. Therefore, the replacement of green or gold monogram inks with blue monogram ink on the cigarette barrel is not of toxicological concern.

S. ENVIRONMENTAL DECISION

Environmental reviews were completed by Dilip Venugopal on December 14, 2018, and March 7, 2019.

¹ 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.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 27, 2019. The FONSI was supported by an environmental assessment prepared by FDA on March 27, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of cork tipping paper ((b) (4) .)
- Addition of cork-on-white tipping paper ((b) (4) .)
- Deletion of filter tow ((b) (4))
- Addition of filter tow ((b) (4))
- Deletion of printed monogram ink (green or gold) on barrel ((b) (4) .)
- Addition of printed monogram ink (blue) on barrel ((b) (4) .)

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 tipping paper, filter tow, and monogram ink on barrel), and addition of tobacco additives (filter tow, cork-on-white tipping paper, and monogram ink on barrel). 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 tipping paper followed by the addition of cork-on-white tipping paper for all Exemption Requests, 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. Additionally, for all Exemption Requests, the reviews conclude that the deletion of monogram ink (green or gold) on the cigarette barrel and the addition of monogram ink (blue) on the cigarette barrel is a minor modification and this is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products and are not expected to alter the HPHC yields of the new tobacco products. A toxicology consult dated December 12, 2018, examined if there were any toxicology concerns when the ink color is changed yet the quantity of ink remains the same. The toxicology consult concluded the quantities of these ingredients are very low and therefore, do not expect an appreciable risk from exposures to these ingredients at these levels. Therefore, the replacement of green or gold monogram inks with blue monogram ink on the cigarette barrel is not of toxicological concern. 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).

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 EX0000303 – EX0000307 as identified on the cover page of this review.