

**Technical Project Lead (TPL) Review:  
Exemption Requests EX0000665 – EX0000670**

EX0000665: Camel Royal	
Length	83 mm
Diameter	7.8 mm
Ventilation	24%
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) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <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> </ul>
EX0000666: Camel Silver	
Length	83 mm
Diameter	7.8 mm
Ventilation	32%
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) (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <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> </ul>
EX0000667: Carlton Red 120 Soft Pack	
Length	120 mm
Diameter	6.7 mm
Ventilation	75%
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) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <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>

EX0000668: Now Red 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	69%
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); target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <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> <li>• Deletion of complex purchased flavor ingredient (b) (4) and ingredient (b) (4) in the (b) (4)</li> </ul> <p>Increasing/Decreasing in the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> <li>• Increasing the quantity of (b) (4) in the (b) (4)</li> </ul>
EX0000669: Carlton Menthol Green 120 Soft Pack	
Length	120 mm
Diameter	6.7 mm
Ventilation	78%
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) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <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>
EX0000670: Now Red Soft Pack	
Length	84 mm
Diameter	7.9 mm
Ventilation	76%
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) target: (b) (4) mg/cigarette)</li> <li>• Addition of filter tow (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> </ul>

	<ul style="list-style-type: none"> <li>• Addition of white tipping paper (b) (4) target: (b) (4) mg/cigarette)</li> <li>• Deletion of complex purchased flavor ingredient (b) (4) and ingredient (b) (4) in the (b) (4)</li> </ul> <p>Increasing/Decreasing in the quantity of existing tobacco additives: Increasing the quantity of (b) (4) in the (b) (4)</p>
<b>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	Box: EX0000665 and EX0000666 Soft Pack: EX0000667 – EX0000670
<b>Recommendation</b>	
Issue Exempt order letter.	

**Technical Project Lead (TPL):**

Digitally signed by Matthew J. Walters -S  
Date: 2020.02.13 11:06:28 -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: 2020.02.13 11:14:19 -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>EX0000665: Camel Royal</b>	
<b>Product Name</b>	Camel Royal
<b>Package Type</b>	Box
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83 mm
<b>Diameter</b>	7.8 mm
<b>Ventilation</b>	24%
<b>Characterizing Flavor</b>	None
<b>EX0000666: Camel Silver</b>	
<b>Product Name</b>	Camel Silver
<b>Package Type</b>	Box
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	83 mm
<b>Diameter</b>	7.8 mm
<b>Ventilation</b>	32%
<b>Characterizing Flavor</b>	None
<b>EX0000667: Carlton 120 Soft Pack</b>	
<b>Product Name</b>	Carlton 120s Soft Pack
<b>Package Type</b>	Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	120 mm
<b>Diameter</b>	6.7 mm
<b>Ventilation</b>	75%
<b>Characterizing Flavor</b>	None
<b>EX0000668: Now Red 100 Soft Pack</b>	
<b>Product Name</b>	Now Ultra Light 100s Soft Pack
<b>Package Type</b>	Soft Pack
<b>Package Quantity</b>	20 Cigarettes
<b>Length</b>	99 mm
<b>Diameter</b>	7.9 mm
<b>Ventilation</b>	69%
<b>Characterizing Flavor</b>	None

EX0000669: Carlton Menthol Green 120 Soft Pack	
Product Name	Carlton Menthol 120s Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	120 mm
Diameter	6.7 mm
Ventilation	78%
Characterizing Flavor	Menthol
EX0000670: Now Red Soft Pack	
Product Name	Now Ultra Light King Soft Pack
Package Type	Box
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	76%
Characterizing Flavor	None

The applicant manufactures the original tobacco products and claims that they are previously found substantially equivalent for EX0000665 and EX0000666; and grandfathered for EX0000667 – EX0000670.

## 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On June 27, 2019, FDA received the Exemption Requests (EX0000665 – EX0000670) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On July 8, 2019, FDA issued an Acknowledgment letter to the applicant.

## 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for this Exemption Request.

## 1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco products contains the following modifications compared to the original tobacco products:

- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)
- Deletion of cork or white tipping paper (b) (4)
- Addition of cork or white tipping paper (b) (4)
- Deletion of complex purchased flavor ingredient (b) (4) and ingredient (b) (4) for EX0000668 and EX0000670
- Increase in the existing quantity of (b) (4) for EX0000668 and EX0000670

## 2. REGULATORY REVIEW

Regulatory reviews were completed by Crystal Caesar on July 5, 2019. The reviews conclude that the Exemption Requests are administratively complete.

## 3. COMPLIANCE REVIEW

The original tobacco products in EX0000665 and EX0000666 were determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act)] by FDA under SE0013013 and SE0013015, respectively. Additionally, 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) for EX0000667 – EX0000670. The OCE reviews dated July 28, 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 Abdurrafay Shareef on February 13, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives as well as increasing existing tobacco additives.<sup>2</sup> Tipping paper, filter tow, the flavorings (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. The review concludes that the individual and collective 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 significant effects on product chemistry. Additionally, this change is 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 ventilation of a product; however, the ventilation of the new and original tobacco products remains the same. Finally, for EX0000668 and EX0000670 only, the deletion of the complex flavoring of (b) (4) and the ingredient (b) (4) along with the increase of the existing additive of (b) (4) is a minor modification in accordance with section 905(j)(3)(A)(i) of the FD&C Act. For EX0000668 and EX0000670, the review concludes that the deletion of (b) (4) and the ingredient (b) (4) along with the increase of the existing additive of (b) (4) is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other

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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> EX0000668 and EX0000670 only.



features) of the tobacco products. Thus, the scientific review has concluded that the individual and collective changes are minor modifications.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on July 12, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 1, 2019. The FONSI was supported by an environmental assessment prepared by FDA on August 1, 2019.

## 6. CONCLUSION AND RECOMMENDATION

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

- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)
- Deletion of cork or white tipping paper (b) (4)
- Addition of cork or white tipping paper (b) (4)
- Deletion of complex purchased flavor ingredient (b) (4) and ingredient (b) (4) for EX0000668 and EX0000670
- Increase in the existing quantity of (b) (4) for EX0000668 and EX0000670

I concur with the conclusion of the scientific review that these individual and collective 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 review that the changes represent the deletion of tobacco additives (cork or white tipping paper, filter tow, and flavorings (b) (4) the addition of tobacco additives (alternate filter tow and cork or white tipping paper), and increase in the quantity of an existing tobacco additive (b) (4). 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 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 ventilation of a product; however, the ventilation remains the same when comparing the new and corresponding original tobacco product. Furthermore, the applicant also proposed the deletion of white or 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. Finally, for EX0000668 and EX0000670, the review concludes that the deletion of (b) (4) and the ingredient (b) (4) along with the increase of the existing additive of (b) (4) 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. Lastly, FDA finds based on the information contained in the Exemption Request 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 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 products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products for EX0000665 and EX0000666 were previously found SE and in compliance with the FD&C Act by FDA under SE0013013 and SE0013015, respectively, and for EX0000667 – EX0000670 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 EX0000665 – EX0000670 as identified on the cover page of this review.