

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000812 – EX0000815**

EX0000812: Carlton Menthol Green Soft Pack	
Length	84 mm
Diameter	7.9 mm
Ventilation	76%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000813: Carlton Menthol Green 100	
Length	97 mm
Diameter	7.9 mm
Ventilation	81%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in quantity of filter sideseam adhesive
EX0000814: Carlton Red 100	
Length	97 mm
Diameter	7.9 mm
Ventilation	81%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of white tipping paper (b) (4)

	<ul style="list-style-type: none"> • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in quantity of filter sideseam adhesive
EX0000815: Carlton Red	
Length	83 mm
Diameter	7.9 mm
Ventilation	78%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in quantity of filter sideseam adhesive
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	Soft Pack: EX0000812 Box: EX0000813–EX0000815
Conclusion	
Issue Exempt order letter.	

Technical Project Lead (TPL):

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Date: 2019.12.05 09:31:47 -05'00'

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: 2019.12.05 10:07:09 -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

EX0000812: Carlton Menthol Green Soft Pack	
Product Name	Carlton Menthol King Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	76%
Characterizing Flavor	Menthol
EX0000813: Carlton Menthol Green 100	
Product Name	Carlton Menthol 100s Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	97 mm
Diameter	7.9 mm
Ventilation	81%
Characterizing Flavor	Menthol
EX0000814: Carlton Red 100	
Product Name	Carlton 100s Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	97 mm
Diameter	7.9 mm
Ventilation	81%
Characterizing Flavor	None
EX0000815: Carlton Red	
Product Name	Carlton King Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.9 mm
Ventilation	78%
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 15, 2019, FDA received Exemption Requests EX0000812-EX0000815 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 28, 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) (EX0000812-EX0000815)
- Addition of white tipping paper (b) (4) (EX0000812-EX0000815)
- Deletion of filter tow (b) (4) (EX0000812-EX0000815)
- Addition of filter tow (b) (4) (EX0000812-EX0000815)
- Deletion of filter center line adhesive (b) (4) (EX0000813-EX0000815)
- Addition of filter center line adhesive (b) (4) (EX0000813-EX0000815)
- Increase in quantity of filter sideseam adhesive (EX0000813-EX0000815)

2. ADMINISTRATIVE REVIEW

Regulatory reviews were completed by Shontelle Dixon on October 24, 2019. The review concludes that these Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco product 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 12, 2019 for EX0000812-EX0000813 and November 14, 2019 for EX0000814-EX0000815 conclude that the original tobacco products are grandfathered products.

Therefore, the original products are eligible for modification under the Exemption Request pathway.¹

4. SCIENTIFIC REVIEW

A scientific review was completed by Margaret Schmierer on 12/4/2019.

The 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

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.

center line adhesive², and filter sideseam adhesive² are substances used in the manufacture of the original tobacco product filters 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 modification of tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

For EX0000813-EX0000815, the review concludes, the deletion of filter center line adhesive in the original products and the addition of an alternate filter center line adhesive and increase in the amount of filter sideseam adhesive in the new products is a minor modification. Because the filter centerline adhesive and filter sideseam adhesive are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the filter are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. The review also concludes for all EX Requests that the deletion of white tipping paper and the addition of 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 and because the tipping paper is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the tipping paper are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. Furthermore, the review concludes that for all EX Requests, the deletion of filter tow and the addition of an alternative 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 products. The differences in the filter tow in the original and new tobacco products is the quantity of (b) (4) used in the new products is lower than the amount used in the original products. The difference in the relative quantities of (b) (4) are not expected to have a meaningful impact on the relative performance of the new and original product filters. As a result, the ingredient differences between the filter tow of the new and original products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original tobacco product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on November 5, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 12, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 12, 2019.

² EX0000813-EX0000815 only

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) (EX0000812-EX0000815)
- Addition of white tipping paper (b) (4) (EX0000812-EX0000815)
- Deletion of filter tow (b) (4) (EX0000812-EX0000815)
- Addition of filter tow (b) (4) (EX0000812-EX0000815)
- Deletion of filter center line adhesive (b) (4) (EX0000813-EX0000815)
- Addition of filter center line adhesive (b) (4) (EX0000813-EX0000815)
- Increase in quantity of filter sideseam adhesive (EX0000813-EX0000815)

I concur with the conclusion of the scientific review that these modifications are a 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 adhesive², and filter sideseam adhesive² are substances used in the manufacture of the original tobacco products' filters 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. I concur with the conclusion in the review that the modifications are minor modification of tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. 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 product to be marketed would be appropriate for protection of the public health. For EX0000812-EX0000815, I also agree with the conclusion that the deletion of filter center line adhesive in the original products, the addition of an alternate filter center line adhesive, and the increase in the filter sideseam adhesive in the new products are minor modifications. These changes are made to the filter of the tobacco product, which is not combusted, volatilized, or otherwise released during normal cigarette consumption, therefore the ingredient differences and relatively small increase in content between the filter adhesive of the new and original products are not expected to significantly alter the relative smoke chemistry or consumer exposure to chemical constituents of the new product relative to the original product. I also agree that the deletion of white tipping paper and the addition of 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 and because the tipping paper is not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of these ingredients in the filter are not expected to significantly alter the smoke chemistry or consumer exposure to chemical constituents while smoking. Additionally, I agree with the review's conclusion that the deletion of filter tow and the addition of an alternative 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 products. The differences in the filter tow in the original and new tobacco products is the quantity of (b) (4) used in

the new products is lower than the amount used in the original products. The difference in the relative quantities of (b) (4) are not expected to have a meaningful impact on the relative performance of the new and original product filters. Lastly, FDA finds, based on the information contained in the Exemption Request 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 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 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 EX0000812-EX0000815 as identified on the cover page of this review.