

**Technical Project Lead (TPL) Review:
Exemption Request EX0000239 – EX0000243**

EX0000239: Newport Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	0 %
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC¹ cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4), Target: (b) (4) mg/cig • Deletion of filter tow (b) (4) • Addition of alternate filter tow (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of alternate cork tipping paper (b) (4)
EX0000240: Newport Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	0 %
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4), Target: (b) (4) mg/cig • Deletion of filter tow (b) (4) • Addition of alternate filter tow (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of alternate cork tipping paper (b) (4)
EX0000241: Newport Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	0 %
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4), Target: (b) (4) mg/cig • Deletion of filter tow (b) (4) • Addition of alternate filter tow (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of alternate cork tipping paper (b) (4)

¹ FSC: Fire Standards Compliant

EX0000242: Newport Kings	
Length	84 mm
Diameter	7.9 mm
Ventilation	0 %
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4) Target: (b) (4) mg/cig) • Deletion of filter tow (b) (4) • Addition of alternate filter tow (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of alternate cork tipping paper (b) (4)
EX0000243: Newport Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	0 %
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non- FSC cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4) Target: (b) (4) mg/cig) • Deletion of filter tow (b) (4) • Addition of alternate filter tow (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of alternate cork tipping paper (b) (4)
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: EX0000239 - EX0000241, and EX0000243 Soft Pack: EX0000242
Recommendation	
Issue Exempt order letters	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.08.22 12:31:47 -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: 2018.08.22 12:36:18 -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 Product

EX0000239: Newport Box 100s	
Product Name	Newport Menthol Box 100s
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000240: Newport Box 100s	
Product Name	Newport Menthol Box 100s
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000241: Newport Box	
Product Name	Newport Menthol Box
Package Type	Box
Package Quantity	20 cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000242: Newport Kings	
Product Name	Newport Menthol Kings
Package Type	Soft Pack
Package Quantity	20 cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol

EX0000243: Newport Box	
Product Name	Newport Menthol Box
Package Type	Box
Package Quantity	20 cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the Exemption Requests (EX0000239 - EX0000243) on July 2, 2018. FDA issued the applicant Acknowledgement letters for these Exemption Requests on July 6, 2018. On July 26, 2018, FDA requested additional information for the Environmental Assessment (EA). On August 2, 2018, FDA received the applicant's response (EX0000257).

1.3. SCOPE OF MEMO

This memo 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 non-FSC cigarette paper
- Addition of FSC cigarette paper
- Deletion of filter tow
- Addition of alternate filter tow
- Deletion of cork tipping paper
- Addition of alternate cork tipping paper

2. REGULATORY REVIEW

Regulatory reviews were completed by Barbara Banchemo on July 6, 2018. The reviews conclude that the 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 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, August 4, 2018 (EX0000239-EX0000241, EX0000243) and August 6, 2018 (EX0000242), concludes that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modifications under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Selena Russell on August 7, 2018.

The review states that the new tobacco products have been modified by adding and deleting tobacco additives. Cigarette paper, tipping paper, and filter tow 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 a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new products is a minor modification. The change from non-FSC to FSC cigarette paper may result in increased Harmful and Potentially Harmful Constituents (HPHC) yields; however, the reduction in household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of the FSC cigarette paper, as outlined in the July 17, 2017 toxicology memo. The review also concludes that the deletion of a cork tipping paper with the addition of an alternative cork 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 or product chemistry. Furthermore, the review concludes that the deletion of filter tow and the addition of an alternative filter tow due to a supplier change 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 product. The filter tow can influence the ventilation of a product; however, the ventilation of the new and original tobacco products remains the same at 0%. Thus, the review concludes that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on August 22, 2018. The FONSI was supported by an environmental assessment prepared by FDA on August 22, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of non-FSC cigarette paper

² 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.

- Addition of FSC cigarette paper
- Deletion of filter tow
- Addition of alternate filter tow
- Deletion of cork tipping paper
- Addition of alternate cork tipping paper

I concur with the conclusion of the scientific review that these modifications are a minor modification 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 deletion of three tobacco additives (non-FSC cigarette paper, cork tipping paper, and filter tow) and, the addition of three tobacco additives (FSC cigarette paper, alternate cork tipping paper, and alternate filter tow). 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. At this time, based on the information available and CTP’s scientific understanding and experience with non-FSC to FSC cigarette paper modifications that are limited to changes in tobacco additives and do not result in other changes to the product (e.g., no changes to blend, filter, design parameters such as ventilation), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. The applicant also proposed the deletion of cork tipping paper followed by the addition of an alternate cork tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. Furthermore, the review concludes that the deletion of filter tow and the addition of an alternative filter tow due to a supplier change 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 product. The filter tow can influence the ventilation of a product; however, the ventilation of the new and original tobacco product remains the same at 0%. 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 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 the exemption from Substantial Equivalence pathway because they are legally marketed in the United States. The original products are grandfathered products (i.e., was 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 EX0000239-EX0000243 as identified on the cover page of this review.