

**Technical Project Lead (TPL) Review:
Exemption Request EX0000221 – EX0000223**

EX0000221: Newport Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC¹ cigarette paper (b) (4)) • Addition of FSC paper (b) (4)) • Deletion of cork tipping paper (b) (4)) • Addition of alternate cork tipping paper (b) (4))
EX0000222: Newport Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4)) • Addition of FSC paper (b) (4)) • Deletion of cork tipping paper (b) (4)) • Addition of alternate cork tipping paper (b) (4))
EX0000223: Newport Kings	
Length	84 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4)) • Addition of FSC paper (b) (4)) • Deletion of cork tipping paper (b) (4)) • Addition of alternate cork tipping paper (b) (4))

¹ Fire Standards Compliant

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: EX0000221 and EX0000222 Soft Pack: EX00000223
Recommendation	
Issue Exempt order letters	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.07.05 14:01:32 -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: 2018.07.05 15:11:44 -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

EX0000221: Newport Box	
Product Name	Newport Menthol Box
Package Quantity	20 cigarettes
Package Type	Box
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Properties	<ul style="list-style-type: none"> • Non-FSC cigarette paper (b) (4) • Cork tipping paper (b) (4)
EX0000222: Newport Box 100s	
Product Name	Newport Menthol Box 100s
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Properties	<ul style="list-style-type: none"> • Non-FSC cigarette paper (b) (4) • Cork tipping paper (b) (4)
EX0000223: Newport Kings	
Product Name	Newport Menthol Kings
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
Additional Properties	<ul style="list-style-type: none"> • Non-FSC cigarette paper (b) (4) • Cork tipping paper (b) (4)

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 (EX0000221 – EX0000223) on May 8, 2018. FDA issued the applicant Acknowledgement letter for these Exemption Requests on May 14, 2018.

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 original tobacco products:

- Deletion of non-FSC cigarette paper (b) (4)
- Addition of FSC paper (b) (4)
- Deletion of cork tipping paper (b) (4)
- Addition of alternate cork tipping paper (b) (4) (EX0000221 and EX0000223) and (b) (4) (EX0000222)

2. REGULATORY REVIEW

Regulatory reviews were completed by Crystal Caesar on May 11, 2018. These 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 legally marketed. The OCE review, dated June 13, 2018, concludes 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). Therefore, the original products are eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Megan Mekoli on June 20, 2018. The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Cigarette paper and tipping paper 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

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.

review concludes that the modifications are a minor modification 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 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 14, 2017 toxicology memo. The applicant also proposed the deletion of a cork tipping paper with the addition of an alternative cork tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception as outlined in the May 16, 2017, social science memo.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on July 5, 2018. The FONSI was supported by an environmental assessment prepared by FDA on July 5, 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 (b) (4)
- Addition of FSC paper (b) (4)
- Deletion of cork tipping paper (b) (4)
- Addition of alternate cork tipping paper (b) (4) (EX0000221 and EX0000223) and (b) (4) (EX0000222)

I concur with the conclusion of the scientific review 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 review that the the modifications are a deletion of non-FSC cigarette paper and the addition of FSC cigarette paper along with the deletion of cork tipping paper with an alternative cork 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 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, etc.), 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. Additionally, the applicant also proposed the deletion of cork tipping paper followed by the addition of an alternative cork tipping paper, which is not expected to have any significant effects on product

chemistry or consumer perception. 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 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 EX0000221-EX0000223 as identified on the cover page of this review.