

**Technical Project Lead (TPL) Review:  
Exemption Request EX0000189 – EX0000191**

<b>EX0000189: Newport Kings</b>	
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	0.0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Removal of tobacco additives: substitution of original FSC <sup>1</sup> cigarette paper with alternate FSC cigarette paper
<b>EX0000190: Newport Box</b>	
Length	80 mm
Diameter	7.9 mm
Filter Ventilation	0.0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Removal of tobacco additives: substitution of original FSC cigarette paper with alternate FSC cigarette paper
<b>EX0000191: Newport Box 100s</b>	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	0.0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Removal of tobacco additives: substitution of original FSC cigarette paper with alternate FSC cigarette paper
<b>Common 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	Soft Pack: EX0000189 Box: EX0000190 and EX0000191
<b>Recommendation</b>	
Issue an Exempt order letter.	

<sup>1</sup> Fire Standards Complaint

**Technical Project Lead (TPL):**

Matthew J. Walters -S  
2017.10.13 14:35:53 -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: 2017.10.13 14:37:36 -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**

EX0000189	
Product Name	Newport Menthol Kings
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	0%
Characterizing Flavor	Menthol
EX0000190	
Product Name	Newport Menthol Box
Package Quantity	20 cigarettes
Package Type	Box
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000191	
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

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 original Exemption Requests EX0000189 – EX0000191 on August 7, 2017. FDA issued the applicant an Acknowledgement letter for these Exemption Requests on August 14, 2017.

### 1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for these Exemption Requests.

#### 1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco products contain the following modification compared to the corresponding tobacco product:

- Substitution of substitution of an original FSC cigarette paper with an alternate FSC cigarette paper

#### 2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Crystal Caesar on August 14, 2017. The review concludes 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 product is a grandfathered product (i.e., was commercially marketed as of February 15, 2007). The OCE review dated, concludes that the original tobacco product is a grandfathered product. Therefore, the original September 14, 2107 product is eligible for modification under the Exemption Request pathway.<sup>2</sup>

#### 4. SCIENTIFIC REVIEW

A scientific review was completed by Jikun Liu on October 10, 2017. The review concludes that the modification is a minor modification of tobacco additives in accordance with section 905(j)(3)(A)(i) of the FD&C Act. The review concludes the substitution of an original FSC cigarette paper with an alternative FSC cigarette paper is a minor modification. The differences between the original FSC cigarette paper and the alternative FSC cigarette paper showed very minor differences with the only difference in the base paper weight (e.g. (b) (4) between the two FSC cigarette papers. These differences are not expected to have a significant impact on the product performance or HPHC yields.

#### 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on October 13, 2017. The FONSI was supported by an environmental assessment prepared by FDA on October 13, 2017.

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<sup>2</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.

## 6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modification compared to the corresponding original tobacco product:

- Substitution of substitution of an original FSC cigarette paper with an alternate FSC cigarette paper

I concur with the chemistry reviewer that the substitution of an original FSC cigarette paper with an alternative FSC cigarette paper adds and deletes a tobacco additive to the new product. I also concur that this modification is a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. In addition, it is my conclusion and 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. The differences between the original FSC cigarette paper and the alternative FSC cigarette paper showed very minor differences with the only difference in the base paper weight (e.g. (b) (4) between the two FSC cigarette papers. These differences are not expected to have a significant impact on the product performance or HPHC yields. Thus, the modification proposed in this Exemption Request 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 product meets statutory requirements because they are legally marketed in the United States. The original products are grandfathered products (i.e., were commercially marketed in the United States 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 product in EX0000189 – EX0000191 as identified on the cover page of this review.