

**Technical Project Lead (TPL) Review:
Exemption Request EX0000182 – EX0000186, EX0000188**

EX0000182: Newport Box	
Length	80 mm
Diameter	7.9 mm
Filter Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Deletion of tobacco additives: substitution of non-FSC ¹ cigarette paper with FSC cigarette paper
EX0000183: Newport Box 100s	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Deletion of tobacco additives: substitution of non-FSC ¹ cigarette paper with FSC cigarette paper
EX0000184: Newport Box 100s	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Deletion of tobacco additives: substitution of non-FSC ¹ cigarette paper with FSC cigarette paper
EX0000185: Newport Box	
Length	80 mm
Diameter	7.9 mm
Filter Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Deletion of tobacco additives: substitution of non-FSC ¹ cigarette paper with FSC cigarette paper
EX0000186: Newport Kings	
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Deletion of tobacco additives: substitution of non-FSC ¹ cigarette paper with FSC cigarette paper

¹ Fire Standards Compliant

EX0000188: Newport Kings	
Length	84 mm
Diameter	7.9 mm
Filter Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Substitution/Deletion of tobacco additives: substitution of non-FSC ¹ cigarette paper with FSC cigarette paper
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	Box: EX0000182- EX0000185
	Soft Pack: EX0000186, EX0000188
Additional Property	FSC Paper 1 (b) (4): EX0000182, EX0000184, EX0000188
	FSC Paper 2 (b) (4): EX0000183, EX0000185, EX0000186
Recommendation	
Issue Exempt order letters	

Technical Project Lead (TPL):

Digitally signed by Colleen K. Rogers -S
 Date: 2017.09.08 13:55:58 -04'00'

For 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: 2017.09.08 14:10:25 -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

EX0000182	
Product Name	Newport Menthol Box
Package Quantity	20 cigarettes
Package Type	Box
Length	80 mm
Diameter	7.9 mm
Filter Ventilation	0%
Characterizing Flavor	Menthol
EX0000183	
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
EX0000184	
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
EX0000185	
Product Name	Newport Menthol Box
Package Quantity	20 cigarettes
Package Type	Box
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol

EX0000186	
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
EX0000188	
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

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 EX0000182 – EX0000186 on July 10, 2017, and EX0000188 on July 14, 2017. FDA issued the applicant an Acknowledgement letter for these Exemption Requests on July 20, 2017. FDA held a teleconference on August 18, 2017 to clarify the applicant's marketing information for the current and future original product production. In response, on August 25, 2017, the applicant submitted a solicited amendment containing this information (EX0000192).

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 non-FSC cigarette paper with FSC cigarette paper

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Brandon Rose on July 20, 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 products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated August 17, 2017, conclude that the original tobacco products are grandfathered products. Therefore the original products are eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Stephanie Daniels on August 25, 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 non-FSC cigarette paper to FSC cigarette paper 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 Division of Nonclinical Science memo.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 8, 2017. The FONSI was supported by an environmental assessment prepared by FDA on September 8, 2017.

6. CONCLUSION AND RECOMMENDATION

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

- Substitution of non-FSC cigarette paper with FSC cigarette paper

I concur with the chemistry reviewer that the substitution of non-FSC cigarette paper with 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, that 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. Thus, the modification proposed in these Exemption Requests are otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, 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.

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 meet 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 products in EX0000182 – EX0000186, and EX0000188 as identified on the cover page of this review.