

**Technical Project Lead (TPL) Review:
Exemption Request EX0000224 – EX0000228**

EX0000224: 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-FSC¹ cigarette paper (b) (4) • Addition of FSC cigarette paper (b) (4) • 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)
EX0000225: 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) • Deletion of cork tipping paper (b) (4) • Addition of alternate cork tipping paper (b) (4)
EX0000226: 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) • 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 Fire Standards Compliant

EX0000227: 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 cigarette paper (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of alternate cork tipping paper (b) (4)
EX0000228: 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 cigarette paper (b) (4) • 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: EX0000224 – EX0000226 Soft Pack: EX0000227 and EX0000228
Recommendation	
Issue Exempt order letters	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.07.05 14:03:56 -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 15:14:45 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

TABLE OF CONTENTS

1. BACKGROUND5

1.1. ORIGINAL TOBACCO PRODUCTS 5

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO 6

1.3. SCOPE OF MEMO 6

1.4. TOBACCO ADDITIVE MODIFICATION..... 6

2. REGULATORY REVIEW6

3. COMPLIANCE REVIEW6

4. SCIENTIFIC REVIEW7

5. ENVIRONMENTAL DECISION.....7

6. CONCLUSION AND RECOMMENDATION7

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Product

EX0000224: 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
EX0000225: 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
EX0000226: 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
EX0000227: 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
EX0000228: 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

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 EX0000224 – EX0000228 on May 11, 2018. FDA issued Acknowledgement letters for these Exemption Requests on May 21, 2018.

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 modifications compared to the original tobacco products:

- Deletion of non-FSC cigarette paper (all EX Requests)
- Addition of FSC cigarette paper (all EX Requests)
- Deletion of filter tow (EX0000224, EX0000226, and EX0000228 only)
- Addition of alternate filter tow (EX0000224, EX0000226, and EX0000228 only)
- Deletion of cork tipping paper (all EX Requests)
- Addition of alternate cork tipping paper (all EX Requests)

2. REGULATORY REVIEW

A regulatory review was completed by Barbara Banchemo on May 21, 2018. 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 products are legally marketed. The OCE review, dated June 20, 2018 (EX0000224 – EX0000227) and June 21, 2018 (EX0000228), 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

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.

4. SCIENTIFIC REVIEW

A scientific review was completed by Melis Coraggio on June 26, 2018. The review states that the new tobacco products have been modified by adding and deleting tobacco additives. 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 because the benefit of using FSC paper to reduce cigarette-related household fires is anticipated to outweigh any potential increased health risks caused by the small increases in HPHC exposures that may occur from the use of the FSC paper (See July 17, 2017 toxicology memo). The applicant also proposed the deletion of 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. Additionally, for EX0000224, EX0000226, and EX0000228, 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 remain 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 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 (all EX Requests)
- Addition of FSC cigarette paper (all EX Requests)
- Deletion of filter tow (EX0000224, EX0000226, and EX0000228 only)
- Addition of alternate filter tow (EX0000224, EX0000226, and EX0000228 only)
- Deletion of cork tipping paper (all EX Requests)
- Addition of alternate cork tipping paper (all EX Requests)

I concur with the scientific reviewer that these modifications are minor modifications of a tobacco product 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 the protection of 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. Furthermore, for EX0000224, EX0000226, and EX0000228, 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 for EX0000224, EX0000226, and EX0000228 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 these modifications 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 can be 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 EX0000224 – EX0000228 as identified on the cover page of this review.