

**Technical Project Lead (TPL) Review:
Exemption Request EX0000215 – EX0000217**

EX0000215: Newport Menthol Gold Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	22%
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) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED]) • Deletion of cork-on-white tipping paper (b) (4) [REDACTED]) • Addition of alternate cork-on-white tipping paper (b) (4) [REDACTED]) • Deletion of printed monogram ink on the barrel
EX0000216: Newport Menthol Blue Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	12%
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) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED]) • Deletion of cork-on-white tipping paper (b) (4) [REDACTED]) • Addition of alternate cork-on-white tipping paper (b) (4) [REDACTED]) • Deletion of printed monogram ink on the barrel
EX0000217: Newport Menthol Blue Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	20%
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) [REDACTED]) • Addition of FSC cigarette paper (b) (4) [REDACTED])

¹ Fire Standards Compliant

	<ul style="list-style-type: none"> • Deletion of cork-on-white tipping paper (b) (4) [REDACTED]) • Addition of alternate cork-on-white tipping paper (b) (4) [REDACTED]) • Deletion of printed monogram ink on the barrel
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
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Matthew J. Walters -S
 2018.06.13 11:20:16 -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: 2018.06.13 11:43:44 -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

EX0000215: Newport Menthol Gold Box	
Product Name	Newport Lights Menthol Gold Box
Package Quantity	20 cigarettes
Package Type	Box
Length	80 mm
Diameter	7.9 mm
Ventilation	22%
Characterizing Flavor	Menthol
EX0000216: Newport Menthol Blue Box 100s	
Product Name	Newport Medium Menthol Blue Box 100s
Package Quantity	20 cigarettes
Package Type	Box
Length	99 mm
Diameter	7.9 mm
Ventilation	12%
Characterizing Flavor	Menthol
EX0000217: Newport Menthol Blue Box	
Product Name	Newport Medium Menthol Blue Box
Package Quantity	20 cigarettes
Package Type	Box
Length	80 mm
Diameter	7.9 mm
Ventilation	20%
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 EX0000215 – EX0000217 on April 17, 2018. FDA issued Acknowledgement letters for these Exemption Requests on April 20, 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 (b) (4)
- Addition of FSC cigarette paper (b) (4)
- Deletion of cork-on-white tipping paper (b) (4)
- Addition of alternate cork-on-white tipping paper (b) (4)
- Deletion of printed monogram ink on the barrel

2. ADMINISTRATIVE REVIEW

A regulatory review was completed by Sarah Vichensont on April 20, 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 May 22, 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 chemistry review was completed by Jikun Liu on May 29, 2018. The review states that the new tobacco products have been modified by adding and deleting tobacco additives and increasing the quantities of existing 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 outweighs any potential increased health risks caused by increases in HPHC exposures that may occur from the use of the FSC paper. (See July 17, 2017 toxicology memo.) Therefore, switching from the non-FSC paper to the FSC paper for the new products is considered appropriate for the protection of public health, and is a minor modification. The applicant also proposed the deletion of a cork-on-white tipping paper with the addition of an alternative cork-on-white 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. Furthermore, the review concludes that the deletion of monogram ink on the cigarette barrel is a minor modification and this removal of the monogram ink is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product and may potentially decrease HPHC yields. Thus, 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 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 June 13, 2018. The FONSI was supported by an environmental assessment prepared by FDA on June 12, 2018.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of non-FSC cigarette paper
- Addition of FSC cigarette paper
- Deletion of cork-on-white tipping paper
- Addition of alternate cork-on-white tipping paper
- Deletion of printed monogram ink on the barrel

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 characteristics 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), . . .” FSC cigarette paper, cork-on-white tipping paper, and monogram ink are ingredients used in the manufacture of the original tobacco products, and thus are additives. I concur with the chemistry reviewer that the deletion of non- FSC cigarette paper and the addition of FSC cigarette paper deletes and adds a tobacco additive to the new products. I also concur with the chemistry reviewer that the deletion of the cork-on-white tipping paper, addition of alternate cork-on-white paper and the deletion of the printed monogram ink on the barrel deletes and adds tobacco additives to the new products.

While cigarette HPHC yields may increase when the cigarette paper is changed from non-FSC to FSC paper, the benefit of using FSC paper to reduce cigarette-related household fires outweighs any potential increased health risks caused by increases in HPHC exposures that may occur from the use of the FSC paper. Further, the addition of FSC paper does not result in other changes to the products (e.g., there are no changes to blend, filter, design parameters such as ventilation). Therefore, viewed from an overall public health perspective and based on the information available at this time, switching from the non-FSC paper to the FSC paper for the new products is a change of an additive that is considered a minor modification and SE Reports are not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health. Additionally, the applicant also proposed the deletion of cork-on-white tipping paper followed by the addition of an alternative cork-on-white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. Furthermore, I agree with the chemistry review, which concludes that the removal of the monogram ink on the barrel is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products and may potentially decrease HPHC yields. For all these reasons, I concur with the chemistry reviewer that all these modifications are

minor modifications of the original tobacco products in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Accordingly, SE Reports are not necessary to ensure that permitting the new tobacco product to be marketed would be appropriate for protection of the public health (section 905(j)(3)(A)(ii) of the FD&C Act). Additionally, for these same reasons, an exemption 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 meet statutory requirements 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 EX0000215 – EX0000217 as identified on the cover page of this review.