

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000313, EX0000316, and EX0000317**

EX0000313: Newport Menthol Blue Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	12%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC¹ cigarette paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) [redacted] Target: (b) (4) mg/cigarette) • Deletion of cork-on-white tipping paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette) • Addition of cork-on-white tipping paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette) • Deletion of printed monogram ink (blue) on barrel
EX0000316: Newport Menthol Blue Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	12%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette) • Deletion of cork-on-white tipping paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette) • Addition of cork-on-white tipping paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette) • Deletion of printed monogram ink (blue) on barrel
EX0000317: Newport Menthol Blue Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	12%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette) • Addition of FSC cigarette paper (b) (4) [redacted]; Target: (b) (4) mg/cigarette)

¹ Fire Standards Compliant

	<ul style="list-style-type: none"> • Deletion of cork-on-white tipping paper (b) (4) [REDACTED]; Target: (b) mg/cigarette • Addition of cork-on-white tipping paper (b) (4) [REDACTED]; Target: (b) mg/cigarette • Deletion of printed monogram ink (blue) on 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
2019.01.14 13:42:36 -05'00'

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 Glen D. Jones -S
Date: 2019.01.14 13:53:25 -05'00'

For 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 Products

EX0000313: Newport Menthol Blue Box 100s	
EX0000316: Newport Menthol Blue Box 100s	
EX0000317: Newport Menthol Blue Box 100s	
Product Name	Newport Medium Menthol Blue Box 100s
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.8 mm
Ventilation	12%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco products and claims that they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the Exemption Requests (EX0000313, EX0000316, and EX0000317) on November 16, 2018. FDA issued Acknowledgement letters on November 21, 2018.

1.3. SCOPE OF REVIEW

This review 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 corresponding 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 cork-on-white tipping paper (b) (4)
- Deletion of printed monogram ink (blue) on barrel

2. REGULATORY REVIEW

Regulatory reviews were completed by Lynn Oldham on November 21, 2018. These reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established 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). The OCE reviews dated December 10, 2018, conclude that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modifications under the Exemption Request pathway.⁴

4. SCIENTIFIC REVIEW

A scientific review was completed by Selena Russell on January 2, 2019.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives and increasing or decreasing the quantities of existing tobacco additives. Cigarette paper, tipping paper, and monogram ink 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 review concludes that the modifications are minor modifications 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 Harmful and Potentially Harmful Constituents (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 17, 2017 toxicology memo. The review also concludes that the deletion of a cork-on-white tipping paper with

² EX0000313 only

³ EX0000316 and EX0000317 only

⁴ 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.

the addition of an alternate cork-on-white tipping paper for all Exemption Requests is a minor modification. This change is not expected to have any significant effects on 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 for all Exemption Requests 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.

5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on December 14, 2018.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on January 14, 2019. The FONSI was supported by an environmental assessment prepared by FDA on January 11, 2019.

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 cigarette paper (b) (4)
- Deletion of cork-on-white tipping paper (b) (4)
- Addition of cork-on-white tipping paper (b) (4)
- Deletion of printed monogram ink (blue) on barrel

I concur with the conclusion of the scientific review that these modifications are a minor modification 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 changes represent deletion of tobacco additives (non-FSC cigarette paper, cork-on-white tipping paper, and monogram ink on barrel), and the addition of tobacco additives (FSC cigarette paper and cork-on-white 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 products 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), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated

⁵ EX0000313 only

⁶ EX0000316 and EX0000317 only

to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. The applicant also proposed the deletion of cork-on-white tipping paper followed by the addition of cork-on-white tipping paper for all Exemption Requests, which is not expected to have any significant effects on product chemistry or consumer perception. Furthermore, the review concludes for all Exemption Requests 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. Lastly, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, that an exemption for these modifications are 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 Request pathway because they are legally marketed in the United States. The original products are grandfathered products (i.e., were 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 EX0000313, EX0000316, and EX0000317 as identified on the cover page of this review.