

Technical Project Lead (TPL) Review:
Exemption Request EX0000229 – EX0000231

EX0000229: Newport Non-Menthol Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	0 %
Characterizing Flavor	None
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 cork tipping paper (b) (4) • Addition of cork-on-white tipping paper (b) (4) • Deletion of (b) (4) • Deletion of printed monogram ink on barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Increase in the quantity of (b) (4)
EX0000230: Newport Non-Menthol Box 100s	
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
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 cork-on-white tipping paper (b) (4) • Deletion of (b) (4) • Deletion of printed monogram ink on barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Increase in the quantity of (b) (4)
EX0000231: Newport Non-Menthol Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of non-FSC cigarette paper (b) (4)

¹ Fire Standards Compliant

	<ul style="list-style-type: none"> • Addition of FSC cigarette paper (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of cork-on-white tipping paper (b) (4) • Deletion of (b) (4) • Deletion of printed monogram ink on barrel <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Increase in the quantity of (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
Recommendation	
Issue Exempt order letters	

Technical Project Lead (TPL):

Matthew J. Walters -S
2018.07.13 13:45:22 -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: 2018.07.13 14:11:02 -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

EX0000229: Newport Non-Menthol Box 100s	
Product Name	Newport Menthol Box 100s
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000230: Newport Non-Menthol Box 100s	
Product Name	Newport Menthol Box 100s
Package Type	Box
Package Quantity	20 cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	0%
Characterizing Flavor	Menthol
EX0000231: Newport Non-Menthol Box	
Product Name	Newport Menthol Box
Package Type	Box
Package Quantity	20 cigarettes
Length	80 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 Exemption Requests (EX0000229 – EX0000231) on May 25, 2018. FDA issued the applicant Acknowledgement letters for these Exemption Requests on May 31, 2018. On June 11, 2018, FDA requested the applicant provide clarification on where (b) (4) were present in the tobacco products. On June 15, 2018, FDA received an amendment containing the requested information (EX0000232).

1.3. SCOPE OF MEMO

This memo 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) (EX0000229 and EX0000231) or (b) (4) (EX0000230))
- Deletion of cork tipping paper (b) (4)
- Addition of cork-on-white tipping paper (b) (4)
- Deletion of (b) (4)
- Deletion of printed monogram ink on barrel
- Decrease in the quantity of (b) (4)
- Increase in the quantity of (b) (4)

2. REGULATORY REVIEW

Regulatory reviews were completed by Lynn Oldham on May 31, 2018. These reviews conclude 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 in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated on July 26, 2018 for EX0000229 and July 27, 2018 for EX0000230 and EX0000231, concludes that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modifications under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Robert Gahl on July 13, 2018.

The review states that the new tobacco products have been modified by adding and deleting tobacco additives and increasing and decreasing the quantities of existing tobacco additives. Cigarette paper, tipping paper, (b) (4), monogram ink, (b) (4) 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

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.

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 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 tipping paper with the addition of cork-on-white tipping paper 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 or product chemistry. 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. Finally, the applicant proposes to delete the additive (b) (4) which also results in a decrease in the quantity of (b) (4) and an increase in the quantities of (b) (4). These modifications are not intended nor expected to materially affect any other characteristic (e.g., materials, ingredients, design, composition, heating source, or other features) of the product. (b) (4) has been used in cigarettes in order to introduce cooling, soothing, and anesthetic effects during product use. As a result, (b) (4) can enhance the effort to continue smoking. These quantities of (b) (4) in the original products (b) (4) mg/cigarette) are high enough to have an effect on use, and these quantities are similar to the levels found in cigarettes that have menthol as a characterizing flavor. However, the new tobacco products do not contain (b) (4) and given that (b) (4) is an additive, the deletion of this additive would be a minor modification and is appropriate for the protection of public health.

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 (b) (4)
- Addition of FSC cigarette paper ((b) (4) (EX0000229 and EX0000231) or (b) (4) (EX0000230))
- Deletion of cork tipping paper (b) (4)
- Addition of cork-on-white tipping paper (b) (4)
- Deletion of (b) (4)
- Deletion of printed monogram ink on barrel
- Decrease in the quantity of (b) (4)
- Increase in the quantity of (b) (4)

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 four tobacco additives (non-FSC cigarette paper, cork tipping paper, monogram ink on barrel, and (b) (4)), the decrease in the quantity of one tobacco additive (b) (4), the addition of two tobacco additives (FSC cigarette paper and cork-on-white tipping paper), and the increase in the quantity of two existing tobacco additives (b) (4). 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 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 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 tipping paper followed by the addition of cork-on-white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. 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. Also, the applicant proposes to delete the additive (b) (4) which also results in a decrease in the quantity of (b) (4) and an increase in the quantities of (b) (4). These modifications are not intended nor expected to materially affect any other characteristic (e.g., materials, ingredients, design, composition, heating source, or other features) of the product. Furthermore, considering that (b) (4) is an additive of a tobacco product, the deletion of (b) (4) would be a minor modification and is appropriate for the protection of public health. Lastly, FDA finds, based on the information contained in the Exemption Request and CTP’s scientific understanding, that an exemption for this modification 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 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 EX0000229-EX0000231 as identified on the cover page of this review.