

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000477 – EX0000480**

EX0000477: Pall Mall Menthol Black Filter	
Length	83 mm
Diameter	7.8 mm
Ventilation	10%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) • Deletion of cork tipping paper (b) (4) • Addition of cork tipping paper (b) (4)
EX0000478: Pall Mall Menthol White Filter	
Length	83 mm
Diameter	7.8 mm
Ventilation	33%
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 filter tow (b) (4) • Deletion of cork-on-white tipping paper (b) (4) • Addition of white tipping paper (b) (4)

¹ FSC: Fire Standards Compliant

EX0000479: Newport Menthol Gold Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	22%
Characterizing Flavor	Menthol
Product Modifications	<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 filter tow (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 (black) on barrel
EX0000480: Newport Menthol Gold Kings	
Length	84 mm
Diameter	7.9 mm
Ventilation	24%
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 filter tow (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 (black) on barrel
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: EX0000477 – EX0000479 Soft Pack: EX0000480
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.04.17 09:43:54 -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: 2019.04.17 09:50:48 -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 REVIEW..... 6

 1.3. SCOPE OF REVIEW 6

 1.4. TOBACCO ADDITIVE MODIFICATION..... 6

2. REGULATORY REVIEW6

3. COMPLIANCE REVIEW6

4. SCIENTIFIC REVIEW7

5. ENVIRONMENTAL DECISION.....7

6. CONCLUSION AND RECOMMENDATION8

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Products

EX0000477: Pall Mall Menthol Black Filter	
Product Name	Camel Filters Menthol Hard Pack
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	10%
Characterizing Flavor	Menthol
EX0000478: Pall Mall Menthol White Filter	
Product Name	Newport Light King Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	33%
Characterizing Flavor	Menthol
EX0000479: Newport Menthol Gold Box	
Product Name	Newport Lights Menthol Gold Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	22%
Characterizing Flavor	Menthol
EX0000480: Newport Menthol Gold Kings	
Product Name	Newport Lights Menthol Gold King
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	24%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 28, 2019, FDA received Exemption Requests (EX0000477-EX0000480) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On March 11, 2019, FDA issued an Acknowledgment letter to the applicant. On March 14, 2019, FDA received an amendment (EX0000489) in response to a request from the Office of Compliance and Enforcement for EX0000477 and EX0000478.

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) for EX0000478 – EX0000480
- Addition of FSC cigarette paper (b) (4) for EX0000478 – EX0000480
- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)
- Deletion of cork or cork-on-white tipping paper (b) (4)
- Addition of cork, white or cork-on-white tipping paper (b) (4)
- Deletion of printed monogram ink (black) on barrel for EX0000479 and EX0000480

2. REGULATORY REVIEW

Regulatory reviews were completed by Camille Hayslett on March 11, 2019. The 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 April 2, 2019, conclude that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modifications 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 Mimy Young on April 8, 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, filter tow, 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. For EX0000478 – EX0000480, 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 for EX0000477 – EX0000480 that the deletion of cork or cork-on-white tipping paper and the addition of cork, white, or 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. Furthermore, for EX0000479 and EX0000480 the review concludes that the deletion of monogram ink (black) 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 products and may potentially decrease HPHC yields. Finally, for EX0000477 – EX0000480, the review concludes that the deletion of filter tow and the addition of an alternative filter tow 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 products. The filter tow can influence the ventilation of a product; however, the ventilation remains the same when comparing the new and corresponding original tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Susana Addo Ntim on March 19, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 17, 2019. The FONSI was supported by an environmental assessment prepared by FDA on April 17, 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) for EX0000478 – EX0000480
- Addition of FSC cigarette paper (b) (4) for EX0000478 – EX0000480
- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)
- Deletion of cork or cork-on-white tipping paper (b) (4)
- Addition of cork, white or cork-on-white tipping paper (b) (4)
- Deletion of printed monogram ink (black) on barrel for EX0000479 and EX0000480

I concur with the conclusion of the scientific review that these modifications are minor modifications 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 the deletion of tobacco additives (non-FSC cigarette paper, cork or cork-on-white tipping paper, filter tow, and monogram ink on barrel), and the addition of tobacco additives (FSC cigarette paper, alternative filter tow, and white, cork, or 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, for EX0000478 – EX0000480, 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. For EX0000477 – EX0000480, the applicant also proposed the deletion of cork or cork-on-white tipping paper and the addition of cork, white, or cork-on-white tipping paper, which is not expected to have any significant effects on product chemistry or consumer perception. Furthermore, the review concludes for EX0000479 and EX0000480 that the deletion of monogram ink (black) on the cigarette barrel 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 products and may potentially decrease HPHC yields. The review finally concludes that for EX0000477 – EX0000480, the deletion of filter tow and the addition of an alternative filter tow 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 products. The filter tow can influence the ventilation of a product; however, the ventilation of the new and corresponding original tobacco products remains the same. 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 EX0000477 - EX0000480 as identified on the cover page of this review.