

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000699 – EX0000712**

EX0000699: Now Menthol Green Soft Pack	
Length	84 mm
Diameter	7.9 mm
Ventilation	76%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000700: Pall Mall Orange Filter 100	
Length	98 mm
Diameter	7.8 mm
Ventilation	60%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000701: Pall Mall Blue Filter	
Length	83 mm
Diameter	7.8 mm
Ventilation	34%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)

EX0000702: Kamel Red Genuine Smooth Taste 100	
Length	98 mm
Diameter	7.8 mm
Ventilation	39%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cork-on-white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) • Deletion of printed (b) (4) on cigarette barrel
EX0000703: Pall Mall Menthol Green Filter 100	
Length	98 mm
Diameter	7.8 mm
Ventilation	44%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cork-on-white tipping paper (b) (4) • Addition of cork-on-white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000704: Pall Mall Orange Filter	
Length	83 mm
Diameter	7.8 mm
Ventilation	58%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)

EX0000705: Pall Mall Blue Filter 100	
Length	98 mm
Diameter	7.8 mm
Ventilation	44%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000706: Pall Mall Classic Menthol 100	
Length	98 mm
Diameter	7.8 mm
Ventilation	44%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000707: Kamel Red Genuine Original 100	
Length	98 mm
Diameter	7.8 mm
Ventilation	12%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cork-on-white tipping paper (b) (4) • Addition of cork-on-white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4) • Deletion of printed (b) (4)) on cigarette barrel

EX0000708: Now Menthol Green 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	73%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000709: Pall Mall Red Filter	
Length	83 mm
Diameter	7.8 mm
Ventilation	33%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cork tipping paper (b) (4) • Addition of cork tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000710: Pall Mall Menthol Green Filter	
Length	83 mm
Diameter	7.8 mm
Ventilation	34%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of cork-on-white tipping paper (b) (4) • Addition of cork-on-white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)

EX0000711: Pall Mall Vintage Gold 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	28%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
EX0000712: Pall Mall Classic Menthol	
Length	83 mm
Diameter	7.8 mm
Ventilation	34%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of white tipping paper (b) (4) • Addition of white tipping paper (b) (4) • Deletion of filter tow (b) (4) • Addition of filter tow (b) (4)
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	Soft Pack: EX0000699, EX0000708, and EX0000711 Box: EX0000700-EX0000707, EX0000709, EX0000710, and EX0000712
Recommendation	
Issue Exempt order letters	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.09.25 13:22:53 -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: 2019.09.25 17:02:36 -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 Products

EX0000699: Now Menthol Green Soft Pack	
Product Name	Now Ultra Light Menthol King Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	76%
Characterizing Flavor	Menthol
EX0000700: Pall Mall Orange Filter 100	
Product Name	Pall Mall Ultra Light 100s Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	60%
Characterizing Flavor	None
EX0000701: Pall Mall Blue Filter	
Product Name	Pall Mall Light King Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	34%
Characterizing Flavor	None
EX0000702: Kamel Red Genuine Smooth Taste 100	
Product Name	Camel Lights 99s Hard Pack
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	39%
Characterizing Flavor	None

EX0000703: Pall Mall Menthol Green Filter 100	
Product Name	Pall Mall Menthol Green Filter 100
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	44%
Characterizing Flavor	Menthol
EX0000704: Pall Mall Orange Filter	
Product Name	Pall Mall Ultra Light Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	58%
Characterizing Flavor	None
EX0000705: Pall Mall Blue Filter 100	
Product Name	Pall Mall Light 100's Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	44%
Characterizing Flavor	None
EX0000706: Pall Mall Classic Menthol 100	
Product Name	Pall Mall Classic Menthol 100s
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	44%
Characterizing Flavor	Menthol
EX0000707: Kamel Red Genuine Original 100	
Product Name	Camel Filters 99s Hard Pack
Package Type	Box
Package Quantity	20 Cigarettes
Length	98 mm
Diameter	7.8 mm
Ventilation	12%
Characterizing Flavor	None

EX0000708: Now Menthol Green 100 Soft Pack	
Product Name	Now Ultra Light Menthol 100s Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	73%
Characterizing Flavor	Menthol
EX0000709: Pall Mall Red Filter	
Product Name	Pall Mall King Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	33%
Characterizing Flavor	None
EX0000710: Pall Mall Menthol Green Filter	
Product Name	Pall Mall Menthol Green Filter
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	34%
Characterizing Flavor	Menthol
EX0000711: Pall Mall Vintage Gold 100 Soft Pack	
Product Name	Pall Mall Gold 100s Soft Pack
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	28%
Characterizing Flavor	None
EX0000712: Pall Mall Classic Menthol	
Product Name	Pall Mall Classic Menthol
Package Type	Box
Package Quantity	20 Cigarettes
Length	83 mm
Diameter	7.8 mm
Ventilation	34%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco products and claims that they are grandfathered for EX0000699 – EX0000702, EX0000704, EX0000705, EX0000707 – EX0000709,

and EX0000711; previously found exempt for EX0000703 and EX0000710, and previously found substantially equivalent for EX0000706 and EX0000712.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On July 30, 2019, FDA received Exemption Requests (EX0000699 – EX0000712) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On August 5, 2019, FDA issued an Acknowledgement letter to the applicant.

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 white, cork, or cork-on-white tipping paper (b) (4)
- Addition of white, cork or cork-on-white tipping paper (b) (4)
- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)
- Deletion of printed (b) (4) on cigarette barrel for EX0000702 and EX0000707

2. REGULATORY REVIEW

Regulatory reviews were completed by Shontelle Dixon on August 5, 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 August 26, 2019, conclude that the original tobacco products for EX0000699 – EX0000702, EX0000704, EX0000705, EX0000707 – EX0000709, and EX0000711 are grandfathered products.

The original tobacco products in EX0000703 and EX0000710 were determined to be exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration of substantial equivalence. Reports under section 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted, and at least 90 days have elapsed since FDA receipt of the Abbreviated Reports.

The original tobacco products in EX0000706 and EX0000712 were determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA.

The original tobacco products referenced for these Exemption Requests are outlined in the table below.

EX Request	Original Tobacco Product	Original Tobacco Product Found SE/Exempt Under:	Date
EX0000699	Now Ultra Light Menthol King Soft Pack	GF1501229	8/26/2019
EX0000700	Pall Mall Ultra Light 100s Box	GF1501189	8/26/2019
EX0000701	Pall Mall Light King Box	GF1501187	8/26/2019
EX0000702	Camel Lights 99s Hard Pack	GF1501092	8/26/2019
EX0000703	Pall Mall Menthol Green Filter 100	EX0000214	5/8/2018
EX0000704	Pall Mall Ultra Light Box	GF1200551	8/26/2019
EX0000705	Pall Mall Light 100's Box	GF1200550	8/26/2019
EX0000706	Pall Mall Classic Menthol 100s	SE0013337	7/19/2016
EX0000707	Camel Filters 99s Hard Pack	GF1200554	8/26/2019
EX0000708	Now Ultra Light Menthol 100s Soft Pack	GF1501211	8/26/2019
EX0000709	Pall Mall King Box	GF1501186	8/26/2019
EX0000710	Pall Mall Menthol Green Filter	EX0000213	5/8/2018
EX0000711	Pall Mall Gold 100s Soft Pack	GF1501199	8/26/2019
EX0000712	Pall Mall Classic Menthol	SE0013336	7/19/2016

Therefore, the original products are eligible for modifications under the Exemption Request pathway.¹

¹ 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 Jason Hsieh on September 20, 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. Tipping paper, filter tow, and monogram ink² 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 cork, white, or cork-on-white tipping paper with 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. The new products include a (b) (4) compared to the original products and possess the same amounts of (b) (4). Because the filter tows are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of ingredients in the filter tow are not expected to significantly alter the smoke chemistry and consumer exposure to chemical constituents from the filter tow while smoking. 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. For EX0000702 and EX0000707 only, 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 tobacco products and may potentially decrease HPHC yields.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Thomas Creaven on August 20, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 12, 2019. The FONSI was supported by an environmental assessment prepared by FDA on September 12, 2019.

² EX0000702 and EX0000707 only

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of white, cork, or cork-on-white tipping paper (b) (4)
- Addition of white, cork or cork-on-white tipping paper (b) (4)
- Deletion of filter tow (b) (4)
- Addition of filter tow (b) (4)
- Deletion of printed (b) (4) on cigarette barrel for EX0000702 and EX0000707

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 (cork, white, or cork-on-white tipping paper, filter tow, and monogram ink on barrel²), and the addition of tobacco additives (filter tow and cork, white 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. The applicant proposed the deletion of cork, white, or cork-on-white tipping paper followed by 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. The new products include a (b) (4) decrease in (b) (4) compared to the original products and possess the same amounts of (b) (4). Because the filter tows are not combusted, volatilized, or otherwise released during normal cigarette consumption, the modifications of ingredients in the filter tow are not expected to significantly alter the smoke chemistry and consumer exposure to chemical constituents from the filter tow while smoking. The filter tow can influence the ventilation of a product; however, the ventilation of the new and corresponding original tobacco products remains the same. Also, for EX0000702 and EX0000707 only, 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 tobacco products 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 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 modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products for EX0000699 – EX0000702, EX0000704, EX0000705, EX0000707 – EX0000709, and EX0000711 are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test

markets as of February 15, 2007). Additionally, the original products for EX0000703 and EX0000710 were previously found Exempt by FDA, reports under 905(j)(1)(A)(ii) (Abbreviated Reports) were submitted by the applicant, and 90 days have elapsed since FDA receipt of the Abbreviated Reports. Finally, the original products for EX0000706 and EX0000712 were previously found SE and in compliance with the FD&C Act by FDA.

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An Exempt order letter should be issued for the new tobacco products in EX0000699 – EX0000712 as identified on the cover page of this review.