

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000746 – EX0000750**

EX0000746: Kent Gold Soft Pack	
Length	84 mm
Diameter	7.9 mm
Ventilation	41%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC¹ cigarette paper (b) (4) target: (b) (4) • Addition of FSC cigarette paper (b) (4) target: (b) (4) • Deletion of printed monogram ink (black) on cigarette barrel
EX0000747: Kent Gold 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	46%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4) target: (b) (4) • Addition of FSC cigarette paper (b) (4) target: (b) (4) • Deletion of printed monogram ink (blue) on cigarette barrel
EX0000748: Kent Gold Soft Pack	
Length	84 mm
Diameter	7.9 mm
Ventilation	41%
Characterizing Flavor	None
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4) target: (b) (4) • Addition of FSC cigarette paper (b) (4) target: (b) (4) • Deletion of filter tow (b) (4) target: (b) (4) • Addition of filter tow (b) (4) target: (b) (4) • Deletion of printed monogram ink (black) on cigarette barrel

¹ FSC: Fire Standard Compliant

EX0000749: Pall Mall Red Filter 100	
Length	97 mm
Diameter	7.9 mm
Ventilation	32%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter tow (b) (4) target: (b) (4) • Addition of filter tow (b) (4) target: (b) (4) • Deletion of cork tipping paper (b) (4) target: (b) (4) • Addition of cork tipping paper (b) (4) target: (b) (4)
EX0000750: Kent Gold 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Ventilation	46%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of FSC cigarette paper (b) (4) target: (b) (4) • Addition of FSC cigarette paper (b) (4) target: (b) (4) • Deletion of filter tow (b) (4) target: (b) (4) • Addition of an alternate filter tow (b) (4) target: (b) (4) • Deletion of printed monogram ink (blue) on cigarette 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	Soft Pack: EX0000746 – EX0000748, and EX0000750 Box: EX0000749
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

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Date: 2019.10.01 17:28:11 -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: 2019.10.02 06:40:06 -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

EX0000746: Kent Gold Soft Pack	
Product Name	Kent Golden Kings
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	41%
Characterizing Flavor	None
EX0000747: Kent Gold 100 Soft Pack	
Product Name	Kent Golden 100s
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	46%
Characterizing Flavor	None
EX0000748: Kent Gold Soft Pack	
Product Name	Kent Golden Kings
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	41%
Characterizing Flavor	None
EX0000749: Pall Mall Red Filter 100	
Product Name	Pall Mall 100s Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	97 mm
Diameter	7.9 mm
Ventilation	32%
Characterizing Flavor	None

EX0000750: Kent Gold 100 Soft Pack	
Product Name	Kent Golden 100s
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	99 mm
Diameter	7.9 mm
Ventilation	46%
Characterizing Flavor	None

For EX0000746 – EX0000748, and EX0000750, the applicant manufactures the original tobacco products and claims that they are previously found substantially equivalent (SE0002161 for EX0000746 and EX0000748; and SE0002160 for EX0000747 and EX0000750). For EX0000749, the applicant manufactures the original tobacco product and claims that it is grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On August 14, 2019, FDA received Exemption Requests (EX0000746 - EX0000750) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On August 20, 2019, FDA issued an Acknowledgment 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 FSC cigarette paper (b) (4) for EX0000746 – EX0000748 and EX0000750
- Addition of FSC cigarette paper (b) (4) for EX0000746 – EX0000748 and EX0000750
- Deletion of filter tow (b) (4) for EX0000748 – EX0000750
- Addition of filter tow (b) (4) for EX0000748 – EX0000750
- Deletion of cork tipping paper (b) (4) for EX0000749
- Addition of cork tipping paper (b) (4) for EX0000749
- Deletion of printed monogram ink (black or blue) on cigarette barrel for EX0000746 – EX0000748 and EX0000750

2. REGULATORY REVIEW

Regulatory reviews were completed by Jennifer Schmitz on August 20, 2019. The 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 product is a grandfathered product (i.e., was commercially marketed in the United States other than exclusively in test markets as of February 15, 2007). The OCE review dated September 20, 2019, concludes that the original tobacco product for EX0000749 is a grandfathered product.

For EX0000746 – EX0000748, and EX0000750, the original tobacco products were previously determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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

EX Requests	Original Tobacco Product	Original Tobacco Product Found GF/SE/Exempt Under:	Date
EX0000746 EX0000748	Kent Golden Kings	SE0002161	April 4, 2019
EX0000749	Pall Mall 100s Box	GF1501099	September 20, 2019
EX0000747 EX0000750	Kent Golden 100s	SE0002160	April 4, 2019

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 October 1, 2019.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Cigarette paper,³ tipping paper,⁴ filter tow,⁵ and monogram ink³ 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 EX0000746 – EX0000748, and EX0000750, the review concludes that the deletion of FSC cigarette paper and the addition of an alternative FSC cigarette paper is a minor modification. The differences between the FSC cigarette paper in the new and original tobacco products are minor differences in the levels of (b) (4) and (b) (4). However, these differences are not expected to have a significant impact on the product performance or HPHC yields. The review also concludes for EX000749 only that the deletion of cork tipping paper and the addition of an alternate cork tipping paper is a minor modification. This change is not expected to have any significant

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.

³ EX0000746 – EX0000748, and EX0000750 only

⁴ EX0000749 only

⁵ EX0000748 - EX0000750 only

effects on consumer perception as outlined in the May 16, 2017, social science memo. Furthermore, for EX0000746 - EX0000748, and EX0000750, the review concludes that the deletion of monogram ink (black or blue) 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. Finally, for EX0000748 - EX0000750, 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 tobacco 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 Dilip Venugopal on August 29, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on September 27, 2019. The FONSI was supported by an environmental assessment prepared by FDA on September 27, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of FSC cigarette paper (b) (4) for EX0000746 – EX0000748 and EX0000750
- Addition of FSC cigarette paper (b) (4) for EX0000746 – EX0000748 and EX0000750
- Deletion of filter tow (b) (4) for EX0000748 – EX0000750
- Addition of filter tow (b) (4) for EX0000748 – EX0000750
- Deletion of cork tipping paper (b) (4) for EX0000749
- Addition of cork tipping paper (b) (4) for EX0000749
- Deletion of printed monogram ink (black or blue) on cigarette barrel for EX0000746 – EX0000748 and EX0000750

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 (FSC cigarette paper,³ cork tipping paper,⁴ filter tow,⁵ and monogram ink on cigarette barrel³), and the addition of tobacco additives (alternate FSC cigarette paper,³ alternative filter tow,⁵ and cork tipping paper⁴). 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. For EX0000746 – EX0000748, and EX0000750, the review concludes that the deletion of FSC cigarette paper and the addition of an alternative FSC cigarette paper is a minor modification. The differences between the FSC cigarette paper in the new and original tobacco products are minor differences in the levels of (b) (4) and (b) (4). However, these differences are not expected to have a significant impact on the product performance or HPHC yields. For EX000749 only, the review concludes that the deletion of cork tipping paper and the addition of an alternate cork tipping paper is a minor modification, and is not expected to have any significant effects on product chemistry or consumer perception. Furthermore, the review concludes for EX0000746 – EX0000748, and EX0000750, that the deletion of monogram ink (black or blue) 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 tobacco products and may potentially decrease HPHC yields. Additionally, the review concludes that for EX000748 - EX0000750, 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 tobacco 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 for EX0000746-EX0000748 and EX0000750 were previously found SE and in compliance with the FD & C Act by FDA. Additionally, the original product for EX0000749 is a grandfathered product (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.

An Exempt order letter should be issued for the new tobacco products in EX0000746 - EX0000750 as identified on the cover page of this review.