

Technical Project Lead (TPL) Review:
Exemption Requests EX0000434 – EX0000437

EX0000434: Old Gold Kings	
Length	84 mm
Diameter	7.9 mm
Ventilation	20 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • (b)(4) Target: (b)(4) • Addition of FSC cigarette paper (b)(4) Target (b)(4)
EX0000435: Old Gold Kings	
Length	84 mm
Diameter	7.9 mm
Ventilation	20 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4) • Deletion of filter tow (b)(4) • Addition of filter tow (b)(4)
EX0000436: Old Gold Kings	
Length	84 mm
Diameter	7.9 mm
Ventilation	20 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of FSC cigarette paper (b)(4) • Addition of FSC cigarette paper (b)(4)

¹ Fire Standards Complaint

EX000043 7: Old Gold Kings	
Length	84 mm
Diameter	7.9 mm
Ventilation	20 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of FSC cigarette paper (b)(4) [REDACTED] Target: (b)(4) • Addition of FSC cigarette paper (b)(4) [REDACTED] Target: (b)(4) • Deletion of filter tow (b)(4) • Addition of filter tow (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	Soft Pack
Recommendation	
Issue Exempt order letters.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
 Date: 2019.03.22 09:44:40 -04'00'

Matthew J. Walters, Ph.D., M.P.H.
 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: 2019.03.22 11:06:49 -04'00'

Matthew R. Holman, Ph.D.
 Director
 Office of Science

TABLE OF CONTENTS

1. BACKGROUND	4
1.1. ORIGINAL TOBACCO PRODUCT	4
1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW	4
1.3. SCOPE OF REVIEW	4
1.4. TOBACCO ADDITIVE MODIFICATION	5
2. REGULATORY REVIEW	5
3. COMPLIANCE REVIEW	5
4. SCIENTIFIC REVIEW	5
5. ENVIRONMENTAL DECISION	6
6. CONCLUSION AND RECOMMENDATION	6

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000434: Old Gold Kings EX0000435: Old Gold Kings EX0000436: Old Gold Kings EX0000437: Old Gold Kings	
Product Name	Old Gold Kings
Package Type	Soft Pack
Package Quantity	20 Cigarettes
Length	84 mm
Diameter	7.9 mm
Ventilation	20%
Characterizing Flavor	None

The applicant manufactures the original tobacco products. The original tobacco products were previously found substantially equivalent by FDA under SE0014486.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On January 30, 2019, FDA received Exemption Requests (EX0000434 – EX0000437) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On February 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 product:

- Deletion of FSC cigarette paper (b)(4).
- Addition of FSC cigarette paper (b)(4)
- Deletion of filter tow (b)(4) for EX0000435 and EX0000437
- Addition of filter tow (b)(4) for EX0000435 and EX0000437

2. REGULATORY REVIEW

Regulatory reviews were completed by Barbara Banchero on February 4, 2019. These reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco product in EX0000434 – EX0000437 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA under SE0014486. Therefore, the original tobacco product is eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A scientific review was completed by Tricia Johnson on March 21, 2019.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives. Cigarette paper and filter tow are used in the manufacturing of the original tobacco product, 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 the deletion of an original FSC cigarette paper with an addition of an alternative FSC cigarette paper is a minor modification. The differences between the original FSC cigarette paper and the alternative FSC cigarette paper showed very minor differences with the only significant difference resulting in a change in the combustion modifiers used between the original and new tobacco products. These differences are not expected to have a significant impact on the product performance or HPHC yields. Furthermore, the review concludes that the deletion of filter tow and the addition of an alternative filter tow, for EX0000435 and EX0000437 only, 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 new products include a 23% decrease in (b)(4) compared to the original product and possess the same amounts of (b)(4). Because the filter tows are not combusted, volatilized, or otherwise released during normal

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.

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 original and new tobacco products.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by William Brenner on March 20, 2019.

The final environmental review found that the applicant did not provide current-year marketing status of the original product, current-year market volume of the original product and market projections of the first- and fifth-years for the new tobacco products. Therefore, additional information is needed to determine whether to prepare an Environmental Impact Statement (EIS) or Finding of No Significant Impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of FSC cigarette paper (b)(4)
- Addition of FSC cigarette paper (b)(4)
- Deletion of filter tow (b)(4) for EX0000435 and EX0000437
- Addition of filter tow (b)(4) for EX0000435 and EX0000437

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 and filter tow³), and the addition of tobacco additives (FSC cigarette paper and alternative filter tow⁴). 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 differences between the original FSC cigarette paper and the alternative FSC cigarette paper showed very minor differences with the only significant difference resulting in a change in the combustion modifiers used between the original and new tobacco products. These differences are not expected to have a significant impact on the product performance or HPHC yields. The review also concludes that the deletion of filter tow and the addition of an alternative filter tow, for EX0000435 and EX0000437 only, is a minor modification and is not expected to materially affect any other characteristic (materials, ingredients, design,

³ For EX0000435 and EX0000437 only

composition, heating source, or other features) of the products. The new products include a 23% decrease in (b)(4) compared to the original product 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 original and new 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 product(s) are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original product was previously found SE and in compliance with the FD&C Act by FDA under SE0014486.

FDA has examined the environmental effects of finding these new tobacco products exempt from substantial equivalence and found additional information is necessary to determine the impact of the action. Without this information, FDA is precluded from issuing EX orders.

An Advice/Information Request letter should be issued requesting the following information:

1. All of your EX Requests lack information about the current marketing status of the original product. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the original product. Provide a statement that says whether the original product is currently marketed or not currently on the market.
2. All of your EX Requests lack information on the current market volume of the original product, if it is currently marketed. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new products. In Table 1, if the original product is currently marketed, provide the market volume. Note any information that you deem confidential, so that it can be placed in a confidential appendix to the public EA document.

Table 1. Market Volume Information			
STN	Original Product		Current-Year Market Volume of Original Product (Cigarettes)
	Name	STN	
EX0000434 EX0000435 EX0000436 EX0000437	Old Gold Kings	SE0014486	

3. All of your EX Requests show projected market volumes for the new products to be the same for the first and fifth year of marketing. It is unclear if the total market projections for all new products combined is the number listed, or if that number is for each new product. Specifically, is the market projection of (b)(4) in the first year and (b)(4) in the fifth year is a cumulative amount for all four new products, or are these individual market projections and therefore the cumulative market projections would be (b)(4) in the first year and (b)(4) in the fifth year? Clarification is needed as this will assist in a more accurate calculation of environmental impacts.

If the applicant adequately responds to the request and an EIS or FONSI is completed, EX order letters should be issued for the new tobacco products in EX0000434-EX0000437, as identified on the cover page of this review.