

Technical Project Lead (TPL) Review: Exemption Requests EX0000368 – EX0000371

EX0000368: Old Gold Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	18 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: - Deletion of FSC¹ cigarette paper (b) (4) [REDACTED]; Target: (b) (4) mg/cig) - Addition of FSC cigarette paper (b) (4) [REDACTED]; Target: (b) (4) mg/cig)
EX0000369: Old Gold Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	18 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: - Deletion of FSC cigarette paper (b) (4) [REDACTED]; Target: (b) (4) mg/cig) - Addition of FSC cigarette paper (b) (4) [REDACTED]; Target: (b) (4) mg/cig) - Deletion of filter tow (b) (4) [REDACTED]) - Addition of filter tow (b) (4) [REDACTED])
EX0000370: Old Gold Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	18 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: - Deletion of FSC cigarette paper (b) (4) [REDACTED]; Target: (b) (4) mg/cig) - Addition of FSC cigarette paper (b) (4) [REDACTED]; Target: (b) (4) mg/cig) - Deletion of the filter tow (b) (4) [REDACTED]) - Addition of filter tow (b) (4) [REDACTED])

¹ Fire Standards Compliant

EX0000371: Old Gold Box	
Length	80 mm
Diameter	7.9 mm
Ventilation	18 %
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: - Deletion of FSC cigarette paper] (b) (4) [REDACTED]; Target: (b) (4) mg/cig) - Addition of FSC cigarette paper (b) (4) [REDACTED]; Target: (b) (4) mg/cig)
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):

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 Date: 2019.03.21 12:32:08 -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: 2019.03.21 14:09:37 -04'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCT

The applicant submitted the following original tobacco product:

Table 1. Original Tobacco Product

EX0000368: Old Gold Box EX0000369: Old Gold Box EX0000370: Old Gold Box EX0000371: Old Gold Box	
Product Name	Old Gold Box
Package Type	Box
Package Quantity	20 Cigarettes
Length	80 mm
Diameter	7.9 mm
Ventilation	18%
Characterizing Flavor	None

The applicant manufactures the original tobacco product and it was previously found substantially equivalent by FDA under SE0014484.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On December 20, 2018, FDA received four Exemption Requests (EX0000368 – EX0000371) from RAI Services Company on behalf of R.J. Reynolds Tobacco Company. On December 26, 2018, FDA issued Acknowledgement letters to the applicant. On January 24, 2019, FDA issued an Advice/Information Request letter. In response, the applicant submitted an amendment (EX0000442) to the Exemption Requests, received by FDA on February 5, 2019.

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)
- Addition of FSC cigarette paper (b) (4) for EX0000368 and EX0000370
- Addition of FSC cigarette paper (b) (4) for EX0000369 and EX0000371
- Deletion of filter tow (b) (4) for EX0000369 and EX0000370
- Addition of filter tow (b) (4) for EX0000369 and EX0000370

2. REGULATORY REVIEW

Regulatory reviews were completed by Crystal Caesar on December 26, 2018. These reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The original tobacco product in EX0000368-EX0000371 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA under SE0014484. Therefore, the original product is eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

Scientific reviews were completed by Stephanie Daniels on January 17, 2019 and March 7, 2019.

The reviews state that the new tobacco products have been modified by adding or deleting tobacco additives. Cigarette paper and filter tow³ 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 reviews conclude 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 reviews conclude the deletion of an original FSC cigarette paper and 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 new and original tobacco products. These differences are not expected to have a significant impact on the product performance or HPHC yields. Furthermore, the reviews conclude that the deletion of filter tow and the addition of an alternative filter tow for EX0000369 and EX0000370 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)

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 For EX0000369 and EX0000370 only

(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 original tobacco products.

5. ENVIRONMENTAL DECISION

Environmental reviews were completed by Susana Addo Ntim on January 11, 2019 and March 20, 2019.

The final environmental review found that the applicant did not provide current-year market volume of the original 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 products:

- Deletion of FSC cigarette paper (b) (4)
- Addition of FSC cigarette paper (b) (4) for EX0000368 and EX0000370
- Addition of FSC cigarette paper (b) (4) for EX0000369 and EX0000371
- Deletion of filter tow (b) (4) for EX0000369 and EX0000370
- Addition of filter tow (b) (4) for EX0000369 and EX0000370

I concur with the conclusion of the scientific reviews 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 reviews 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 new and

⁴ For EX0000369 and EX0000370 only

original tobacco products. These differences are not expected to have a significant impact on the product performance or HPHC yields. The reviews also conclude that the deletion of filter tow and the addition of an alternative filter tow for EX0000369 and EX0000370 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 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. 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 product was previously found substantially equivalent by FDA under SE0014484.

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 and amendments lack information on the current market volume of the original product. Marketing information is used to quantitatively assess the environmental impact of manufacturing, use, and disposal of the new products. In Table 1, provide the current-year market volume of the original product. If you deem any of this information confidential, mark it as such 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	
EX0000368	Old Gold Box	SE0014484	
EX0000369	Old Gold Box		
EX0000370	Old Gold Box		
EX0000371	Old Gold Box		

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 EX0000368-EX0000371, as identified on the cover page of this review.