FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Request EX0000206

EX0000206: Old Gold Blue Filter 100 Soft Pack	
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	64%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of non-FSC[1] cigarette paper • Addition of FSC cigarette paper • Deletion of a complex purchased flavor (b) (4) [redacted] • Increased quantities of existing additives (glycerin and water) • Deletion of printed monogram ink on the 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
Recommendation	
Issue an Exempt order letter.	

[1] Fire Standards Compliant

Technical Project Lead (TPL):

Matthew J. Walters -S
2017.12.22 07:51:50 -05'00'

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: 2017.12.22 07:54:15 -05'00'

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

TABLE OF CONTENTS

1. BACKGROUND 4

1.1. ORIGINAL TOBACCO PRODUCTS 4
1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO 4
1.3. SCOPE OF MEMO 4
1.4. TOBACCO ADDITIVE MODIFICATION 4

2. ADMINISTRATIVE REVIEW 4

3. COMPLIANCE REVIEW 5

4. SCIENTIFIC REVIEW 5

5. ENVIRONMENTAL DECISION 5

6. CONCLUSION AND RECOMMENDATION 6

1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The applicant submitted the following original tobacco products:

Table 1. Original Tobacco Product

EX0000206	
Product Name	Old Gold Ultra Lights 100s
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	99 mm
Diameter	7.9 mm
Filter Ventilation	64%
Characterizing Flavor	None

The applicant manufactures the original tobacco product and claims that it is grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS MEMO

The applicant submitted the original Exemption Request EX0000206 on October 31, 2017. FDA issued the applicant an Acknowledgement letter for this Exemption Request on November 6, 2017.

1.3. SCOPE OF MEMO

This memo captures all administrative, compliance, and scientific reviews completed for this Exemption Request.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Deletion of non-FSC cigarette paper
- Addition of FSC cigarette paper
- Deletion of a complex purchased flavor (b) (4)
- Increased quantities of existing additives (glycerin and water)
- Deletion of printed monogram ink on the barrel

2. ADMINISTRATIVE REVIEW

An acceptance review was completed by Nia White on November 6, 2017. The review concludes that the Exemption Request is 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 legally marketed. The OCE review, dated December 5, 2017, concludes 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). Therefore, the original product is eligible for modification under the Exemption Request pathway.[2]

4. SCIENTIFIC REVIEW

A chemistry review was completed by Jikun Liu on December 14, 2017. The review states that the new tobacco product has been modified by adding and deleting tobacco additives and increasing the quantities of existing tobacco additives. The review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new product is a minor modification because the benefit of using FSC paper to reduce cigarette-related household fires outweighs any potential increased health risks caused by increases in HPHC exposures that may occur from the use of the FSC paper. (See July 14, 2017 toxicology memo.) Therefore, switching from the non-FSC paper to the FSC paper for the new product is considered appropriate for the protection of public health, and is a minor modification. Additionally, [redacted] is removed in the new product and this is accompanied by minor increases in glycerin and water. The removal of [redacted], along with minor increases in glycerin and water, is not expected to materially affect the product's composition or HPHC yields. Furthermore, 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 product and may potentially decrease HPHC yields. Thus, the review concludes that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on December 21, 2017. The FONSI was supported by an environmental assessment prepared by FDA on December 21, 2017.

[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.

6. CONCLUSION AND RECOMMENDATION

The new tobacco product contains the following modifications compared to the original tobacco product:

- Deletion of non-FSC cigarette paper
- Addition of FSC cigarette paper
- Deletion of a complex purchased flavor (b) (4)
- Increased quantities of existing additives (glycerin and water)
- Deletion of printed monogram ink on the barrel

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 characteristics 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), . . ." FSC cigarette paper, (b) (4) glycerin, water, and monogram ink are ingredients used in the manufacture of the original tobacco products, and thus are additives. I thus concur with the chemistry reviewer that the deletion of non- FSC cigarette paper and the addition of FSC cigarette paper deletes and adds a tobacco additive to the new product. I also concur with the chemistry reviewer that the deletion of the complex ingredient (b) (4) and the deletion of the printed monogram ink on the barrel along with a slight increase in glycerin and water correspondingly deletes and adds tobacco additives to the new product.

While cigarette HPHC yields may increase when the cigarette paper is changed from non-FSC to FSC paper, the benefit of using FSC paper to reduce cigarette-related household fires outweighs any potential increased health risks caused by increases in HPHC exposures that may occur from the use of the FSC paper. Further, the addition of FSC paper does not result in other changes to the product (e.g., there are no changes to blend, filter, design parameters such as ventilation, etc.). Therefore, viewed from an overall public health perspective and based on the information available at this time, switching from the non-FSC paper to the FSC paper for the new product is a change of an additive that is considered a minor modification and an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health. In the new product, the removal of (b) (4) is accompanied by minor increases in glycerin and water. The removal of (b) (4), along with minor increases in glycerin and water, is not expected to materially affect the product's composition or HPHC yields. Furthermore, I agree with the chemistry review which concludes that the removal of the monogram ink on the barrel is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product and may potentially decrease HPHC yields. For all these reasons, I concur with the chemistry reviewer that all these modifications are minor modifications of the original tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Accordingly, an SE Report is not necessary to ensure that permitting the new tobacco product to be marketed would be appropriate for protection of the public health (Section 905(j)(3)(A)(ii) of the FD&C Act). Additionally, for these same reasons, an exemption is otherwise appropriate as required by section 905(j)(3)(a)(iii) of the FD&C Act. Therefore, the new tobacco product 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 meets statutory requirements for modification through the exemption from substantial equivalence pathway because they are legally marketed in the United States. The original product is a grandfathered product (i.e., was commercially marketed in the United States 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 product in EX0000206 as identified on the cover page of this review.