FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Requests EX0000816 and EX0000817

EX0000816: Winston Blue Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	25%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of non-FSC[1] cigarette paper (b) (4) [redacted] • **Addition** of FSC cigarette paper (b) (4) [redacted] • Deletion of filter center line adhesive (b) (4) [redacted] • **Addition** of filter center line adhesive (b) (4) [redacted] • Deletion of (b) (4) [redacted] • Addition of (b) (4) [redacted]
EX0000817: Winston Full Flavor 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	14%
Characterizing Flavor	None
Product Modifications	Addition/Deletion of tobacco additives: • **Deletion** of non-FSC cigarette paper (b) (4) [redacted] • **Addition** of FSC cigarette paper (b) (4) [redacted] • Deletion of filter center line adhesive (b) (4) [redacted] • Addition of filter center line adhesive (b) (4) [redacted] • Deletion of (b) (4) [redacted] • Addition of (b) (4) [redacted]
Common Attributes of Exemption Requests	
Applicant	ITG Brands, LLC
Product Category	Cigarettes
Product Sub-Category	Combusted, Filtered
Package Quantity	20 Cigarettes
Package Type	Box
Recommendation	
Issue Exempt order letter.	

[1] FSC: Fire Standards Compliant

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.11.22 12:38:12 -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: 2019.11.22 12:42:26 -05'00'

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

EX0000816: Winston Blue Box	
Product Name	Winston Platinum Lights
Package Quantity	20 Cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	25%
Characterizing Flavor	None
EX0000817: Winston Full Flavor 100's Box	
Product Name	Winston Platinum Full Flavor 100's Box
Package Quantity	20 Cigarettes
Package Type	Box
Length	98 mm
Diameter	7.79 mm
Ventilation	14%
Characterizing Flavor	None

The applicant manufactures the original tobacco products and claims that they are grandfathered.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 21, 2019, FDA received two Exemption Requests (EX0000816 – EX0000817) from ITG Brands, LLC. FDA issued an Acceptance letter for these Exemption Requests on October 24, 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 non-FSC cigarette paper (b) (4) [redacted]
- Addition of FSC cigarette paper (b) (4) [redacted]
- **Deletion** of filter center line adhesive (b) (4) [redacted]

- Addition of filter center line adhesive (b) (4) [redacted]
- Deletion of (b) (4) [redacted]
- Addition of (b) (4) [redacted]

2. REGULATORY REVIEW

Regulatory reviews were completed by Elizabeth Eydelman on October 23, 2019. The reviews conclude that these 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 November 17, 2019, conclude that the original tobacco products are grandfathered products. Therefore, the original products are eligible for modification under the Exemption Request pathway.[2]

4. SCIENTIFIC REVIEW

A scientific review was completed by Sandra Salido on November 19, 2019.

The review states that the new tobacco products have been modified by adding and deleting three tobacco additives. Cigarette paper, filter center line adhesive, and (b) (4) [redacted] 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 Federal Food, Drug, and Cosmetic Act (FD&C Act). The review concludes that the deletion of non-FSC cigarette paper and addition of FSC cigarette paper in the new products is a minor modification. The change from non-FSC to FSC cigarette paper may result in increased HPHC yields; however, the reduction in household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of the FSC cigarette paper, as outlined in the July 14, 2017 toxicology memo. Additionally, the review determines that the deletion of filter center adhesive (b) (4) [redacted] and the addition of an alternate center line adhesive (b) (4) [redacted] due to a change from a customized adhesive to an adhesive that is purchased commercially by (b) (4) [redacted] are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. In addition, the deletion of the (b) (4) [redacted] and the addition of (b) (4) [redacted] is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. This modification is unlikely to have an appreciable effect on an increase in HPHCs during combustion as well as an

[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.

effect on consumer perception with a change in (b) (4) at this quantity given that the same quantity of the (b) (4) were used between the new and orginal tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on November 22, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 22, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 20, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of non-FSC cigarette paper (b) (4)
- Addition of FSC cigarette paper (b) (4)
- Deletion of filter center line adhesive (b) (4)
- Addition of filter center line adhesive (b) (4)
- Deletion of (b) (4)
- Addition of (b) (4)

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 deletion of non-FSC cigarette paper, filter center adhesive, and (b) (4) and addition of FSC cigarette paper, alternate center line adhesive, and (b) (4) is an addition/deletion of a tobacco additive. 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. At this time, based on the information available and CTP's scientific understanding and experience with non-FSC to FSC cigarette paper modifications that are limited to changes in tobacco additives and do not result in other changes to the product (e.g., no changes to blend, filter, design parameters such as ventilation, etc.), the benefit of using FSC paper in cigarettes to reduce household fires is anticipated to outweigh any potential increased health risks from the small increases in HPHC exposures that may occur from the use of FSC paper. The review determines that the deletion of the filter center adhesive (b) (4) and the addition of an alternate center line adhesive (b) (4) due to a change from a customized adhesive to an adhesive that is purchased commercially by (b) (4) it is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Specifically, these modifications are made to the non-combusted component of the cigarettes; the alternate center line adhesive is not combusted, volatilized or otherwise released during normal cigarette

consumption and so consumer exposure to chemical constituents from the alternate center line adhesive is not expected. In addition, the deletion of the (b) (4) and the addition of (b) (4) is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. This modification is unlikely to have an appreciable effect on an increase in HPHCs during combustion as well as an effect on consumer perception with a change in (b) (4) at this quantity given that the same quantity of the (b) (4) were used between the new and orginal tobacco products. Thus, these changes are considered minor modifications and meet the requirements set forth in section 905(j)(3)(A)(i) of the FD&C Act. 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 modification through the Exemption Request pathway because they can be legally marketed in the United States. The original products are grandfathered products (i.e., were 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 EX0000816 and EX0000817 as identified on the cover page of this review.