FDA U.S. FOOD & DRUG ADMINISTRATION

Technical Project Lead (TPL) Review: Exemption Request EX0000482

EX0000482: Kool Soft Pack	
Length	83 mm
Diameter	7.79 mm
Ventilation	10%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: • Deletion of filter center line adhesive (*custom-made,* (b) (4) • Addition of filter center line adhesive ((b) (4)) • Deletion of the complex tobacco additive (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: • Increase in the quantity of (b) (4)
Attributes of Exemption Request	
Applicant	ITG Brands, LLC
Product Category	Cigarette
Product Sub-Category	Combusted, Filtered
Package Quantity	20 cigarettes
Package Type	Soft Pack
Recommendation	
Issue Exempt order letter.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S
Date: 2019.05.03 08:33:25 -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: 2019.05.03 09:10:52 -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

EX0000482: Kool Soft Pack	
Product Name	Kool King Soft Pack
Package Quantity	20 cigarettes
Package Type	Soft Pack
Length	83 mm
Diameter	7.79 mm
Ventilation	10%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco product and claims that it is grandfathered.[1]

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On March 8, 2019, FDA received an Exemption Request (EX0000482) from ITG Brands, LLC. On March 27, 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 this Exemption Request.

1.4. TOBACCO ADDITIVE MODIFICATION

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

- Deletion of filter center line adhesive (*custom-made,* (b) (4))
- Addition of filter center line adhesive (b) (4)
- Deletion of the complex tobacco additive (b) (4)
- Increase in the quantity of (b) (4)

2. REGULATORY REVIEW

A regulatory review was completed by Donna Cheung on March 27, 2019. The review concluded that this Exemption Request is administratively complete.

[1] The applicant is ITG Brand, LLC, however, the grandfathered registrant is R.J. Reynolds Tobacco Company.

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 April 23, 2019, concludes that the original tobacco product is a grandfathered product.

4. SCIENTIFIC REVIEW

A scientific review was completed by Salome Bhagan on April 18, 2019.

The review states that the new tobacco product has been modified by adding and deleting two tobacco additives along with increasing the quantity of an existing additive. Filter center line adhesive, complex ingredient (b) (4), and (b) (4) 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 product. 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 determines that the deletion of filter center adhesive (*custom-made*, (b) (4)) and the addition of an alternative center line adhesive ((b) (4)) due to a change from a customized adhesive to an adhesive that is purchased commercially by (b) (4), are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. In addition, the deletion of the complex ingredient (b) (4)) and the increase of an existing additive of (b) (4) by ((b) (4)) is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. This modification results in the removal of nine individual additives that were found in the complex ingredient that would no longer be found in the new tobacco product.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Thomas Creaven on April 10, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on May 2, 2019. The FONSI was supported by an environmental assessment prepared by FDA on May 2, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of filter center line adhesive (*custom-made,* (b) (4))
- Addition of filter center line adhesive (b) (4)
- Deletion of the complex tobacco additive (b) (4)
- Increase in the quantity 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 the filter center adhesive (*custom-made*, (b) (4)) and complex ingredient (b) (4) and addition of an alternative center line adhesive ((b) (4)) is an addition/deletion of a tobacco additive. Additionally, I concur with the scientific review that the increase in the amount of (b) (4) is an increase in the quantity of an existing 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 product to be marketed would be appropriate for protection of the public health. The review determines that the deletion of the filter center adhesive (*custom-made*, (b) (4)) and the addition of an alternative center line adhesive ((b) (4)) due to a change from a customized adhesive to an adhesive that is purchased commercially by (b) (4), is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. Specifically, these modifications are made to the non-combusted component of the cigarettes; the alternative center line adhesive is not combusted, volatilized or otherwise released during normal cigarette consumption and so consumer exposure to chemical constituents from the alternative center line adhesive is not expected. In addition, the deletion of the complex ingredient (b) (4)) and the increase of an existing additive of (b) (4) by (b) (4) is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the product. This modification results in the removal of nine individual additives that were found in the complex ingredient that would no longer be found in the new tobacco product. 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 Request and CTP's scientific understanding, that an exemption for these modifications 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 is eligible for modification through the Exemption Request pathway because it can be legally marketed in the United States. The original 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).

FDA has examined the environmental effects of finding the new tobacco product exempt and made a finding of no significant impact.

An Exempt order letter should be issued for the new tobacco product in EX0000482 as identified on the cover page of this review.