

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000443 – EX0000448**

EX0000443: Kool 100s Box	
Length	97 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of the complex tobacco additive (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of (b) (4)
EX0000444: Kool Blue 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	30%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of the complex tobacco additive (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of (b) (4)
EX0000445: Kool Blue Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	29%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of the complex tobacco additive (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of (b) (4)

EX0000446: Kool Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	10%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of the complex tobacco additive (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of (b) (4)
EX0000447: Salem 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of the complex tobacco additive (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of (b) (4)
EX0000448: Salem Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) • Addition of filter center line adhesive (b) (4) • Deletion of the complex tobacco additive (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of (b) (4)
Common Attributes of Exemption Requests	
Applicant	ITG Brands, LLC
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: 2019.03.29 08:55:51 -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: 2019.03.29 09:08:12 -04'00'

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

EX0000443: Kool 100s Box	
Product Name	Kool Super Longs Box
Package Quantity	20 cigarettes
Package Type	Box
Length	97 mm
Diameter	7.89 mm
Ventilation	23%
Characterizing Flavor	Menthol
EX0000444: Kool Blue 100's Box	
Product Name	Kool Milds 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	98 mm
Diameter	7.79 mm
Ventilation	30%
Characterizing Flavor	Menthol
EX0000445: Kool Blue Box	
Product Name	Kool Milds King Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	29%
Characterizing Flavor	Menthol
EX0000446: Kool Box	
Product Name	Kool Filter Kings Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	10%
Characterizing Flavor	Menthol

EX0000447: Salem 100's Box	
Product Name	Salem Full Flavor Green Label 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	98 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	Menthol
EX0000448: Salem Box	
Product Name	Salem Green Label Full Flavor
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	0%
Characterizing Flavor	Menthol

The applicant manufactures the original tobacco products and claims that they are grandfathered.¹

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 6, 2019, FDA received Exemption Requests (EX0000443 – EX0000448) from ITG Brands, LLC. On February 8, 2019, FDA issued Acknowledgment letters to the applicant. On February 26, 2019, for EX0000448, FDA requested additional information on the name of the original product as it was commercially marketed as of February 15, 2007. On February 28, 2019, FDA received a response under EX0000448.

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 filter center line adhesive (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)

¹ The applicant is ITG Brand, LLC, however, the grandfathered registrant is RJ Renolds Tobacco.

2. REGULATORY REVIEW

Regulatory reviews were completed by Donna Cheung on February 8, 2019. The reviews concluded 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 March 12, 2019, conclude that the original tobacco products are grandfathered products.

4. SCIENTIFIC REVIEW

A scientific review was completed by Robert Gahl on March 6, 2019.

The review states that the new tobacco products have 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 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 FD&C Act. The review determines that the deletion of filter center adhesive (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 products. In addition, the deletion of the complex ingredient (b) (4) (0.02 mg/cig) and the increase of an existing additive of (b) (4) by (0.02 mg/cig) is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. 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 products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on March 14, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 28, 2019. The FONSI was supported by an environmental assessment prepared by FDA on March 28, 2019.

6. CONCLUSION AND RECOMMENDATION

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

- Deletion of filter center line adhesive (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 (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 products to be marketed would be appropriate for protection of the public health. The review determines that the deletion of the filter center adhesive (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), it is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. 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) (0.02 mg/cig) and the increase of an existing additive of (b) (4) by (0.02 mg/cig) is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the products. 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 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.

Exempt order letters should be issued for the new tobacco products in EX0000443 – EX0000448 as identified on the cover page of this review.