

**Technical Project Lead (TPL) Review:
Exemption Requests EX0000338 – EX0000342**

EX0000338: Salem Gold Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	25%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) () • Addition of filter center line adhesive (b) (4) ()
EX0000339: Salem Gold 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	48%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) () • Addition of filter center line adhesive (b) (4) () • Deletion of complex ingredients (b) (4) () and (b) (4) () Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) ()
EX0000340: Salem Slim 100's Box	
Length	98 mm
Diameter	7.20 mm
Ventilation	47%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) () • Addition of filter center line adhesive (b) (4) ()
EX0000341: Salem Silver Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	55%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of filter center line adhesive (b) (4) () • Addition of filter center line adhesive (b) (4) () • Deletion of complex ingredients (b) (4) () and (b) (4) () Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) ()

EX0000342: Salem Silver 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	57%
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 complex ingredients (b) (4) () and (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):

Matthew J. Walters -S
2019.02.08 08:33:01 -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: 2019.02.08 08:48:38 -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

EX0000338: Salem Gold Box	
Product Name	Salem Lights Green Label Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	25%
Characterizing Flavor	Menthol
EX0000339: Salem Gold 100's Box	
Product Name	Salem Lights Green Label 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	98 mm
Diameter	7.79 mm
Ventilation	48%
Characterizing Flavor	Menthol
EX0000340: Salem Slim 100's Box	
Product Name	Salem Lights Green Label Slim 100s box
Package Quantity	20 cigarettes
Package Type	Box
Length	98 mm
Diameter	7.20 mm
Ventilation	47%
Characterizing Flavor	Menthol
EX0000341: Salem Silver Box	
Product Name	Salem Ultra Lights Green Label Box
Package Quantity	20 cigarettes
Package Type	Box
Length	83 mm
Diameter	7.79 mm
Ventilation	55%
Characterizing Flavor	Menthol

EX0000342: Salem Silver 100's Box	
Product Name	Salem Ultra Lights Green Label 100s Box
Package Quantity	20 cigarettes
Package Type	Box
Length	98 mm
Diameter	7.79 mm
Ventilation	57%
Characterizing Flavor	Menthol

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

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the Exemption Requests (EX0000338 – EX0000342) on December 19, 2018. FDA issued Acknowledgement letters on December 21, 2018. On January 4, 2019 and January 18, 2019, the Office of Compliance and Enforcement sent emails to the applicant to clarify the packaging type for EX0000340 and EX0000342. In response, the applicant submitted amendments EX0000409 and EX0000422, received by FDA on January 14, 2019 and January 22, 2019, respectively. On January 31, 2019, the applicant submitted a withdrawal (EX0000439) for EX0000340. On February 1, 2019, the applicant rescinded the withdrawal (EX0000440) of EX0000340.

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 complex ingredients (b) (4) and (b) (4) for EX0000339, EX0000341, and EX0000342 only
- Increase in the quantity of (b) (4) for EX0000339, EX0000341, and EX0000342 only

2. REGULATORY REVIEW

Regulatory reviews were completed by Linhua Tzeng on December 21, 2018. The reviews concluded that these Exemption Requests are 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 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 January 14, 2019 for EX0000338, EX0000339, and EX0000341, and January 31, 2019 for EX0000340 and EX0000342, concludes that the original tobacco products are grandfathered products.

4. SCIENTIFIC REVIEW

A scientific review was completed by Stephanie Daniels on January 31, 2019. The review states that the new tobacco products have been modified by adding and deleting tobacco additives for all EX Requests. For EX0000339, EX0000341, and EX0000342, the new tobacco products have also been modified by increasing the quantity of an existing additive. Filter center line adhesive for all EX Requests and (b) (4) and (b) (4) for EX0000339, EX0000341, and EX0000342 only, 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 for all EX Requests 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 tobacco products. In addition, for EX0000339, EX0000341, and EX0000342 only, the deletion of the complex ingredients – (b) (4) (b) (4) mg/cig and (b) (4) (b) (4) mg/cig and the increase of an existing additive of (b) (4) by (b) (4) mg/cig is not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on January 17, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on February 7, 2019. The FONSI was supported by an environmental assessment prepared by FDA on February 7, 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 complex ingredients ((b) (4)) and ((b) (4)) for EX0000339, EX0000341, and EX0000342 only
- Increase in the quantity ((b) (4)) for EX0000339, EX0000341, and EX0000342 only

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 for all EX Requests that the deletion of filter center adhesive ((b) (4)) and addition of an alternative center line adhesive ((b) (4)) is an addition/deletion of a tobacco additive. Additionally, for EX0000339, EX0000341, and EX0000342, I concur with the scientific review that that the deletion of ((b) (4)) and ((b) (4)) is a deletion of tobacco additives and 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, this modification is made to the non-combusted component of the cigarette; 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, for EX0000339, EX0000341, and EX0000342 only, the deletion of the complex ingredients – ((b) (4)) ((b) (4) mg/cig) and ((b) (4)) ((b) (4) mg/cig) and the increase of an existing additive of ((b) (4)) by ((b) (4) 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 will result in the elimination or reduction of many individual additives in the ((b) (4)) and ((b) (4)) ((b) (4)) when comparing the new products to that of the original 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 EX0000338 – EX0000342 as identified on the cover page of this review.