

**Technical Project Lead (TPL) Review:  
Exemption Requests EX0000791 – EX0000797**

EX0000791: Salem 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	17%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of cigarette paper banding solution (b) (4)</li> <li>• Addition of cigarette paper banding solution (b) (4)</li> </ul>
EX0000792: Salem Box	
Length	83 mm
Diameter	7.79 mm
Ventilation	0%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of cigarette paper banding solution (b) (4)</li> <li>• Addition of cigarette paper banding solution (b) (4)</li> </ul>
EX0000793: 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"> <li>• Deletion of cigarette paper banding solution (b) (4)</li> <li>• Addition of cigarette paper banding solution (b) (4)</li> </ul>
EX0000794: 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"> <li>• Deletion of cigarette paper banding solution (b) (4)</li> <li>• Addition of cigarette paper banding solution (b) (4)</li> </ul>

EX0000795: Salem Silver 100's Box	
Length	98 mm
Diameter	7.79 mm
Ventilation	57%
Characterizing Flavor	Menthol
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of cigarette paper banding solution (b) (4)</li> <li>• Addition of cigarette paper banding solution (b) (4)</li> </ul>
EX0000796: 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"> <li>• Deletion of cigarette paper banding solution (b) (4)</li> <li>• Addition of cigarette paper banding solution (b) (4)</li> </ul>
EX0000797: 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"> <li>• Deletion of cigarette paper banding solution (b) (4)</li> <li>• Addition of cigarette paper banding solution (b) (4)</li> </ul>
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):**

Digitally signed by Matthew J. Walters -S  
Date: 2019.11.18 17:32:38 -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: 2019.11.18 18:38:04 -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**

<b>EX0000791: Salem 100's Box</b>	
<b>Product Name</b>	Salem 100's Box
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Box
<b>Length</b>	98 mm
<b>Diameter</b>	7.79 mm
<b>Ventilation</b>	17%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000792: Salem Box</b>	
<b>Product Name</b>	Salem Box
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Box
<b>Length</b>	83 mm
<b>Diameter</b>	7.79 mm
<b>Ventilation</b>	0%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000793: Salem Gold 100's Box</b>	
<b>Product Name</b>	Salem Gold 100's Box
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Box
<b>Length</b>	98 mm
<b>Diameter</b>	7.79 mm
<b>Ventilation</b>	48%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000794: Salem Gold Box</b>	
<b>Product Name</b>	Salem Gold Box
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Box
<b>Length</b>	83 mm
<b>Diameter</b>	7.79 mm
<b>Ventilation</b>	25%
<b>Characterizing Flavor</b>	Menthol

<b>EX0000795: Salem Silver 100's Box</b>	
<b>Product Name</b>	Salem Silver 100's Box
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Box
<b>Length</b>	98 mm
<b>Diameter</b>	7.79 mm
<b>Ventilation</b>	57%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000796: Salem Silver Box</b>	
<b>Product Name</b>	Salem Silver Box
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Box
<b>Length</b>	83 mm
<b>Diameter</b>	7.79 mm
<b>Ventilation</b>	55%
<b>Characterizing Flavor</b>	Menthol
<b>EX0000797: Salem Slim 100's Box</b>	
<b>Product Name</b>	Salem Slim 100's Box
<b>Package Quantity</b>	20 Cigarettes
<b>Package Type</b>	Box
<b>Length</b>	98 mm
<b>Diameter</b>	7.20 mm
<b>Ventilation</b>	47%
<b>Characterizing Flavor</b>	Menthol

The applicant manufactures the original tobacco products and claims that they are previously found Exempt.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On October 2, 2019, FDA received Exemption Requests (EX0000791 – EX0000797) from ITG Brands LLC. FDA issued an Acceptance letter for these Exemption Requests on October 8, 2019.

### 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

#### 1.4. TOBACCO ADDITIVE MODIFICATIONS

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

- Deletion of cigarette paper banding solution (b) (4)
- Addition of cigarette paper banding solution (b) (4)

#### 2. REGULATORY REVIEW

Regulatory reviews were completed by Elizabeth Eydelman on October 8, 2019. The reviews conclude that the Exemption Requests are administratively complete.

#### 3. COMPLIANCE REVIEW

The original tobacco products in EX0000791 – EX0000797 were previously found Exempt by FDA, a report under section 905(j)(1)(A)(ii) (Abbreviated Reports) was submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Reports as shown in the table below.

EX Requests	Original Tobacco Product	Original Tobacco Product Found EX Under:	Order Date	Abbreviated Report	Abbreviated Report Date
EX0000791	Salem 100's Box	EX0000447	March 29, 2019	AS0000126	April 17, 2019
EX0000792	Salem Box	EX0000448	March 29, 2019	AS0000125	April 17, 2019
EX0000793	Salem Gold 100's Box	EX0000339	February 13, 2019	AS0000110	March 22, 2019
EX0000794	Salem Gold Box	EX0000338	February 13, 2019	AS0000112	March 22, 2019
EX0000795	Salem Silver 100's Box	EX0000342	February 13, 2019	AS0000113	March 22, 2019
EX0000796	Salem Silver Box	EX0000341	February 13, 2019	AS0000115	March 22, 2019
EX0000797	Salem Slim 100's Box	EX0000340	February 13, 2019	AS0000111	March 22, 2019

Therefore, the original products are eligible for modification under the Exemption Request pathway.<sup>1</sup>

#### 4. SCIENTIFIC REVIEW

A scientific review was completed by Jiu Ai on November 7, 2019.

The review states that the new tobacco products have been modified by adding and deleting a tobacco additive. Cigarette paper banding solution is used in the manufacturing of the original tobacco products and is an additive because its intended use may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of the tobacco product. The review concludes that the modification is a minor modification 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 cigarette paper banding solution (b) (4) ) and the addition of an alternate cigarette paper banding solution (b) (4) resulting in the deletion of eight additives,

<sup>1</sup> 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.

and the addition of one additive is not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Additionally, the modification of the cigarette paper banding solution is not expected to alter the function of the new tobacco products to allow self-extinguishment.

## 5. ENVIRONMENTAL DECISION

An environmental review was completed by William Brenner on November 7, 2019.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on November 15, 2019. The FONSI was supported by an environmental assessment prepared by FDA on November 15, 2019.

## 6. CONCLUSION AND RECOMMENDATION

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

- Deletion of cigarette paper banding solution (b) (4)
- Addition of cigarette paper banding solution (b) (4)

I concur with the conclusion of the scientific review that this modification is a minor modification 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 cigarette paper banding solution (b) (4) and the addition of an alternative cigarette paper banding solution (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. The review determines that the deletion of cigarette paper banding solution (b) (4) and the addition of an alternate cigarette paper banding solution (b) (4) resulting is the deletion of eight additives and the addition of one additive is not expected to materially affect any other characteristics (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Additionally, the modification of the cigarette paper banding solution is not expected to alter the function of the new tobacco products to allow self-extinguishment. Thus, this change is considered a minor modification and meets 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 this modification is 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 were previously

found Exempt by FDA, a report under section 905(j)(1)(A)(ii) (Abbreviated Reports) was submitted, and 90 days have elapsed since FDA receipt of the Abbreviated Reports.

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 EX0000791 – EX0000797, as identified on the cover page of this review.