

February 13, 2019

**EXEMPT**

ITG Brands, LLC  
ATTENTION: Carole Folmar, J.D., Director of Regulatory & Scientific Affairs  
714 Green Valley Road  
Greensboro, NC 27408

**FDA Submission Tracking Number (STN):** MULTIPLE STNs, SEE APPENDIX A

Dear Ms. Folmar:

The Food and Drug Administration (FDA) completed review of your Requests for Exemption from Substantial Equivalence (EX REQ), submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for the tobacco products specified in Appendix A.

Based on our review of your EX REQs, we find the new tobacco products specified in Appendix A are exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco products are substantially equivalent (see section 905(j)(3)(A) of the FD&C Act).

**To market each of the new tobacco products that are the subject of these EX REQs, the following must be met:**

- 1. Submit a report under section 905(j)(1) (Abbreviated Report) that includes the information required in sections 905(j)(1)(A)(ii) and 905(j)(1)(B); and**
- 2. Ninety days have passed since FDA receipt of your Abbreviated Report.**

See Appendix B for FDA's recommended format for the submission of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

Our finding does not mean FDA "approved" the new tobacco products specified in Appendix A; therefore, you may not promote or in any way represent the modified tobacco product specified in Appendix A, or its labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act. These orders are subject to reconsideration and rescission to the extent authorized by law. See 21 CFR 1107.1(d).

We remind you that all regulated tobacco products, including the new tobacco products specified in Appendix A, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at <http://www.fda.gov/TobaccoProducts>. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov), or [SmallBiz.Tobacco@fda.hhs.gov](mailto:SmallBiz.Tobacco@fda.hhs.gov).

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm>)<sup>1</sup> using eSubmitter (<http://www.fda.gov/ForIndustry/FDAeSubmitter>). Alternatively, submissions may be mailed to:

Food and Drug Administration  
Center for Tobacco Products  
Document Control Center (DCC)  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by courier or physical mail will be considered timely if received during delivery hours on or before the due date (see <http://www.fda.gov/tobaccoproducts/aboutcontactus/default.htm>); if the due date falls on a weekend or holiday the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, you may contact Megan Nguyen, Regulatory Health Project Manager, at (301) 796 - 7826 or [Megan.Nguyen@fda.hhs.gov](mailto:Megan.Nguyen@fda.hhs.gov).

Sincerely,

Digitally signed by Matthew R. Holman -S  
Date: 2019.02.13 13:40:34 -05'00'

Matthew R. Holman, Ph.D.  
Director  
Office of Science  
Center for Tobacco Products

Enclosures – Appendix A: List of New Tobacco Products Subject of This Letter  
Appendix B: FDA's Recommended Format of the Submission of an Abbreviated Report

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<sup>1</sup> The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

## Appendix A

List of new tobacco products that FDA has found exempt from the requirements of section 905(j) of the FD&C Act relating to the demonstration that the tobacco products are substantially equivalent

Common Attributes of EX REQs	
Date of Submission:	December 19, 2018
Date of Receipt:	December 19, 2018
Product Manufacturer:	ITG Brands, LLC
Product Category:	Cigarettes
Product Sub-Category:	Combusted, Filtered
New Tobacco Product Specific Attributes	
Submission Tracking Number	EX0000338
Tobacco Product Name: <sup>2</sup>	Salem Gold Box
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	25%
Modification:	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of filter center line adhesive (b) (4)</li> <li>• Addition of filter center line adhesive (b) (4)</li> </ul>
Original Tobacco Product Specific Attributes	
Product Name: <sup>2</sup>	Salem Lights Green Label Box
Package Type:	Box
Package Quantity:	20 cigarettes
Characterizing Flavor:	Menthol
Eligibility Status:	Grandfathered
Length:	83 mm
Diameter:	7.79 mm
Ventilation:	25%

<sup>2</sup> Brand/sub-brand or other commercial name used in commercial distribution.

<b>New Tobacco Product Specific Attributes</b>	
<b>Submission Tracking Number</b>	EX0000339
<b>Tobacco Product Name:<sup>2</sup></b>	Salem Gold 100's Box
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Characterizing Flavor:</b>	Menthol
<b>Length:</b>	98 mm
<b>Diameter:</b>	7.79 mm
<b>Ventilation:</b>	48%
<b>Modification:</b>	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of filter center line adhesive ((b) (4) (b) (4) (b) (4))</li> <li>• Addition of filter center line adhesive ((b) (4) (b) (4))</li> <li>• Deletion of complex ingredients ((b) (4) (b) (4) and (b) (4))</li> </ul> <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>
<b>Original Tobacco Product Specific Attributes</b>	
<b>Product Name:<sup>2</sup></b>	Salem Lights Green Label 100s Box
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Characterizing Flavor:</b>	Menthol
<b>Eligibility Status:</b>	Grandfathered
<b>Length:</b>	98 mm
<b>Diameter:</b>	7.79 mm
<b>Ventilation:</b>	48%

<b>New Tobacco Product Specific Attributes</b>	
<b>Submission Tracking Number</b>	EX0000340
<b>Tobacco Product Name:</b> <small>Error! Bookmark not defined.</small>	Salem Slim 100's Box
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Characterizing Flavor:</b>	Menthol
<b>Length:</b>	98 mm
<b>Diameter:</b>	7.20 mm
<b>Ventilation:</b>	47%
<b>Modification:</b>	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of filter center line adhesive ((b) (4) (b) (4), (b) (4))</li> <li>• Addition of filter center line adhesive ((b) (4) (b) (4))</li> </ul>
<b>Original Tobacco Product Specific Attributes</b>	
<b>Product Name:</b> <sup>2</sup>	Salem Lights Green Label Slim 100s Box
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Characterizing Flavor:</b>	Menthol
<b>Eligibility Status:</b>	Grandfathered
<b>Length:</b>	98 mm
<b>Diameter:</b>	7.20 mm
<b>Ventilation:</b>	47%

New Tobacco Product Specific Attributes	
<b>Submission Tracking Number</b>	EX0000341
<b>Tobacco Product Name:</b> <small>Error! Bookmark not defined.</small>	Salem Silver Box
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Characterizing Flavor:</b>	Menthol
<b>Length:</b>	83 mm
<b>Diameter:</b>	7.79 mm
<b>Ventilation:</b>	55%
<b>Modification:</b>	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of filter center line adhesive ((b) (4) (b) (4), (b) (4) )</li> <li>• Addition of filter center line adhesive ((b) (4) (b) (4) )</li> <li>• Deletion of complex ingredients ((b) (4) (b) (4) and (b) (4) )</li> </ul> <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>
Original Tobacco Product Specific Attributes	
<b>Product Name:<sup>2</sup></b>	Salem Ultra Lights Green Label Box
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Characterizing Flavor:</b>	Menthol
<b>Eligibility Status:</b>	Grandfathered
<b>Length:</b>	83 mm
<b>Diameter:</b>	7.79 mm
<b>Ventilation:</b>	55%

<b>New Tobacco Product Specific Attributes</b>	
<b>Submission Tracking Number</b>	EX0000342
<b>Tobacco Product Name:</b> <small>Error! Bookmark not defined.</small>	Salem Silver 100's Box
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Characterizing Flavor:</b>	Menthol
<b>Length:</b>	98 mm
<b>Diameter:</b>	7.79 mm
<b>Ventilation:</b>	57%
<b>Modification:</b>	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> <li>• Deletion of filter center line adhesive ((b) (4) (b) (4), (b) (4) )</li> <li>• Addition of filter center line adhesive ((b) (4) (b) (4) )</li> <li>• Deletion of complex ingredients ((b) (4) (b) (4) and (b) (4) )</li> </ul> <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>
<b>Original Tobacco Product Specific Attributes</b>	
<b>Product Name:<sup>2</sup></b>	Salem Ultra Lights Green Label 100s Box
<b>Package Type:</b>	Box
<b>Package Quantity:</b>	20 cigarettes
<b>Characterizing Flavor:</b>	Menthol
<b>Eligibility Status:</b>	Grandfathered
<b>Length:</b>	98 mm
<b>Diameter:</b>	7.79 mm
<b>Ventilation:</b>	57%

Appendix B  
FDA's Recommended Format of the Submission of an Abbreviated Report

Mock-up Tobacco Company

April 3, 2015

US Department of Health and Human Services  
Food and Drug Administration  
Center for Tobacco Products  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

RE: Abbreviated Report

To Whom It May Concern:

Mock-Up Tobacco Company provides this Abbreviated Report at least 90 days prior to the introduction or delivery for introduction into interstate commerce for commercial distribution of the new product, Cigarette Brand A. We submitted an Exemption Request (EX0000XXX) under section 905(j)(3) for the new product on February 1, 2015, and received a found exempt order from FDA on March 20, 2015.

I, John Doe, on behalf of Mock-Up Tobacco Company, certify that Cigarette Brand A is modified within the meaning of section 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act, all the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3), and I have taken actions to comply with the requirements under section 907 that are applicable to the product. I certify that this information is true and correct, and that I am authorized to submit this on the company's behalf. I understand that under section 1001 of title 18 of the United States Code, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the United States is subject to criminal penalties.

Sincerely,  
John Doe  
Vice President  
Mock-Up Tobacco Company