

July 17, 2020

**EXEMPT**

Al Fakher Distribution USA, Inc.  
Attention: Bryan M. Haynes, Counsel  
Troutman Sanders LLP  
1001 Haxall Point  
Richmond, VA 23219

**FDA Submission Tracking Numbers (STNs):** Multiple STNs, see Appendix A

Dear Mr. Haynes:

We completed review of your EX REQs<sup>1</sup> and determined that the new tobacco products listed in Appendix A are exempt from the requirements of Substantial Equivalence.<sup>2</sup>

Our finding does not mean we “approved” the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being “approved” by FDA (see Section 301(tt) of the FD&C Act).

**To market 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 submitting of an Abbreviated Report.

In accordance with 40 CFR 1506.6, we will make your Environmental Assessment (EA) publicly available.

All regulated tobacco products, including the tobacco products specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco products specified in Appendix A comply with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

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<sup>1</sup> Requests for Exemption from Substantial Equivalence (EX REQs) submitted under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

<sup>2</sup> See section 910(a)(3)(a) of the FD&C Act

We encourage you to submit all regulatory correspondence electronically via the CTP Portal<sup>3,4</sup> using eSubmitter.<sup>5</sup> 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 FDA's 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<sup>6</sup>; 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, please contact Kathryn Mueller, Regulatory Health Project Manager, at (301) 796 - 6711 or Kathryn.Mueller@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2020.07.17 13:27:34 -04'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Original Tobacco Products Subject of This Letter  
Appendix B – FDA's Recommended Format for Submitting an Abbreviated Report

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<sup>3</sup> For more information about CTP Portal, see <https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

<sup>4</sup> FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

<sup>5</sup> For more information about eSubmitter, see <http://www.fda.gov/ForIndustry/FDAeSubmitter>

<sup>6</sup> <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

Appendix A

Common Attributes of EX REQs		
<b>Date of Submission:</b>	April 14, 2020	
<b>Date of Receipt:</b>	April 14, 2020	
<b>Product Manufacturer:</b>	Al Fakher Distribution USA, Inc.	
<b>Product Category:</b>	Waterpipe Tobacco Products	
<b>Product Sub-Category:</b>	Waterpipe Tobacco Filler	
	<b>New Tobacco Product</b>	<b>Original Tobacco Product</b>
	EX0001036: Al Fakher Apricot Flavour 1000 grams <sup>7</sup>	GF1908358: Al Fakher Apricot Flavour 1Kg <sup>7</sup>
<b>Package Type:</b>	Plastic Pouch	Plastic Pouch
<b>Package Quantity:</b>	1000 grams	1000 grams <sup>8</sup>
<b>Characterizing Flavor:</b>	Apricot	Apricot
<b>Eligibility Status:</b>	N/A	Grandfathered
<b>Additional Properties:</b>	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b>		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> <li>Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Addition of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Addition of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Addition of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		

<sup>7</sup> Brand/sub-brand or other commercial name used in commercial distribution.

<sup>8</sup> The package quantity was stated as 1 Kg, which was converted to 1000 grams.

	New Tobacco Product	Original Tobacco Product
	EX0001038: Al Fakher Banana Flavour 250 grams <sup>7</sup>	GF1908354: Al Fakher Banana Flavour 250 grams <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Banana	Banana
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b>		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> <li>Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		
	EX0001039: Al Fakher Banana Flavour 1000 grams <sup>7</sup>	GF1908357: Al Fakher Banana Flavour 1Kg <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams <sup>8</sup>
Characterizing Flavor:	Banana	Banana
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b>		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> <li>Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		

	New Tobacco Product	Original Tobacco Product
	EX0001042: Al Fakher Apricot Flavour 50 grams <sup>7</sup>	GF1908356: Al Fakher Apricot Flavour 50 grams <sup>7</sup>
<b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <b>Eligibility Status:</b> <b>Additional properties:</b>	Plastic Pouch 50 grams Apricot N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Plastic Pouch 50 grams Apricot Grandfathered Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b> Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Addition of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Addition of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Addition of (b) (4) in the complex purchased flavor (b) (4)</li> </ul> Increase/Decrease in quantity of existing additives: <ul style="list-style-type: none"> <li>• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		
	EX0001043: Al Fakher Apricot Flavour 250 grams <sup>7</sup>	GF1908355: Al Fakher Apricot Flavour 250 grams <sup>7</sup>
<b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <b>Eligibility Status:</b> <b>Additional properties:</b>	Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b> Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Addition of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Addition of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Addition of (b) (4) in the complex purchased flavor (b) (4)</li> </ul> Increase/Decrease in quantity of existing additives: <ul style="list-style-type: none"> <li>• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		

	New Tobacco Product	Original Tobacco Product
	EX0001044: Al Fakher Banana Flavour 50 grams <sup>7</sup>	GF1908352: Al Fakher Banana Flavour 50 grams <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Banana	Banana
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b> Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> </ul> Increase/Decrease in quantity of existing additives: <ul style="list-style-type: none"> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		
	EX0001046: Al Fakher Rose Flavour 250 grams <sup>7</sup>	GF1908307: Al Fakher Rose Flavour 250 grams <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Rose	Rose
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b> Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Addition of (b) (4) in the complex purchased flavor (b) (4)</li> </ul> Increase/Decrease in quantity of existing additives: <ul style="list-style-type: none"> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> <li>Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		

	New Tobacco Product	Original Tobacco Product
	EX0001047: Al Fakher Rose Flavour 50 grams <sup>7</sup>	GF1908312: Al Fakher Rose Flavour 50 grams <sup>7</sup>
<b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <b>Eligibility Status:</b> <b>Additional properties:</b>	Plastic Pouch 50 grams Rose N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Plastic Pouch 50 grams Rose Grandfathered Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b> Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Addition of (b) (4) in the complex purchased flavor (b) (4)</li> </ul> Increase/Decrease in quantity of existing additives: <ul style="list-style-type: none"> <li>• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		
	EX0001051: Al Fakher Rose Flavour 1000 grams <sup>7</sup>	GF1908311: Al Fakher Rose Flavour 1 Kg <sup>7</sup>
<b>Package Type:</b> <b>Package Quantity:</b> <b>Characterizing Flavor:</b> <b>Eligibility Status:</b> <b>Additional properties:</b>	Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %	Plastic Pouch 1000 grams <sup>8</sup> Rose Grandfathered Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) (4) %
<b>Modifications:</b> Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Addition of (b) (4) in the complex purchased flavor (b) (4)</li> </ul> Increase/Decrease in quantity of existing additives: <ul style="list-style-type: none"> <li>• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		

	New Tobacco Product	Original Tobacco Product
	EX0001052: Al Fakher Plum Flavour 1000 grams <sup>7</sup>	GF1908316: Al Fakher Plum Flavour 1 Kg <sup>7</sup>
<b>Package Type:</b>	Plastic Pouch	Plastic Pouch
<b>Package Quantity:</b>	1000 grams	1000 grams <sup>8</sup>
<b>Characterizing Flavor:</b>	Plum	Plum
<b>Eligibility Status:</b>	N/A	Grandfathered
<b>Additional properties:</b>	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
<b>Modifications:</b>		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> <li>• Deletion of (b) (4) in the complex purchased flavor (b) (4)</li> </ul>		



- Deletion of [REDACTED] in the complex purchased flavor [REDACTED]
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- Addition of (b) (4) in the complex purchased flavor (b) (4)
- Addition of (b) (4) in the complex purchased flavor (b) (4)
- Addition of (b) (4) in the complex purchased flavor [REDACTED]
- Addition of (b) (4) in the complex purchased flavor (b) (4)



**Appendix B**  
FDA's Recommended Format for Submitting 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 **[ink or digital signature]**  
Vice President  
Mock-Up Tobacco Company