

August 10, 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 REQ¹s and determined that the new tobacco products listed in Appendix A are exempt from the requirements of Substantial Equivalence.²

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.

¹ 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)

² See section 910(a)(3)(a) of the FD&C Act

We encourage you to submit all regulatory correspondence electronically via the CTP Portal^{3,4} using eSubmitter.⁵ 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 date⁶; 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: 2020.08.10 10:12:13 -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

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

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

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

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

Appendix A
New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes of EX REQs		
Date of Submission:	April 14, 2020	
Date of Receipt:	April 14, 2020	
Product Manufacturer:	Al Fakher Distribution USA, Inc.	
Product Category:	Waterpipe Tobacco Products	
Product Sub-Category:	Waterpipe Tobacco Filler	
	New Tobacco Product	Original Tobacco Product
	EX0001037: Al Fakher Apple Flavour 1000 grams ⁷	GF1908361: Al Fakher Apple Flavour 1Kg ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams ⁸
Characterizing Flavor:	Apple	Apple
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) Addition of (b) (4) in the complex purchased flavor (b) (4) 		
	EX0001040: Al Fakher Apple Flavour 50 grams⁷	GF1908359: Al Fakher Apple Flavour 50 grams⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Apple	Apple
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) Addition of (b) (4) in the complex purchased flavor (b) (4) 		

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

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

	New Tobacco Product	Original Tobacco Product
	EX0001041: Al Fakher Apple Flavour 250 grams ⁷	GF1908360: Al Fakher Apple Flavour 250 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Apple	Apple
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications: Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) Addition of (b) (4) in the complex purchased flavor (b) (4) 		
	EX0001045: Al Fakher Mango Flavour 250 grams ⁷	GF1908321: Al Fakher Mango Flavour 250 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Mango	Mango
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications: Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) Increase/Decrease in quantity of existing additives: <ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 		
	EX0001048: Al Fakher Strawberry Flavour 1000 grams ⁷	GF1908306: Al Fakher Strawberry Flavour 1Kg ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams ⁸
Characterizing Flavor:	Strawberry	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications: Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of acetaldehyde in the complex purchased flavor (b) (4) Addition of propionaldehyde in the complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001049: Al Fakher Strawberry Flavour 50 grams ⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Strawberry	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of acetaldehyde in the complex purchased flavor (b) (4) Addition of propionaldehyde in the complex purchased flavor (b) (4) 		
	EX0001050: Al Fakher Strawberry Flavour 250 grams ⁷	GF1908303: Al Fakher Strawberry Flavour 250 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Strawberry	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) Addition of (b) (4) in the complex purchased flavor (b) (4) 		
	EX0001053: Al Fakher Melon Flavour 250 grams ⁷	GF1908324: Al Fakher Melon Flavour 250 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Melon	Melon
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) Decreasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001054: Al Fakher Melon Flavour 1000 grams ⁷	GF1908323: Al Fakher Melon Flavour 1 Kg ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams ⁸
Characterizing Flavor:	Melon	Melon
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) Decreasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 		
	EX0001055: Al Fakher Cocktail Flavour 1000 grams ⁷	GF1908345: Al Fakher Cocktail Flavour 1 Kg ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams ⁸
Characterizing Flavor:	Cocktail	Cocktail
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 		
	EX0001056: Al Fakher Mango Flavour 1000 grams ⁷	GF1908325: Al Fakher Mango Flavour 1Kg ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams ⁸
Characterizing Flavor:	Mango	Mango
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001057: Al Fakher Cocktail Flavour 250 grams ⁷	GF1908342: Al Fakher Cocktail Flavour 250 grams ⁷
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:	Plastic Pouch 250 grams Cocktail N/A Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Plastic Pouch 250 grams Cocktail Grandfathered Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications: Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) Increase/Decrease in quantity of existing additives: <ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 		
	EX0001058: Al Fakher Two Apples Flavour 250 grams ⁷	GF1908301: Al Fakher Two Apples Flavour 250 grams ⁷
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:	Plastic Pouch 250 grams Two Apples N/A Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Plastic Pouch 250 grams Two Apples Grandfathered Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications: Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) Addition of (b) (4) in the complex purchased flavor (b) (4) 		
	EX0001059: Al Fakher Two Apples Flavour 1000 grams ⁷	GF1908305: Al Fakher Two Apples Flavour 1 Kg ⁷
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:	Plastic Pouch 1000 grams Two Apples N/A Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Plastic Pouch 1000 grams ⁸ Two Apples Grandfathered Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications: Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) Addition of (b) (4) in the complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001060: Al Fakher Two Apples Flavour 50 grams ⁷	GF1908302: Al Fakher Two Apples Flavour 50 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Two Apples	Two Apples
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %	Tobacco Cut Size: (b) (4) mm Tobacco Moisture: (b) (4) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Deletion of (b) (4) in the complex purchased flavor (b) (4) • 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