

December 16, 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 REQs¹ 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 Todd L. Cecil -S
Date: 2020.12.16 07:48:52 -05'00'

Todd L. Cecil, Ph.D.
Deputy 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		
Product Manufacturer:	Al Fakher Tobacco Factory, F.Z.E.	
Product Category:	Waterpipe Tobacco Products	
Product Sub-Category:	Waterpipe Tobacco Filler	
	New Tobacco Product	Original Tobacco Product
	EX0001082:Al Fakher Cherry with Mint Flavour 1000 grams⁷	GF1908347: Al Fakher Cherry Flavour 1 Kg⁷
Date of Submission:	May 5, 2020	N/A
Date of Receipt:	May 5, 2020	N/A
Product Name:⁷	Al Fakher Cherry with Mint Flavour 1000 grams	Al Fakher Cherry Flavour 1 Kg
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Cherry with Mint	Cherry
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) 		
(b) (4)		

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

	New Tobacco Product	Original Tobacco Product
	EX0001083: Al Fakher Grape with Mint Flavour 1000 grams⁷	GF1908331: Al Fakher Grape Flavour 1 Kg⁷
Date of Submission:	May 5, 2020	N/A
Date of Receipt:	May 5, 2020	N/A
Product Name:⁷	Al Fakher Grape with Mint Flavour 1000 grams	Al Fakher Grape Flavour 1 Kg
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Grape with Mint	Grape
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increase in the quantity of (b) (4) Decrease in the quantity of the complex purchased flavor (b) (4) 		
(b) (4)		
	New Tobacco Product	Original Tobacco Product
	EX0001087: Al Fakher Lemon with Mint Flavour 1000 grams⁷	GF1908332: Al Fakher Lemon Flavour 1 Kg⁷
Date of Submission:	May 5, 2020	N/A
Date of Receipt:	May 5, 2020	N/A
Product Name:⁷	Al Fakher Lemon with Mint Flavour 1000 grams	Al Fakher Lemon Flavour 1 Kg
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Lemon with Mint	Lemon
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Decrease in the quantity of (b) (4) Decrease in the quantity of complex purchased flavor (b) (4) (b)(4) Increase in the quantity of complex purchased flavor (b) (4) 		
(b) (4)		

⁹ Page 4 of EX0001087 and EX0001088 describe changes to the complex purchased ingredient (b) (4) rather than (b) (4) as listed in Exhibit C in these EX Requests. This is presumably a typographical error by the applicant and (b) (4) is used in this review to describe modifications of the new and original tobacco products of EX0001087 and EX0001088.

	New Tobacco Product	Original Tobacco Product
	EX0001088: Al Fakher Lemon with Mint Flavour 50 grams⁷	GF1908326: Al Fakher Lemon Flavour 50 grams⁷
Date of Submission:	May 5, 2020	N/A
Date of Receipt:	May 5, 2020	N/A
Product Name:⁷	Al Fakher Lemon with Mint Flavour 50 grams	Al Fakher Lemon Flavour 50 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Lemon with Mint	Lemon
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increase in the quantity of complex purchased flavor (b) (4) (b) (4) Decrease in the quantity of (b) (4) Decrease in the quantity of complex purchased flavor (b) (4) (b) (4) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001089: Al Fakher Grape with Mint Flavour 50 grams⁷	GF1908333: Al Fakher Grape Flavour 50 grams⁷
Date of Submission:	May 5, 2020	N/A
Date of Receipt:	May 5, 2020	N/A
Product Name:⁷	Al Fakher Grape with Mint Flavour 50 grams	Al Fakher Grape Flavour 50 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Grape with Mint	Grape
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increase in the quantity of (b) Decrease in the quantity of complex purchased flavor (b) (4) (b) 		

	New Tobacco Product	Original Tobacco Product
	EX0001092: Al Fakher Two Apples with Mint Flavour 1000 grams⁷	GF1908305: Al Fakher Two Apple Flavour 1 Kg⁷
Date of Submission:	May 5, 2020	N/A
Date of Receipt:	May 5, 2020	N/A
Product Name:⁷	Al Fakher Two Apples with Mint Flavour 1000 grams	Al Fakher Two Apple Flavour 1 Kg
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Two Apples with Mint	Two Apple
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of (b) (4) in the complex flavor ingredient (b) (4) • Addition of the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex flavor ingredient (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Decrease in the quantity of complex purchased flavor (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001093: Al Fakher Orange with Mint Flavour 250 grams⁷	GF1908315: Al Fakher Orange Flavour 250 grams⁷
Date of Submission:	May 5, 2020	N/A
Date of Receipt:	May 5, 2020	N/A
Product Name:⁷	Al Fakher Orange with Mint Flavour 250 grams	Al Fakher Orange Flavour 250 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Orange with Mint	Orange
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001094: Al Fakher Orange with Mint Flavour 50 grams⁷	GF1908318: Al Fakher Orange Flavour 50 grams⁷
Date of Submission:	May 5, 2020	N/A
Date of Receipt:	May 5, 2020	N/A
Product Name:⁷	Al Fakher Orange with Mint Flavour 250 grams	Al Fakher Orange Flavour 250 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Orange with Mint	Orange
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Decrease in the quantity of complex purchased flavor (b) (4) • Decrease in the quantity of complex purchased flavor (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001120: Al Fakher Mint with Cream Flavour 50 grams⁷	GF1908313: Al Fakher Mint Flavour 50 grams⁷
Date of Submission:	May 21, 2020	N/A
Date of Receipt:	May 21, 2020	N/A
Product Name:⁷	Al Fakher Mint with Cream Flavour 50 grams	Al Fakher Mint Flavour 50 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Mint with Cream	Mint
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b)(4) • Decrease in the quantity of the complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001121: Al Fakher Mint with Cream Flavour 250 grams⁷	GF1908319: Al Fakher Mint Flavour 250 grams⁷
Date of Submission:	May 21, 2020	N/A
Date of Receipt:	May 21, 2020	N/A
Product Name:⁷	Al Fakher Mint with Cream Flavour 250 grams	Al Fakher Mint Flavour 250 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Mint with Cream	Mint
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001122: Al Fakher Orange with Cream Flavour 250 grams⁷	GF1908315: Al Fakher Orange Flavour 250 grams⁷
Date of Submission:	May 21, 2020	N/A
Date of Receipt:	May 21, 2020	N/A
Product Name:⁷	Al Fakher Orange with Cream Flavour 250 grams	Al Fakher Orange Flavour 250 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Orange with Cream	Orange
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001123: Al Fakher Orange with Cream Flavour 50 grams⁷	GF1908318: Al Fakher Orange Flavour 50 grams⁷
Date of Submission:	May 21, 2020	N/A
Date of Receipt:	May 21, 2020	N/A
Product Name:⁷	Al Fakher Orange with Cream Flavour 50 grams	Al Fakher Orange Flavour 50 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Orange with Cream	Orange
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001124: Al Fakher Strawberry with Cream Flavour 250 grams⁷	GF1908303: Al Fakher Strawberry Flavour 250 grams⁷
Date of Submission:	May 21, 2020	N/A
Date of Receipt:	May 21, 2020	N/A
Product Name:⁷	Al Fakher Strawberry with Cream Flavour 250 grams	Al Fakher Strawberry Flavour 250 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Strawberry with Cream	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001125: Al Fakher Strawberry with Cream Flavour 50 grams⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams⁷
Date of Submission:	May 21, 2020	N/A
Date of Receipt:	May 21, 2020	N/A
Product Name:⁷	Al Fakher Strawberry with Cream Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Strawberry with Cream	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional Property:	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"> • Addition of the complex purchased flavor (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Decrease in the quantity of (b) (4) • Decrease in the quantity of the complex purchased flavor (b) (4) 		
	EX0001208: Al Fakher Plum Flavour 50 grams⁷	SE0015700: Al Fakher Plum Flavour 50 grams⁷
Date of Submission:	May 21, 2020	N/A
Date of Receipt:	May 21, 2020	N/A
Product Name:⁷	Al Fakher Plum Flavour 50 grams	Al Fakher Plum Flavour 50 grams
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Plum	Plum
Eligibility Status:	N/A	Previously Found SE
Additional Property:	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 multiple additives in the complex purchased flavor (b) (4) 		
<ul style="list-style-type: none"> • Addition of multiple additives in the alternate 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

Appendix C

Appendix C. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Status	Brief Description
November 3, 2020	November 3, 2020	EX0001317	EX0001082- EX0001083, EX0001087- EX0001089, EX0001092- EX0001094, EX0001120- EX0001125	Yes	Active	Response to October 29, 2020 FDA Information Request
November 19, 2020	November 19, 2020	EX0001365	EX0001089	Yes	Active	Response to November 18, 2020 email request from OCE
November 20, 2020	November 20, 2020	EX0001366	EX0001089	Yes	Active	Response to November 20, 2020 email request