

January 19, 2021

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: 2021.01.19 14:49:32 -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		
Date of Submission:	June 12, 2020	
Date of Receipt:	June 12, 2020	
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
	EX0001139: Al Fakher Fresh Flavour 1000 grams (g)⁷	GF1908322: Al Fakher Mint Flavour 1 Kilogram (Kg)⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Fresh	Mint
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
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) in the tobacco filler Decrease in the quantity of the complex purchased flavor (b)(4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001140: Al Fakher Fresh Flavour 250 grams⁷	GF1908319: Al Fakher Mint Flavour 250 grams⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Fresh	Mint
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
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) in the tobacco filler Decrease in the quantity of the complex purchased flavor (b)(4) 		

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

	New Tobacco Product	Original Tobacco Product
	EX0001142: Al Fakher Cinnamon Flavour 50 grams⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams⁷
Package Type:	Polypropylene Plastic Pouch	Polypropylene Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Cinnamon	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of the complex purchased flavor (b)(4) • Deletion 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) in the tobacco filler 		
	New Tobacco Product	Original Tobacco Product
	EX0001145: Al Fakher Bubble Gum Flavour 250 grams⁷	GF1908303: Al Fakher Strawberry Flavour 250 grams⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Bubble Gum	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of the complex purchased flavor (b)(4) • Deletion 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) in the tobacco filler 		
	New Tobacco Product	Original Tobacco Product
	EX0001147: Al Fakher Bubble Gum Flavour 50 grams⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams⁷
Package Type:	Polypropylene Plastic Pouch	Polypropylene Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Bubble Gum	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of the complex purchased flavor (b)(4) • Deletion 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) in the tobacco filler 		

	New Tobacco Product	Original Tobacco Product
	EX0001148: Al Fakher Grapefruit with Mint Flavour 250 grams⁷	GF1908319: Al Fakher Mint Flavour 250 grams⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Grapefruit with Mint	Mint
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of the complex purchased flavor (b)(4) • 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) in the tobacco filler • Decrease in the quantity of the complex purchased flavor (b)(4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001149: Al Fakher Grapefruit Flavour 1000 grams⁷	GF1908306: Al Fakher Strawberry Flavour 1 Kg⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Grapefruit	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of the complex purchased flavor (b)(4) • Addition of the complex purchased flavor (b)(4) • Deletion 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) in the tobacco filler 		

	New Tobacco Product	Original Tobacco Product
	EX0001150: Al Fakher Grapefruit with Mint Flavour 50 grams⁷	GF1908313: Al Fakher Mint Flavour 50 grams⁷
Package Type:	Polypropylene Plastic Pouch	Polypropylene Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Grapefruit with Mint	Mint
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of the complex purchased flavor (b)(4) • 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) in the tobacco filler • Decrease in the quantity of the complex purchased flavor (b)(4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001153: Al Fakher Grenadine Flavour 50 grams⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams⁷
Package Type:	Polypropylene Plastic Pouch	Polypropylene Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Grenadine	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of the complex purchased flavor (b)(4) • Addition of the complex purchased flavor • Deletion of the complex purchased flavor 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b)(4) in the tobacco filler 		

	New Tobacco Product	Original Tobacco Product
	EX0001155: Al Fakher Grenadine Flavour 250 grams⁷	GF1908303: Al Fakher Strawberry Flavour 250 grams⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Grenadine	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of the complex purchased flavor (b)(4) • Addition of the complex purchased flavor (b)(4) • Deletion 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) in the tobacco filler 		

	New Tobacco Product	Original Tobacco Product
	EX0001158: Al Fakher Guava Flavour 1000 grams ⁷	GF1908306: Al Fakher Strawberry Flavour 1 Kg ⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Guava	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of the complex purchased flavor (b)(4) Deletion 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) in the tobacco filler 		
	New Tobacco Product	Original Tobacco Product
	EX0001161: Al Fakher Guava Flavour 50 grams ⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams ⁷
Package Type:	Polypropylene Plastic Pouch	Polypropylene Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Guava	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of the complex purchased flavor (b)(4) Deletion 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) in the tobacco filler 		
	New Tobacco Product	Original Tobacco Product
	EX0001163: Al Fakher Gum with Cinnamon Flavour 1000 grams ⁷	GF1908306: Al Fakher Strawberry Flavour 1 Kg ⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Gum with Cinnamon	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of the complex purchased flavor (b)(4) Addition of the complex purchased flavor (b)(4) Deletion 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) in the tobacco filler 		

	New Tobacco Product	Original Tobacco Product
	EX0001167: Al Fakher Mojito Flavour 1000 grams⁷	GF1908322: Al Fakher Mint Flavour 1 Kg⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Mojito	Mint
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
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) in the tobacco filler Decrease in the quantity of the complex purchased flavor (b)(4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001168: Al Fakher Vanilla Flavour 1000 grams⁷	GF1908306: Al Fakher Strawberry Flavour 1 Kg⁷
Package Type:	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Vanilla	Strawberry
Eligibility Status:	N/A	Grandfathered
Additional property:	Tobacco cut size: (b)(4) Tobacco moisture: 10%	Tobacco cut size: (b)(4) Tobacco moisture: 10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of the complex purchased flavor (b)(4) Deletion 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) in the tobacco filler 		

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