

October 30, 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: 2020.10.30 11:41:00 -04'00'

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:	May 7, 2020	
Date of Receipt:	May 7, 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
	EX0001098: Al Fakher Citrus with Mint Flavour 1000 grams⁷	GF1908322: Al Fakher Mint Flavour 1Kg⁷
Package Type:	Box	Box
Package Quantity:	1Kg	1 Kg
Characterizing Flavor:	Citrus with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) • Addition of complex purchased flavor (b) (4) 		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001099: Al Fakher Citrus with Mint Flavour 250 grams⁷	GF1908319: Al Fakher Mint Flavour 250 grams⁷
Package Type:	Box	Box
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Citrus with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) • Addition of complex purchased flavor (b) (4) 		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 		

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

	New Tobacco Product	Original Tobacco Product
	EX0001101: Al Fakher Grape with Berry Flavour 250 grams⁷	GF1908334: Al Fakher Grape Flavour 250 grams⁷
Package Type:	Box	Box
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Grape with Berry	Grape
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4) [redacted]” 		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) [redacted] • Decreasing the quantity of complex purchased flavor “(b) (4) [redacted]” 		
	EX0001102: Al Fakher Grape with Berry Flavour 1000 grams⁷	GF1908331: Al Fakher Grape Flavour 1Kg⁷
Package Type:	Box	Box
Package Quantity:	1Kg	1 Kg
Characterizing Flavor:	Grape with Berry	Grape
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) [redacted] 		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) [redacted] • Decreasing the quantity of complex purchased flavor (b) (4) [redacted] 		

	New Tobacco Product	Original Tobacco Product
	EX0001103: Al Fakher Citrus with Mint Flavour 50 grams⁷	GF1908313: Al Fakher Mint Flavour 50 grams⁷
Package Type:	Box	Box
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Citrus with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) • Addition of complex purchased flavor (b) (4) 		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001104: Al Fakher Gum with Mint Flavour 50 grams⁷	GF1908313: Al Fakher Mint Flavour 50 grams⁷
Package Type:	Box	Box
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Gum with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) 		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001105: Al Fakher Gum with Mint Flavour 250 grams⁷	GF1908319: Al Fakher Mint Flavour 250 grams⁷
Package Type:	Box	Box
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Gum with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of complex purchased flavor (b) (4) 		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> Decreasing the quantity of (b) (4) Decreasing the quantity of complex purchased flavor (b) (4) 		
	EX0001106: Grape with Berry Flavour 50 grams⁷	GF1908333: Al Fakher Grape Flavour 50 Grams⁷
Package Type:	Box	Box
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Grape with Berry	Grape
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of complex purchased flavor (b) (4) 		
Increasing/Decreasing the quantity of existing tobacco additives:		
<ul style="list-style-type: none"> Decreasing the quantity of (b) (4) Decreasing the quantity of complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001107: Al Fakher Gum with Mint Flavour 1000 grams⁷	GF1908322: Al Fakher Mint Flavour 1Kg⁷
Package Type:	Box	Box
Package Quantity:	1 Kg	1 Kg
Characterizing Flavor:	Gum with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001108: Al Fakher Watermelon with Mint Flavour 1000 grams⁷	GF1908322: Al Fakher Mint Flavour 1Kg⁷
Package Type:	Box	Box
Package Quantity:	1 Kg	1 Kg
Characterizing Flavor:	Watermelon with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
<p>Modifications:</p> <p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001109: Al Fakher Watermelon with Mint Flavour 250 grams⁷	GF1908319: Al Fakher Mint Flavour 250 grams⁷
Package Type:	Box	Box
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Watermelon with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	11 mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) 		
Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 		
	EX0001110: Al Fakher Watermelon with Mint Flavour 50 grams⁷	GF1908313: Al Fakher Mint Flavour 50 grams⁷
Package Type:	Box	Box
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Watermelon with Mint	Mint
Tobacco Cut Size:	(b) (4) mm	(b) (4) mm
Additional Properties:	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Eligibility Status:	Not applicable	Grandfathered
Modifications:		
Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) 		
Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of 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