

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 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 <u>not</u> 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.

<sup>&</sup>lt;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>&</sup>lt;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: 2020.08.10 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

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

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

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

<sup>&</sup>lt;sup>6</sup> 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 REOs	
Date of Submission:	April 14, 2020	
Date of Receipt:	April 14, 2020	
Product Manufacturer:	• •	
Product Category:	Waterpipe Tobacco Products	
Product Sub-Category:	Waterpipe Tobacco Filler	
Trouble out of the service of the se	New Tobacco Product	Original Tobacco Product
	EX0001037: Al Fakher Apple Flavour	GF1908361: Al Fakher Apple Flavour
	1000 grams <sup>7</sup>	1Kg <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams <sup>8</sup>
Characterizing Flavor:	Apple	Apple
Eligibility Status:	N/A	Grandfathered
<b>Additional Properties:</b>	Tobacco Cut Size: mm	Tobacco Cut Size: mm
	Tobacco Moisture: 8 %	Tobacco Moisture: 8 %
• Addition of (b) (4)	in the complex purchased fla	vor <sup>(b) (4)</sup>
	EX0001040: Al Fakher Apple Flavour	GF1908359: Al Fakher Apple Flavour
	50 grams <sup>7</sup>	50 grams <sup>7</sup>
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 mm	Tobacco Cut Size mm
•		
·	Tobacco Moisture: 8 %	Tobacco Moisture: 2 %
Modifications:	Tobacco Moisture: 28 %	Tobacco Moisture: 8%
·	Tobacco Moisture: 28 %	Tobacco Moisture: 2 %
Modifications:	Tobacco Moisture: 28 %	

 $<sup>^{7}\ \</sup>text{Brand/sub-brand}$  or other commercial name used in commercial distribution.

 $<sup>^{\</sup>rm g}$  The package  $\,$  quantity was stated as 1 Kg, which was converted to 1000 grams.

	New Tobacco Product	Original Tobacco Product
	EX0001041: Al Fakher Apple	GF1908360: Al Fakher Apple
	Flavour 250 grams <sup>7</sup>	Flavour 250 grams <sup>7</sup>
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: mm	Tobacco Cut Size: 🖁 mm
	Tobacco Moisture: 🖁 %	Tobacco Moisture: 87%
Modifications:	<del></del>	
Addition/Deletion of tobacco	additives:	
<ul> <li>Deletion of (b) (4)</li> </ul>	in the complex purchased flavor (b) (4	))
	_	
<ul> <li>Addition of (b) (4)</li> </ul>	in the complex purchased flavor	0) (4)
<del></del>	EX0001045: Al Fakher Mango	GF1908321: Al Fakher
	Flavour 250 grams <sup>7</sup>	MangoFlavour 250 grams <sup>7</sup>
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: mm	Tobacco Cut Size mm
	Tobacco Moisture: 8 %	Tobacco Moisture: 8 %
Modifications:		
Addition/Deletion_oftobacco	additives:	
<ul> <li>Deletion of (b) (4)</li> </ul>	in the complex purchased flavor	
		0
Increase/Decrease in quantit	ry of existing additives:	
Increase/Decrease in quantity Increasing the quantity	ry of existing additives:	chased flavor <sup>(b) (4)</sup>
MILLIAN COLUMN TO THE STATE OF	ry of existing additives:	chased flavor <sup>(b) (4)</sup>
MILLIAN COLUMN TO THE STATE OF	y of existing additives: y of (b) (6) in the complex pure	ry GF1908306: Al Fakher Strawbe
MILLER COLUMN TO THE PARTY OF T	ry of existing additives: y of <sup>(0)(4)</sup> in the complex pure	
Increasing the quantity	y of existing additives: y of (b) (6) in the complex pure	ry GF1908306: Al Fakher Strawbe
MILLIAN COLUMN TO THE STATE OF	ey of existing additives:  y of of one of on	ry GF1908306: Al Fakher Strawbe Flavour 1Kg <sup>7</sup>
Increasing the quantity     Package Type:	ey of existing additives:  y of of one of on	Flavour 1Kg <sup>7</sup> Plastic Pouch
Increasing the quantity  Package Type:  Package Quantity:	ey of existing additives:  y of (b) (4) in the complex pure in the complex pure EX0001048: Al Fakher Strawber Flavour 1000 grams 7  Plastic Pouch 1000 grams	Flavour 1Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup>
Increasing the quantity  Package Type: Package Quantity: Characterizing Flavor:	ey of existing additives:  y of (10)(4)  in the complex pure  EX0001048: Al Fakher Strawber  Flavour 1000 grams  Plastic Pouch 1000 grams  Strawberry	Fry GF1908306: Al Fakher Strawbe Flavour 1Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup> Strawberry
• Increasing the quantity  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status:	EX0001048: Al Fakher Strawber Flavour 1000 grams Plastic Pouch 1000 grams Strawberry N/A	Fry GF1908306: Al Fakher Strawber Flavour 1Kg 7  Plastic Pouch 1000 grams8  Strawberry  Grandfathered
• Increasing the quantity  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status:	EX0001048: Al Fakher Strawber Flavour 1000 grams 7  Plastic Pouch 1000 grams Strawberry N/A Tobacco Cut Size: mm	Flavour 1Kg Teleprocess  Plastic Pouch 1000 grams Strawberry Grandfathered Tobacco Cut Size: mm
• Increasing the quantity  Package Type:  Package Quantity:  Characterizing Flavor:  Eligibility Status:  Additional Properties:	EX0001048: Al Fakher Strawber Flavour 1000 grams Plastic Pouch 1000 grams Strawberry N/A Tobacco Cut Size: mm Tobacco Moisture: 55	Flavour 1Kg Teleprocess  Plastic Pouch 1000 grams Strawberry Grandfathered Tobacco Cut Size: mm
• Increasing the quantity  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:  Modifications: Addition/Deletion of tobacco	EX0001048: Al Fakher Strawber Flavour 1000 grams  Plastic Pouch 1000 grams Strawberry N/A Tobacco Cut Size: mm Tobacco Moisture: 5%	Flavour 1Kg Teleprocess  Plastic Pouch 1000 grams Strawberry Grandfathered Tobacco Cut Size: mm
• Increasing the quantity  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:  Modifications: Addition/Deletion of tobacco	EX0001048: Al Fakher Strawber Flavour 1000 grams Plastic Pouch 1000 grams Strawberry N/A Tobacco Cut Size: mm Tobacco Moisture: 55	Flavour 1Kg Teleprocess  Plastic Pouch 1000 grams Strawberry Grandfathered Tobacco Cut Size: mm
• Increasing the quantity  Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:  Modifications: Addition/Deletion of tobacco	EX0001048: Al Fakher Strawber Flavour 1000 grams  Plastic Pouch 1000 grams Strawberry N/A Tobacco Cut Size: mm Tobacco Moisture: 5%	Plastic Pouch 1000 grams <sup>8</sup> Strawberry Grandfathered Tobacco Cut Size: mm Tobacco Moisture: %

	New Tobacco Product	Original Tobacco Product
	EX0001049: Al Fakher Strawber	ry GF1908308: Al Fakher Strawber
	Flavour 50 grams <sup>7</sup>	Flavour 50 grams <sup>7</sup>
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: mm	Tobacco Cut Size: mm
	Tobacco Moisture: 8%	Tobacco Moisture: 8 %
Modifications:		120-2-2
Addition/Deletion of tobacco	additives:	
•	le in the complex purchased flavor	4)
Deletion of acetaideny	le ili tile complex parchasea havor	
		FIS. 243
<ul> <li>Addition of propionalde</li> </ul>	hyde in the complex purchased flavo	r (4)
	20 00	
	EX0001050: Al Fakher Strawber	ry GF1908303: Al Fakher Strawbe
	Flavour 250 grams <sup>7</sup>	Flavour 250 grams <sup>7</sup>
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: mm	Tobacco Cut Size: mm
	Tobacco Moisture:	Tobacco Moisture: 8 %
Modifications:		
Addition/Deletion of tobacco	additives:	
<ul> <li>Deletion of (b) (4)</li> </ul>	in the complex purchased flavor	4)
<ul> <li>Addition of (b) (4)</li> </ul>	in the complex purchased flavo	r (b) (4)
Addition of (b) (4)	The complex parenased have	'
	EX0001053: Al Fakher Melon	GF1908324: Al Fakher Melon
	Flavour 250 grams <sup>7</sup>	Flavour 250 grams <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Melon	Melon
Eligibility Status:	N/A	Grandfathered
Additional Properties:	(6)	160
Additional Floperties.	The state of the s	
8.6 - 1151 - 11	Tobacco Moisture 8 %	Tobacco Moisture: 16 %
Modifications:	Contract Liber	
Increase/Decrease in quantity		(5) (4)
I am a manage at the second at the contract at	of in the complex pure	hased flavor
<ul> <li>Increasing the quantity</li> </ul>	in the complex part	
<ul> <li>Increasing the quantity</li> <li>Decreasing the quantity</li> </ul>		

	New Tobacco Product EX0001054: Al Fakher Melon Flavour 1000 grams 7	Original Tobacco Product  GF1908323: Al Fakher Melon Flavour 1 Kg <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams <sup>8</sup>
Characterizing Flavor:	Melon	Melon
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: mm	Tobacco Cut Size: mm
	Tobacco Moisture: 6 %	Tobacco Moisture: 8 %
Modifications		

### **Modifications:**

Increase/Decrease in quantity of existing additives:

Increasing the quantity of (5)(4) in the complex purchased flavor

Decreasing the quantity of (b) (4) in the complex purchased flavor (0)

		GF1908345: Al Fakher Cocktail
		Flavour 1 Kg <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams <sup>8</sup>
Characterizing Flavor:	Cocktail	Cocktail
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: mm	Tobacco Cut Size: mm
	Tobacco Moisture: 8 %	Tobacco Moisture: %

# **Modifications:**

Addition/Deletion of tobacco additives:

• Deletion of (b) (4) in the complex purchased flavor (b) (4)

Increase/Decrease in quantity of existing additives:

Increasing the quantity of (b)(4)
 in the complex purchased flavor (b)(4)

		GF1908325: Al Fakher Mango Flavour 1Kg <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams <sup>8</sup>
Characterizing Flavor:	Mango	Mango
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: mm	Tobacco Cut Size: mm
	Tobacco Moisture: 8 %	Tobacco Moisture: 8 %

# **Modifications:**

Addition/Deletion of tobacco additives:

Deletion of (b) (4) in the complex purchased flavor (b) (4)

Increase/Decrease in quantity of existing additives:

• Increasing the quantity of (b)(4) in the complex purchased flavor (b)(4)

	New Tobacco Product	Original Tobacco Product
	EX0001057: Al Fakher Cocktail	GF1908342: Al Fakher Cocktai
	Flavour 250 grams <sup>7</sup>	Flavour 250 grams <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Cocktail	Cocktail
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: mm	Tobacco Cut Size: mm
	Tobacco Moisture: 🖁 %	Tobacco Moisture: 2 %
Modifications:	<del></del>	10 m
Addition/Deletion of tobacco	additives:	
<ul> <li>Deletion of (b) (4)</li> </ul>	in the complex purchased flavor [6]	4)
	_	
Increase/Decrease in quantit	y of existing additives:	
<ul> <li>Increasing the quantity</li> </ul>	of of in the complex purch	ased flavor <sup>(b) (4)</sup>
	EX0001058: Al Fakher Two	GF1908301: Al Fakher Two
	Apples Flavour 250 grams <sup>7</sup>	Apples Flavour 250 grams <sup>7</sup>
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Two Apples	Two Apples
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: mm	Tobacco Cut Size: mm
	Tobacco Moisture: 🖁 %	Tobacco Moisture: 🖁 %
Modifications:		\$ <del>!</del>
Addition/Deletion of tobacco	additives:	
<ul> <li>Deletion of (b) (4)</li> </ul>	in the complex purchased flavor (b) (4	
<ul> <li>Addition of (b) (4)</li> </ul>	in the complex purchased flavor	
		CE100000E ALE II T
	EX0001059: Al Fakher Two	GF1908305: Al Fakher Two
	EX0001059: Al Fakher Two Apples Flavour 1000 grams <sup>7</sup>	Apples Flavour 1 Kg <sup>7</sup>
Package Type:		
Package Type: Package Quantity:	Apples Flavour 1000 grams <sup>7</sup>	Apples Flavour 1 Kg <sup>7</sup>
	Apples Flavour 1000 grams <sup>7</sup> Plastic Pouch	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch
Package Quantity:	Apples Flavour 1000 grams <sup>7</sup> Plastic Pouch 1000 grams	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup>
Package Quantity: Characterizing Flavor:	Apples Flavour 1000 grams <sup>7</sup> Plastic Pouch 1000 grams Two Apples	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup> Two Apples
Package Quantity: Characterizing Flavor: Eligibility Status:	Apples Flavour 1000 grams <sup>7</sup> Plastic Pouch 1000 grams Two Apples N/A	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup> Two Apples Grandfathered
Package Quantity: Characterizing Flavor: Eligibility Status:	Apples Flavour 1000 grams <sup>7</sup> Plastic Pouch 1000 grams Two Apples N/A Tobacco Cut Size: mm	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup> Two Apples Grandfathered Tobacco Cut Size: mm
Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties: Modifications:	Plastic Pouch 1000 grams Two Apples N/A Tobacco Cut Size: mm Tobacco Moisture: 69 %	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup> Two Apples Grandfathered Tobacco Cut Size: mm
Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:  Modifications: Addition/Deletion of tobacco	Apples Flavour 1000 grams 7  Plastic Pouch 1000 grams Two Apples N/A Tobacco Cut Size: 6 Tobacco Moisture: 6  additives:	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup> Two Apples Grandfathered Tobacco Cut Size: mm
Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:  Modifications: Addition/Deletion of tobacco	Plastic Pouch 1000 grams Two Apples N/A Tobacco Cut Size: mm Tobacco Moisture: 69 %	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup> Two Apples Grandfathered Tobacco Cut Size: mm
Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:  Modifications: Addition/Deletion of tobacco	Apples Flavour 1000 grams 7  Plastic Pouch 1000 grams Two Apples N/A Tobacco Cut Size: 6 Tobacco Moisture: 6  additives:	Apples Flavour 1 Kg <sup>7</sup> Plastic Pouch 1000 grams <sup>8</sup> Two Apples Grandfathered Tobacco Cut Size: mm

	New Tobacco Product	Original Tobacco Product
	EX0001060: Al Fakher Two Apples Flavour 50 grams <sup>7</sup>	GF1908302: Al Fakher Two Apples Flavour 50 grams <sup>7</sup>
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 mm	Tobacco Cut Size: mm
	Tobacco Moisture: # %	Tobacco Moisture: 8 %
Modifications:	25	37-73
Addition/Deletion of tobacco	additives:	
<ul> <li>Deletion of Deletion of Delet</li></ul>	in the complex purchased flavor	(4)
<ul> <li>Addition of (b) (4)</li> </ul>	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