

July 17, 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 <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.

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: 2020.07.17 13:27:34 -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

Common Attributes of EX REQs		
Date of Submission:		
Date of Receipt:	April 14, 2020	
Product Manufacturer:	·	
Product Category:	Waterpipe Tobacco Products	
Product Sub-Category:	Waterpipe Tobacco Filler	
	New Tobacco Product	Original Tobacco Product
	EX0001036: Al Fakher Apricot Flavour	GF1908358: Al Fakher Apricot Flavour
	1000 grams ⁷	1Kg ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams ⁸
Characterizing Flavor:	Apricot	Apricot
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco Cut Size: (6)(4)	Tobacco Cut Size:
	Tobacco Moisture: % % Tobacco Moisture: % %	
Modifications:		
Addition/Deletion of tol	pacco additives:	INVAN
Deletion of	in the complex purchased flavor	(0) (4)
Deletion of (b) (4)	in the complex purchased flavo	r ^{(D) (4)}
Addition of (b)	on of (b) (4) in the complex purchased flavor (b) (4)	
Addition of (b) (4)	Addition of (b) (4) in the complex purchased flavor (b) (4)	
Addition of in the complex purchased flavor (b) (4)		
Increase/Decrease in quantity of existing additives: • Increasing the quantity of (a) (a) (a) (b) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c		

 $^{^{7}}$ Brand/sub-brand or other commercial name used in commercial distribution.

 $^{^{8}\,\}text{The package}$ quantity was stated as 1 Kg, which was converted to 1000 grams.

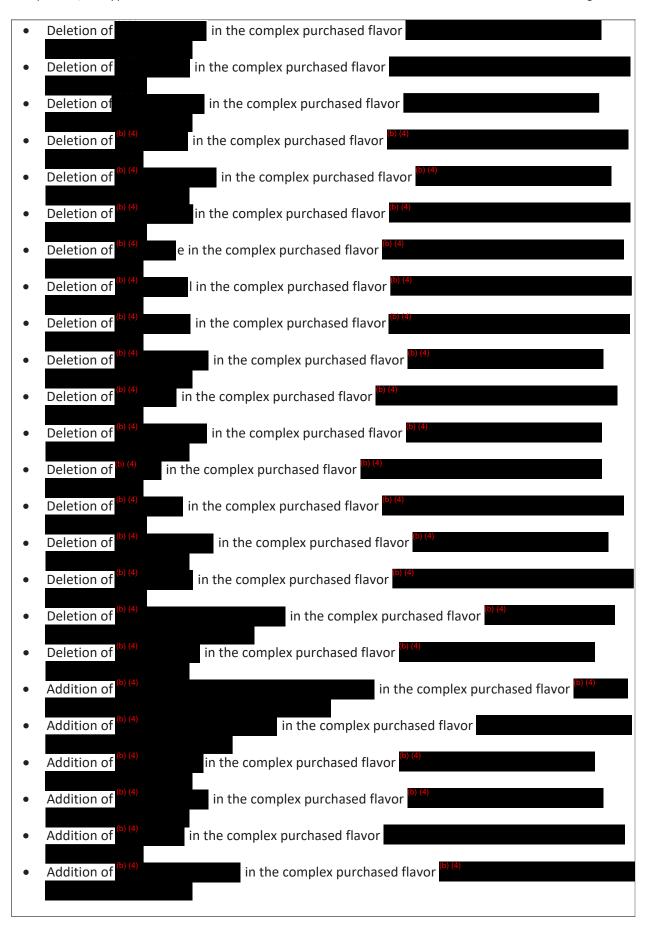
	New Tobacco Product	Original Tobacco Product
	EX0001038: Al Fakher Banana	GF1908354: Al Fakher Banana
	Flavour 250 grams ⁷	Flavour 250 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Banana	Banana
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: 🖁 %	Tobacco Moisture: 🖁 %
Modifications:	· 	 -
Addition/Deletion of tobacco	additives:	
 Deletion of (b) (4) 	in the complex purchased flavor	0) (4)
	, , , , , , , , , , , , , , , , , , , ,	
Increase/Decrease in quantit	v of existing additives:	
Increasing the quantit		chased flavor (b) (4)
- mereasing the qualities	in the complex put	chasca havor
 Increasing the quantit 	ry of ^{(b) (4)} in the complex pu	shased flavor (b) (4)
increasing the quantit	in the complex pul	chased havor
	EX0001039: Al Fakher Banana	GF1908357: Al Fakher Banana
	Flavour 1000 grams 7	Flavour 1Kg ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams ⁸
Characterizing Flavor:	Banana	Banana
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
Additional properties:		
	Tobacco Moisture %	Tobacco Moisture: 8 %
Modifications:		
Addition/Deletion of tobacco	6	
Deletion of D	in the complex purchased flavor	,
	9	
Increase/Decrease in quanti	ty of existing additives:	
THE RESERVE OF THE PROPERTY OF	of (in the complex purch	ased flavor (b) (4)
 Increasing the quantity 	01	
 Increasing the quantity 	or and somplement	
 Increasing the quantity Increasing the quantity 		(C. 1.4)

	New Tobacco Product	Original Tobacco Product
	EX0001042: Al Fakher Apricot	GF1908356: Al Fakher Apricot
	Flavour 50 grams ⁷	Flavour 50 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Apricot	Apricot
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (8) %	Tobacco Moisture: 6 %
Modifications:		
Addition/Deletion of tobacco	additives:	
 Deletion of (b) (4) 	in the complex purchased flavor (b) (4)	
 Deletion of (b) (4) 	in the complex purchased flavor (5) (4)	
 Addition of (b) (4) 	in the complex purchased flavor	4)
 Addition of (b) (4) 	in the complex purchased flavor	4)
	in the second se	
761/41	complex purchased flavor (b) (4)	
 Addition of in the 	complex parenasea haver	
• Addition of in the		
	of existing additives:	
Increase/Decrease in quantity	75.3 7.43	nurchased flavor
	75.3 7.43	purchased flavor
Increase/Decrease in quantity	in the complex	<u> </u>
Increase/Decrease in quantity	in the complex EX0001043: Al Fakher Apricot	GF1908355: Al Fakher Apricot
Increase/Decrease in quantity Increasing the quantity o	in the complex	<u> </u>
Increase/Decrease in quantity Increasing the quantity of the property of the p	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch
Increase/Decrease in quantity Increasing the quantity of the property of the p	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams 7 Plastic Pouch 250 grams	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams
Increase/Decrease in quantity Increasing the quantity of the property of the p	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch
Increase/Decrease in quantity Increasing the quantity of the property of the p	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot N/A	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered
Increase/Decrease in quantity Increasing the quantity of the property of the p	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size:	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: (1) (4)
Increase/Decrease in quantity of Increasing the quantity of Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties:	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot N/A	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered
Increase/Decrease in quantity Increasing the quantity of the properties of the prope	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (b) %	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: (1) (4)
Increase/Decrease in quantity Increasing the quantity of the properties: Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives:	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size:
Increase/Decrease in quantity Increasing the quantity of the properties: Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (b) %	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size:
Increase/Decrease in quantity Increasing the quantity of the properties: Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of tobacco	EX0001043: Al Fakher Apricot Flavour 250 grams Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives: in the complex purchased flavor	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size:
Increase/Decrease in quantity Increasing the quantity of the properties: Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco	in the complex EX0001043: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives:	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size:
Increase/Decrease in quantity Increasing the quantity of package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of package Quantity: Deletion of package Quantity: Deletion of package Type: Package Type: Package Quantity: Package Type: Package Quantity: Packa	EX0001043: Al Fakher Apricot Flavour 250 grams Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (b) % additives: in the complex purchased flavor (b) (4) in the complex purchased flavor (b) (4)	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size:
Increase/Decrease in quantity Increasing the quantity of package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of package in quantity of package in quantit	EX0001043: Al Fakher Apricot Flavour 250 grams Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives: in the complex purchased flavor	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size:
Increase/Decrease in quantity Increasing the quantity of package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of package Quantity: Output Deletion of package Quantity: Addition of package Quantity: Deletion of package Quantity: Deletion of package Quantity: Addition of package Quantity: Deletion of package Quantity: Addition	EX0001043: Al Fakher Apricot Flavour 250 grams Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives: in the complex purchased flavor in the complex purchased flavor in the complex purchased flavor (6) (4)	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size:
Increase/Decrease in quantity Increasing the quantity of package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of page 100 (4) Deletion of page 100 (4)	EX0001043: Al Fakher Apricot Flavour 250 grams Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (b) % additives: in the complex purchased flavor (b) (4) in the complex purchased flavor (b) (4)	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: (1) (4)
Increase/Decrease in quantity Increasing the quantity of package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of package Quantity: Output	EX0001043: Al Fakher Apricot Flavour 250 grams 7 Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives: in the complex purchased flavor	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: (1) (4)
Increase/Decrease in quantity Increasing the quantity of package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of package Quantity: Output Addition of package Quantity: Addition of package Quantity: Deletion of package Quantity: Addition	EX0001043: Al Fakher Apricot Flavour 250 grams Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives: in the complex purchased flavor in the complex purchased flavor in the complex purchased flavor (6) (4)	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: (1) (4)
Increase/Decrease in quantity Increasing the quantity of lineracing the quantity of lineracing the quantity of lineracing flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of lineracing flavor Deletion of lineracing flavor Addition of lineracing flavor Increase/Decrease in quantity of lineracing flavor Addition of lineracing flavor Increasing the quantity of lineracing flavor Addition of lineracing flavor Increasing the quantity of lineracing flavor Addition of lineracing flavor Increasing the quantity of lineracing flavor Addition of lineracing flavor Increase flavor Addition of lineracing flavor Increase flavor Addition of lineracing flavor Addition of lineracing flavor Addition of lineracing flavor Increase flavor Addition of lineracing flavor Increase flavor Increase flavor Increase flavor Addition of lineracing flavor Increase flavor	EX0001043: Al Fakher Apricot Flavour 250 grams Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (b) % additives: in the complex purchased flavor complex purchased flavor in the complex purchased flavor complex purchased flavor (b)(4)	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: (1) (4)
Increase/Decrease in quantity Increasing the quantity of lineracing the quantity of lineracing flavor: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of lineracing flavor Addition of lineracing flavor Increase/Decrease in quantity	EX0001043: Al Fakher Apricot Flavour 250 grams 7 Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives: in the complex purchased flavor complex purchased flavor of existing additives:	GF1908355: Al Fakher Apricot Flavour 250 grams Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: Tobacco Moisture: (1) %
Increase/Decrease in quantity Increasing the quantity of package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco Deletion of package Quantity: Output	EX0001043: Al Fakher Apricot Flavour 250 grams 7 Plastic Pouch 250 grams Apricot N/A Tobacco Cut Size: Tobacco Moisture: (6) % additives: in the complex purchased flavor complex purchased flavor of existing additives:	GF1908355: Al Fakher Apricot Flavour 250 grams ⁷ Plastic Pouch 250 grams Apricot Grandfathered Tobacco Cut Size: (1) (4)

	New Tobacco Product	Original Tobacco Product
	EX0001044: Al Fakher Banana	GF1908352: Al Fakher Banana
	Flavour 50 grams ⁷	Flavour 50 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 grams	50 grams
Characterizing Flavor:	Banana	Banana
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size:	Tobacco Cut Size:
	Tobacco Moisture: 7 %	Tobacco Moisture: 7 %
Modifications:		
Addition/Deletion of tobacco add	itives:	
Deletion of (b) (4) in	the complex purchased flavor (6) (4)	
Increase/Decrease in quantity of	existing additives:	
 Increasing the quantity of 	in the complex purcha	sed flavor (b) (4)
 Increasing the quantity of 	in the complex purcha	ased flavor (b) (4)
9 , ,		
	EX0001046: Al Fakher Rose	GF1908307: Al Fakher Rose
	Flavour 250 grams 7	Flavour 250 grams ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	250 grams	250 grams
Characterizing Flavor:	Rose	Rose
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: 8 %	Tobacco Moisture: 🖁 %
Modifications:		·
Addition/Deletion of tobacco add	litives:	
Deletion of (b) (4) in	the complex purchased flavor (b) (4)	
• Deletion of (b) (4)	the complex purchased flavor (b) (4)	
• Addition of (b) (4) in the	e complex purchased flavor ^{(b) (4)}	
Increase/Decrease in quantity of	existing additives:	
Increasing the quantity of		ourchased flavor (b) (4)
• Increasing the quantity of the complex purchased flavor to the complex purchased flavor		
Increasing the guantity of	in the complex results	od flavor (b) (4)
• Increasing the quantity of (1)(4) in the complex purchased flavor (1)(4)		

	New Tobacco Product	Original Tobacco Product			
	EX0001047: Al Fakher Rose	GF1908312: Al Fakher Rose			
	Flavour 50 grams ⁷	Flavour 50 grams 7			
Package Type:	Plastic Pouch	Plastic Pouch			
Package Quantity:	50 grams	50 grams			
Characterizing Flavor:	Rose	Rose			
Eligibility Status:	N/A	Grandfathered			
Additional properties:	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)			
	Tobacco Moisture: 2 %	Tobacco Moisture: 6 %			
Modifications:					
Addition/Deletion of tobacco add	itives:				
	the complex purchased flavor (6) (4)				
Deletion of (b) (4) in to	the complex purchased flavor (b) (4)				
• Addition of (b) (4) in the	e complex purchased flavor (b) (4)				
Increase/Decrease in quantity of	existing additives:				
 Increasing the quantity of 	in the complex p	ourchased flavor ^{(b) (4)}			
9 1 7					
• Increasing the quantity of in the complex purchased flavor					
- Increasing the qualitity Of	word of the state				
increasing the qualitity of	otto cottapion p ai citae				
- moreasing the quantity of	EX0001051: Al Fakher Rose	GF1908311: Al Fakher Rose			
increasing the quantity of					
Package Type:	EX0001051: Al Fakher Rose	GF1908311: Al Fakher Rose			
	EX0001051: Al Fakher Rose Flavour 1000 grams ⁷	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷			
Package Type:	EX0001051: Al Fakher Rose Flavour 1000 grams ⁷ Plastic Pouch	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch			
Package Type: Package Quantity:	EX0001051: Al Fakher Rose Flavour 1000 grams ⁷ Plastic Pouch 1000 grams	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸			
Package Type: Package Quantity: Characterizing Flavor:	EX0001051: Al Fakher Rose Flavour 1000 grams ⁷ Plastic Pouch 1000 grams Rose	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status:	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status:	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: [6)(4)	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (4)	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (4)	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: Tobacco Moisture: (b) (4) %	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add • Deletion of	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: Tobacco Moisture: (b) (4) %	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add • Deletion of	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) % itives: the complex purchased flavor	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add Deletion of Deletion of tobacco add Deletion of Deletion of tobacco add	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (b) % itives: the complex purchased flavor	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add Deletion of Deletion of tobacco add Deletion of Deletion of tobacco add	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: Tobacco Moisture: (b) (4) itives: the complex purchased flavor (b) (4) the complex purchased flavor	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add Deletion of Deletion of tobacco add Deletion of Deletion of tobacco add	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: Tobacco Moisture: (b) (4) (c) (4) the complex purchased flavor (b) (4) ce complex purchased flavor (c) (4)	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add Deletion of (b) (4) in the	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: Tobacco Moisture: (b) (4) (itives: the complex purchased flavor (b) (4) e complex purchased flavor (b) (4) existing additives:	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size:			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add Deletion of (0) (4) in the continuous in the	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: Tobacco Moisture: (b) (4) (itives: the complex purchased flavor (b) (4) e complex purchased flavor (b) (4) existing additives:	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size: Tobacco Moisture: (1) %			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add Deletion of (0) (4) in the continuous in the	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: Tobacco Moisture: (b) (4) (itives: the complex purchased flavor (b) (4) e complex purchased flavor (b) (4) existing additives:	GF1908311: Al Fakher Rose Flavour 1 Kg 7 Plastic Pouch 1000 grams 8 Rose Grandfathered Tobacco Cut Size: (b) (4) Tobacco Moisture: (4) %			
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional properties: Modifications: Addition/Deletion of tobacco add Deletion of in in the in the interest of interest	EX0001051: Al Fakher Rose Flavour 1000 grams Plastic Pouch 1000 grams Rose N/A Tobacco Cut Size: (b) (4) Tobacco Moisture: (4) % itives: the complex purchased flavor (b) (4) the complex purchased flavor (c) (4) existing additives: (d) in the complex purchased	GF1908311: Al Fakher Rose Flavour 1 Kg ⁷ Plastic Pouch 1000 grams ⁸ Rose Grandfathered Tobacco Cut Size: Tobacco Moisture: (6) %			

	New Tobacco Product	Original Tobacco Product
	EX0001052: Al Fakher Plum	GF1908316: Al Fakher Plum
	Flavour 1000 grams ⁷	Flavour 1 Kg ⁷
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	1000 grams	1000 grams ⁸
Characterizing Flavor:	Plum	Plum
Eligibility Status:	N/A	Grandfathered
Additional properties:	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture 🖁 %	Tobacco Moisture: 8 %
Modifications:		
Addition/Deletion of tobacco ad	ditives:	
Deletion of (b) (4) in	the complex purchased flavor (b) (4)	
		7 . 202245
Deletion of (b) (4)	in the complex purchased	flavor (b) (4)
Deletion of b)(4) in the complex purchased flavor (b)(4)		
	1 CONTROL OF THE STATE OF THE S	
Deletion of (b) (4) in th	e complex purchased flavor (0)(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