



July 08, 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 REQ¹s 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,
Todd L. Cecil, Ph.D.
Deputy Director for Regulatory Management
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:	November 19, 2020	
Date of Receipt:	November 19, 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
	EX0001353-PD1: Al Fakher Magic Love Flavour 50 grams⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams⁷
Package Type:	Polypropylene Pouch	Plastic Pouch
Package Quantity:	50 grams (g)	50 g
Characterizing Flavor:	Magic Love	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	10%	10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4)” (Symrise AG) • Addition of complex purchased flavor (b) (4)” (Hertz Flavors) • Deletion of complex purchased flavor “(b) (4)” (Hertz Flavors GmbH & Co. KG) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001354-PD1: Al Fakher Pina Colada Flavour 50 grams⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams⁷
Package Type:	Polypropylene Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Pina Colada	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4)” • Deletion of complex purchased flavor “(b) (4)” ((b) (4)) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

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

	New Tobacco Product	Original Tobacco Product
	EX0001355-PD1: Al Fakher Magic Love Flavour 1000 grams ⁷	GF1908306: Al Fakher Strawberry Flavour 1Kg ⁷
Package Type:	Polyethylene Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kilogram (Kg)
Characterizing Flavor:	Magic Love	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4) (b) (4)) • Addition of complex purchased flavor “(b) (4) (b) (4)) • Deletion of complex purchased flavor “(b) (4) (b) (4)) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001356-PD1: Al Fakher Super Lemon Mint Flavour 250 grams ⁷	GF1908303: Al Fakher Strawberry Flavour 250 grams ⁷
Package Type:	Polyethylene Pouch	Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Super Lemon Mint	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) “ (b) (4)) • Addition of complex purchased flavor “(b) (4) (b) (4)) • Addition of complex purchased flavor “(b) (4) (b) (4)) • Deletion of complex purchased flavor “(b) (4) (b) (4)) • Deletion of FD&C (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001357-PD1: Al Fakher Super Lemon Mint Flavour 50 grams⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams⁷
Package Type:	Polypropylene Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Super Lemon Mint	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4) ” (b) (4)) • Addition of complex purchased flavor “(b) (4) ” (b) (4)) • Addition of complex purchased flavor “(b) (4) ” (b) (4)) • Deletion of complex purchased flavor “(b) (4) ” (b) (4)) • Deletion of FD&C (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001358-PD1: Al Fakher Super Lemon Mint Flavour 1000 grams⁷	GF1908306: Al Fakher Strawberry Flavour 1 Kg⁷
Package Type:	Polyethylene Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Super Lemon Mint	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) ” (b) (4)) • Addition of complex purchased flavor (b) (4) ” (b) (4)) • Addition of complex purchased flavor (b) (4) ” (b) (4)) • Deletion of complex purchased flavor “(b) (4) ” (b) (4)) • Deletion of FD&C (b) (4) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001359-PD1: Al Fakher Pina Colada Flavour 250 grams ⁷	GF1908303: Al Fakher Strawberry Flavour 250 grams ⁷
Package Type:	Polyethylene Pouch	Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Pina Colada	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of complex purchased flavor “(b) (4)” Deletion of complex purchased flavor “(b) (4)” (Hertz Flavors GmbH & Co. KG) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001360-PD1: Al Fakher Pina Colada Flavour 1000 grams ⁷	GF1908306: Al Fakher Strawberry Flavour 1 Kg ⁷
Package Type:	Polyethylene Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Pina Colada	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of complex purchased flavor “(b) (4)” Deletion of complex purchased flavor “(b) (4)” ((b) (4)) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001361-PD1: Al Fakher Sweet Passion Fruit Flavour 50 grams ⁷	GF1908308: Al Fakher Strawberry Flavour 50 grams ⁷
Package Type:	Polypropylene Pouch	Plastic Pouch
Package Quantity:	50 g	50 g
Characterizing Flavor:	Sweet Passion Fruit	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> Addition of complex purchased flavor “(b) (4)” ((b) (4)) Deletion of complex purchased flavor “(b) (4)” ((b) (4)) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001362-PD1: Al Fakher Sweet Passion Fruit Flavour 1000 grams ⁷	GF1908306: Al Fakher Strawberry Flavour 1 Kg ⁷
Package Type:	Polyethylene Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Sweet Passion Fruit	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4) ” (b) (4)) • Deletion of complex purchased flavor “(b) (4) ” (b) (4)) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		
	New Tobacco Product	Original Tobacco Product
	EX0001363-PD1: Al Fakher Sweet Passion Fruit Flavour 250 grams ⁷	GF1908303: Al Fakher Strawberry Flavour 250 grams ⁷
Package Type:	Polyethylene Pouch	Plastic Pouch
Package Quantity:	250 g	250 g
Characterizing Flavor:	Sweet Passion Fruit	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	10%	10%
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) ” (b) (4)) • Deletion of complex purchased flavor “(b) (4) ” (b) (4)) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		

	New Tobacco Product	Original Tobacco Product
	EX0001364-PD1: Al Fakher Iced Raspberry Mint Flavour 1000 grams ⁷	GF1908306: Al Fakher Strawberry Flavour 1 Kg ⁷
Package Type:	Polyethylene Pouch	Plastic Pouch
Package Quantity:	1000 g	1 Kg
Characterizing Flavor:	Iced Raspberry Mint	Strawberry
Eligibility Status:	Not applicable	Grandfathered
Tobacco cut size:	(b) mm	(b) mm
Tobacco moisture:	(b) %	(b) %
Modifications:		
Addition/Deletion of tobacco additives:		
<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) " (b) (4)) • Addition of complex purchased flavor " (b) (4) " (b) (4)) • Addition of complex purchased flavor (b) (4) " (b) (4)) • Addition of complex purchased flavor " (b) (4) " (b) (4)) • Deletion of complex purchased flavor " (b) (4) " (b) (4)) 		
Increase/Decrease in quantity of existing additives:		
<ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 		