

February 18, 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 -
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Date: 2021.02.18 10:41:09 -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 A⁷

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 Applicant:	Al Fakher Distribution USA Inc.	
Product Manufacturer:	Al Fakher Tobacco Factory, F.Z.E., UAE	
Product Category:	Waterpipe Tobacco Products	
Product Sub-Category:	Waterpipe Tobacco Filler	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001096	GF1908322
Product Name	Al Fakher Blueberry with Mint Flavour 1000 grams	Al Fakher Mint Flavour 1Kg
Eligibility Status	Not Applicable	Grandfathered
Marketing Authorization Date	Not Applicable	Not Applicable
Abbreviated report date	Not applicable	Not Applicable
Package Type⁸	Pouch	Pouch
Package Quantity	1 Kg	1 Kg
Characterizing Flavor	Blueberry with Mint	Mint
Additional property	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)
Product Modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decrease in the quantity of (b)(4) • (b)(4) • Decrease in the quantity of (b)(4) 	

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

⁸ Polyethylene

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001097	GF1908319
Product name	Al Fakher Blueberry with Mint Flavour 250 grams	Al Fakher Mint Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type ⁸	Pouch	Pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Blueberry with Mint	Mint
Additional property	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decrease in the quantity of (b)(4) • Decrease in the quantity of (b)(4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001100	GF1908313
Product name	Al Fakher Blueberry with Mint Flavour 50 grams	Al Fakher Mint Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type ⁸	Pouch	Pouch
Package quantity	50 grams	50 grams
Characterizing flavor	Blueberry with Mint	Mint
Additional property	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of (b)(4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decrease in the quantity of (b)(4) • Decrease in the quantity of (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