



July 15, 2021

**EXEMPT**

Al Fakher Distribution USA, Inc.  
Attention: Bryan Haynes, Counsel  
Troutman Pepper Hamilton 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 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 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.

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<sup>1</sup> Request 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>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](mailto:Kathryn.Mueller@fda.hhs.gov).

Sincerely,

Digitally signed by Todd L. Cecil -S  
Date: 2021.07.15 16:52:55 -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

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<sup>3</sup> For more information about CTP Portal, see

<https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal>

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

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

<sup>6</sup> <https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp/contact-ctp>

Appendix A<sup>7</sup>

## New and Corresponding Original Tobacco Products Subject of This Letter

Common Attributes		
Submission date	November 19, 2020	
Receipt date	November 19, 2020	
Applicant	Al Fakher Distribution USA, Inc.	
Product manufacturer	Al Fakher Distribution USA, Inc.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001329-PD1	GF1908303
Product name	Al Fakher Blueberry Vanilla Ice Cream Flavour 250 grams	Al Fakher Strawberry Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Blueberry Vanilla Ice Cream	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of Blueberry Ice Cream flavor (b) (4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	

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

Attributes	New Product	Original Product
STN	EX0001330-PD1	GF1908308
Product name	Al Fakher Earl Grey Tea Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polypropylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Earl Grey Tea	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	
Attributes	New Product	Original Product
STN	EX0001331-PD1	GF1908306
Product name	Al Fakher Blueberry Vanilla Ice Cream Flavour 1000 grams	Al Fakher Strawberry Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Blueberry Vanilla Ice Cream	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of Blueberry Ice Cream flavor (b) (4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	

Attributes	New Product	Original Product
STN	EX0001332-PD1	GF1908308
Product name	Al Fakher Blueberry Vanilla Ice Cream Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polypropylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Blueberry Vanilla Ice Cream	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of Blueberry Ice Cream flavor (b) (4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	
Attributes	New Product	Original Product
STN	EX0001333-PD1	GF1908303
Product name	Al Fakher Earl Grey Tea Flavour 250 grams	Al Fakher Strawberry Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Earl Grey Tea	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor ((b) (4) .)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	

Attributes	New Product	Original Product
STN	EX0001334-PD1	GF1908306
Product name	Al Fakher Earl Grey Tea Flavour 1000 grams	Al Fakher Strawberry Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Earl Grey Tea	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	
Attributes	New Product	Original Product
STN	EX0001335-PD1	GF1908308
Product name	Al Fakher Frosty Mint Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polypropylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Frosty Mint	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	

Attributes	New Product	Original Product
STN	EX0001339-PD1	GF1908308
Product name	Al Fakher Frosty Two Apples Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polypropylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Frosty Two Apples	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	
Attributes	New Product	Original Product
STN	EX0001340-PD1	GF1908306
Product name	Al Fakher Frosty Mint Flavour 1000 grams	Al Fakher Strawberry Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Frosty Mint	Strawberry
Additional property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
	Tobacco moisture: (b) (4) %	Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> <li>• Addition of (b) (4) flavor (b) (4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	

**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