

August 16, 2022

**EXEMPT**

AIR Distribution USA Inc.  
Attention: Bryan M. Haynes, U.S. Agent  
Troutman Pepper Hamilton Sanders LLP  
1001 Haxall Point  
Richmond, VA 23219

**FDA Submission Tracking Numbers (STNs):** Multiple STNs, see Appendix A

Dear Bryan 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 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>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>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 Noor Dawood, Regulatory Health Project Manager, at (240) 402-8048 or [Noor-UI-Huda.Dawood@fda.hhs.gov](mailto:Noor-UI-Huda.Dawood@fda.hhs.gov).

Sincerely,

Todd L.  
Cecil -S

Digitally signed by  
Todd L. Cecil -S  
Date: 2022.08.16  
09:45:50 -04'00'

Todd L. Cecil, Ph.D.  
Acting 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>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>7,8</sup>**  
**New and Corresponding Original Tobacco Products Subject of This Letter**

Common Attributes		
Submission Date	July 26, 2021	
Receipt Date	July 26, 2021	
Applicant	AIR Distribution USA Inc.	
Product Manufacturer	Al Fakher Tobacco Factory, F.Z.E.	
Product Category	Waterpipe	
Product Subcategory	Waterpipe Tobacco Filler	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002185	GF1908308
Static Product ID	PD1	Not applicable (N/A)
Product Name	Al Fakher Magic Love Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
Package Type	Polypropylene pouch	Plastic pouch
Package Quantity	50 grams (g)	50 g
Characterizing Flavor	Magic Love	Strawberry
Eligibility Status	N/A	Grandfathered
Tobacco Cut Size	11 millimeters (mm)	11 mm
Tobacco Moisture	10%	10%
Product Modifications	Addition/ Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> </ul> Increasing the quantity of existing tobacco additive: <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.

<sup>8</sup> As provided by the applicant. For purposes of an EX REQ, a numerical value is not necessary as the tobacco itself cannot be modified as the exemption is limited to additives.

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0002186	GF1908306
Static Product ID	PD1	N/A
Product Name	Al Fakher Magic Love Flavour 1000 grams	Al Fakher Strawberry Flavour 1 Kg
Package Type	Polyethylene pouch	Plastic pouch
Package Quantity	1000 g	1 Kilogram <sup>9</sup> (kg)
Characterizing Flavor	Magic Love	Strawberry
Eligibility status	N/A	Grandfathered
Tobacco Cut Size	11 mm	11 mm
Tobacco Moisture	10%	10%
Product Modifications	Addition/ Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> </ul> Increasing the quantity of existing tobacco additive: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	
STN	EX0002187	GF1908303
Static Product ID	PD1	N/A
Product Name	Al Fakher Magic Love Flavour 250 grams	Al Fakher Strawberry Flavour 250 grams
Package Type	Polyethylene pouch	Plastic pouch
Package Quantity	250 g	250 g
Characterizing Flavor	Magic Love	Strawberry
Eligibility status	N/A	Grandfathered
Tobacco Cut Size	11 mm	11 mm
Tobacco Moisture	10%	10%
Product Modifications	Addition/ Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> </ul> Increasing the quantity of existing tobacco additive: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	

<sup>9</sup> 1 Kilogram = 1000 grams

**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