



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

June 30, 2020

SUBSTANTIALLY EQUIVALENT

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 our review of your SE Reports¹ and determined that the new tobacco products are substantially equivalent to the corresponding predicate tobacco products listed in Appendix A and are in compliance with the requirements of the FD&C Act. Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce or deliver for introduction into interstate commerce the new tobacco products subject of this letter.

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).

For information on how to fulfill the provisions of section 910(a)(4) of the FD&C Act, refer to Appendix B.

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 complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

¹ Substantially Equivalent (SE) Reports submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

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: 2020.06.30 16:55:40 -04'00'

Matthew R. Holman, Ph.D.

Director

Office of Science

Center for Tobacco Products

Enclosures:

Appendix A – New and Corresponding Predicate Tobacco Products Subject of This Letter

Appendix B – Health Information Summary

Appendix A
New and Corresponding Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Reports		
Date of Submission:	February 7, 2020	
Date of Receipt:	February 7, 2020	
Product Manufacturer:	Al Fakher Distribution USA, Inc.	
Product Category:	Waterpipe Tobacco Products	
Product Sub-Category:	Waterpipe Tobacco Filler	
	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
	SE0015696: Al Fakher Melon Flavour 50 grams ²	GF1908324: Al Fakher Melon Flavour 250 grams ²
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	250 grams
Characterizing Flavor:	Melon	Melon
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco moisture: 10%	Tobacco moisture: 10%
	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	SE0015697: Al Fakher Pineapple Flavour 50 grams ²	GF1908317: Al Fakher Pineapple Flavour 250 grams ²
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	250 g
Characterizing Flavor:	Pineapple	Pineapple
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco moisture: 10%	Tobacco moisture: 10%
	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	SE0015698: Al Fakher Coconut Flavour 50 grams ²	GF1908343: Al Fakher Coconut Flavour 250 grams ²
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	250 g
Characterizing Flavor:	Coconut	Coconut
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco moisture: 10%	Tobacco moisture: 10%
	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	SE0015699: Al Fakher Mango Flavour 50 grams ²	GF1908321: Al Fakher Mango Flavour 250 grams ²
Package Type:	Plastic Pouch	Plastic Pouch
Package Quantity:	50 g	250 g
Characterizing Flavor:	Mango	Mango
Eligibility Status:	N/A	Grandfathered
Additional Properties:	Tobacco moisture: 10%	Tobacco moisture: 10%
	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)

² Properties to uniquely identify the new and predicate tobacco products were provided by the applicant as of the date of this letter, and not confirmed by FDA. Upon scientific review, the unique identification may be revised.

	New Tobacco Product Specific Attributes	Predicate Tobacco Product Specific Attributes
	SE0015700: Al Fakher Plum Flavour 50 grams ²	GF1908310: Al Fakher Plum Flavour 250 grams ²
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:	Plastic Pouch 50 g Plum N/A Tobacco moisture: 10% Tobacco Cut Size: (b) (4)	Plastic Pouch 250 g Plum Grandfathered Tobacco moisture: 10% Tobacco Cut Size: (b) (4)
	SE0015701: Al Fakher Cocktail Flavour 50 grams ²	GF1908342: Al Fakher Cocktail Flavour 250 grams ²
Package Type: Package Quantity: Characterizing Flavor: Eligibility Status: Additional Properties:	Plastic Pouch 50 g Cocktail N/A Tobacco moisture: 10% Tobacco Cut Size: (b) (4)	Plastic Pouch 250 g Cocktail Grandfathered Tobacco moisture: 10% Tobacco Cut Size: (b) (4)

Appendix B

Health Information Summary

Your SE Reports did not provide a summary of any health information related to the new tobacco products, required by section 910(a)(4) of the FD&C Act; however, your SE Reports stated that such information will be available upon request to any person. Consistent with the requirements of section 910(a)(4), you may wish to consider providing the following when information is requested:

- A. A copy of your final SE Reports upon which the Substantially Equivalent order was based, redacted only to the extent necessary to exclude patient identifiers and trade secret and confidential commercial information as defined in 21 CFR 20.61 and 20.63.
- B. Any research or data you have in your possession or otherwise know of specifically regarding the adverse health effects of the new tobacco products, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

Alternatively, you may provide the following when information is requested:

- Description of the new tobacco products
- Description of the predicate tobacco products
- List of all differences in characteristics between the new and predicate tobacco products
- Summary of the evidence and scientific rationale concerning why the differences in characteristics do not raise different questions of public health
- Any research or data you have in your possession or otherwise know of regarding the adverse health effects of the new tobacco product, or the following statement if such statement is accurate: “[Insert manufacturer name] does not have or know of any research or data regarding any adverse health effects specifically related to [insert tobacco product name].”

There may be other accurate, complete, and not false or misleading ways to satisfy the requirements of section 910(a)(4) not included above. If you wish to discuss other ways to meet the requirements of section 910(a)(4), submit a meeting request to us