

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001144, EX0001152, EX0001164, EX0001169, EX0001173, and EX0001176 – EX0001185
Common Attributes	
Submission date	June 12, 2020 ¹ or June 22, 2020 ²
Receipt date	June 12, 2020 ¹ or June 22, 2020 ²
Applicant	Al Fakher Distribution USA, Inc.
Product manufacturer	Al Fakher Distribution USA, Inc.
Product category	Waterpipe Tobacco Products
Product subcategory	Waterpipe Tobacco Filler
Cross-Referenced Submissions	
All EX Requests	None
Supporting FDA Memoranda Relied Upon in this Review	
All EX Requests	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Matthew J. Walters -S3
Date: 2020.12.07 10:37:04 -05'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Division Director
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2020.12.07 10:56:12 -05'00'

Todd L. Cecil, Ph.D.
Deputy Director
Office of Science

¹ EX0001144, EX0001152, EX0001164, EX0001169, and EX0001173

² EX0001176 – EX0001185

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1. BACKGROUND

1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

The applicant submitted information for the new and original tobacco products listed in detail in the Appendix.

1.2. REGULATORY ACTIVITY

See appendices for tobacco products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1: Reviewers	Review Date
regulatory	Kathryn Mueller	6/18/2020 ³ and 6/26/2020 ⁴
	Ranjeeta Gupta	6/19/2020 ⁵
chemistry	Sandra Salido	11/17/2020
environmental science	Thomas Creaven	11/10/2020

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE review dated November 18, 2020, concludes that the evidence submitted by the applicant is adequate to demonstrate original tobacco products are grandfathered products. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.⁶

3. TOBACCO ADDITIVE MODIFICATION

The applicant claims that the modifications of the original tobacco products compared to the corresponding new tobacco products are the result of:

- deleting an additive (complex ingredient (b) (4)) in all EX Requests
- adding an additive (complex ingredient (b) (4)) in EX0001144
- adding additives (complex ingredients (b) (4) and (b) (4)) in EX0001152

³ EX0001144 and EX0001152

⁴ EX0001176 – EX0001185

⁵ EX0001164, EX0001169, and EX0001173

⁶ Any tobacco product that can be sold under the FD&C Act (e.g., legally marketed in the United States) is eligible for modification under the Exemption Request pathway.

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001178	GF1908303
Product name	Al Fakher AF 24 Flavour 250 grams ¹	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	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Mango Peach	Strawberry
Additional properties	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"> Deletion of complex ingredient (b) (4) (b) (4) Addition of complex ingredient (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increase in the quantity of (b) (4) 	
STN	EX0001179	GF1908303
Product name	Al Fakher AF 04 Flavour 250 grams ¹	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	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Apple with Mint	Strawberry
Additional properties	Tobacco Cut Size: 11 mm	Tobacco Cut Size: 11 mm
	Tobacco Moisture: 10%	Tobacco Moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of complex ingredient (b) (4) (b) (4) Addition of complex ingredient (b) (4) Inc.) Addition of complex ingredient (b) (4) (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increase in the quantity of (b) (4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001180	GF1908303
Product name	Al Fakher AF 22 Flavour 250 grams ¹	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	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Lime	Strawberry
Additional properties	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"> • Deletion of complex ingredient (b) (4) • Addition of complex ingredient (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	
STN	EX0001181	GF1908303
Product name	Al Fakher AF 05 Flavour 250 grams ¹	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	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Mint	Strawberry
Additional properties	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"> • Deletion of complex ingredient (b) (4) • Addition of complex ingredient (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001182	GF1908303
Product name	Al Fakher AF 03 Flavour 250 grams ¹	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	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Lime	Strawberry
Additional properties	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"> Deletion of complex ingredient (b) (4) (b) (4) Addition of complex ingredient (b) (4) (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increase in the quantity of (b) (4) 	
STN	EX0001183	GF1908303
Product name	Al Fakher AF 86 Flavour 250 grams ¹	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	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Cocktail	Strawberry
Additional properties	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"> Deletion of complex ingredient (b) (4) (b) (4) Addition of complex ingredient (b) (4) (b) (4) Addition of complex ingredient (b) (4) (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increase in the quantity of (b) (4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001184	GF1908303
Product name	Al Fakher AF 66 Flavour 250 grams ¹	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	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Peach	Strawberry
Additional properties	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"> Deletion of complex ingredient (b) (4) (b) (4) Addition of complex ingredient (b) (4) (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increase in the quantity of (b) (4) 	
STN	EX0001185	GF1908303
Product name	Al Fakher AF 51 Flavour 250 grams ¹	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	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Mango	Strawberry
Additional properties	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"> Deletion of complex ingredient (b) (4) (b) (4) Addition of complex ingredient (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increase in the quantity of (b) (4) 	

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications Being Amended	Reviewed	Status	Brief Description
November 3, 2020	November 3, 2020	EX0001317	All EX Requests	Yes	Active	Response to October 29, 2020, FDA Information Request. The amendment was reviewed by OCE during GF review.