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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.

- adding additives (complex ingredients (b) (4) and (b) (4)) in EX0001164
- adding an additive (complex ingredient (b) (4)) in EX0001169
- adding an additive (complex ingredient (b) (4)) in EX0001173
- adding an additive (complex ingredient (b) (4)) in EX0001176
- adding an additive (complex ingredient (b) (4)) in EX0001177
- adding an additive (complex ingredient (b) (4)) in EX0001178
- adding additives (complex ingredients (b) (4) and (b) (4)) in EX0001179
- adding an additive (complex ingredient (b) (4)) in EX0001180 and EX0001183
- adding an additive (complex ingredient (b) (4)) in EX0001181
- adding an additive (complex ingredient (b) (4)) in EX0001182
- adding an additive (complex ingredient (b) (4)) in EX0001183
- adding an additive (complex ingredient (b) (4)) in EX0001184
- adding an additive (complex ingredient (b) (4)) in EX0001185
- increasing the quantity of an existing additive (b) (4) in all EX Requests

4. SCIENTIFIC REVIEW

The review finds these modified ingredients (see Section 3) are additives because their intended use may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of the tobacco products. The review concludes that the modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on November 16, 2020. The FONSI was supported by an environmental assessment prepared by FDA on November 16, 2020.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are a minor modification of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. I concur that the modified ingredients are “additives” as defined in section 900(1) of the FD&C Act. In addition, it is my conclusion that, consistent with section 905(j)(3)(A)(ii) of the FD&C Act, an SE Report is not necessary to ensure that permitting the new tobacco products to be marketed would be appropriate for the protection of the public health. I also concur with the scientific review that the changes represent adding or deleting tobacco additives and increasing the quantity of an existing additive for all EX Requests. For all EX Requests, the complex ingredient (b) (4) is deleted from the tobacco product and various tobacco additives (b) (4)

(b) (4)

(b) (4) , and (b) (4) were added depending on the specific tobacco product where this modification is being made. In addition, for all EX Requests, the existing additive of (b) (4) is increased. In all of the above EX Requests, the change in these additives resulted in small changes in total quantity of additives in the new tobacco products and are not expected to affect or alter smoke yields between the new and original tobacco products. Additionally, the modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products. Lastly, I find that an exemption for this modification is otherwise appropriate as required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new tobacco products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original tobacco products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original tobacco products are grandfathered products; i.e., were commercially marketed in the United States as of February 15, 2007.

FDA has examined the environmental effects of finding the new tobacco products exempt and made a finding of no significant impact.

An exempt order should be issued for the new tobacco products in EX0001144, EX0001152, EX0001164, EX0001169, EX0001173, and EX0001176 – EX0001185, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes of EX REQs		
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	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001144	GF1908306
Product name	Al Fakher Berry Flavour 1000 grams	Al Fakher Strawberry Flavour 1Kg
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	1 Kg	1 Kg
Characterizing flavor	Berry	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	EX0001152	GF1908308
Product name	Al Fakher Grapefruit 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	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Grapefruit	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) Addition of complex ingredient (b) (4) 	
STN	EX0001164	GF1908303
	Product name	Al Fakher Gum with Cinnamon 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	Gum with Cinnamon	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) Addition of complex ingredient (b) (4) 	
Increasing/Decreasing the quantity of tobacco additives:		
<ul style="list-style-type: none"> Increase in the quantity of (b) (4) 		

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001169	GF1908308
Product name	Al Fakher Vanilla 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	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Vanilla	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	EX0001173	GF1908306
Product name	Al Fakher Kiwi Flavour 1000 grams	Al Fakher Strawberry Flavour 1Kg
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	1 Kg	1 Kg
Characterizing flavor	Kiwi	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) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001176	GF1908303
Product name	Al Fakher AF 07 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	Grapefruit	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	EX0001177	GF1908303
Product name	Al Fakher AF 08 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	Spiced Green Tea	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) 	

¹ In certain sections of the application, the product name does not include "Flavour."

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) • 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	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) • Addition 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	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.