

Technical Project Lead (TPL) Review of Exemption Requests

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001098, EX0001099, EX0001101-EX0001110
Common Attributes	
Submission date	May 7, 2020
Receipt date	May 7, 2020
Applicant	Al Fakher Distribution USA, Inc.
Product manufacturer	Al Fakher Tobacco Factory, F.Z.E., UAE
Product category	Waterpipe Tobacco Products
Product subcategory	Waterpipe Tobacco Filler
Cross-Referenced Submissions	
All STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All STNs	None
Recommendation	
Issue Exempt (EX) order for the new tobacco products subject of this review.	

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2020.10.29 16:19:47 -04'00'

Jeannie Jeong-Im, Ph.D.
Chemistry Branch Chief
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2020.10.30 08:48:30 -04'00'

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

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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: Reviewer(s)	Review Date
regulatory	Kathryn Muller	5/15/2020
chemistry	Jason Hsieh	10/29/2020
environmental science	Hermes Reyes Caballero	10/2/2020

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 reviews dated September 21, 2020,¹ September 28, 2020,² October 13, 2020,³ and October 14, 2020⁴ conclude 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.⁵

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:

- adding an additive (b) (4) and (b) (4) in EX0001098, EX0001099, and EX0001103
- decreasing the quantities of an existing additive (b) (4) and (b) (4) in EX0001098, EX0001099, and EX0001103
- adding an additive (b) (4) in EX0001101, EX0001102, and EX0001106

¹ For EX0001098, EX0001107, and EX0001108

² For EX0001099, EX0001103-EX0001105, and EX0001109-EX0001110

³ For EX0001101 and EX0001102

⁴ For EX0001106

⁵ 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.

- decreasing the quantities of existing additives (b) (4) and (b) (4) in EX0001101, EX0001102, and EX0001106
- adding an additive (b) (4) in EX0001104, EX0001105, and EX0001107
- decreasing the quantities of existing additives (b) (4) and (b) (4) in EX0001104, EX0001105, and EX0001107
- adding an additive (b) (4) in EX0001108, EX0001109, and EX0001110
- decreasing the quantities of existing additives (b) (4) and (b) (4) in EX0001108, EX0001109, and EX0001110

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 October 14, 2020. The FONSI was supported by an environmental assessment prepared by FDA on October 14, 2020.

6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications 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.

In EX0001098, EX0001099, and EX0001103, (b) (4) and (b) (4) are added, which results in the addition of (b) (4) mg/g, (b) (4) mg/g, and (b) (4) mg/g). Also, there is a decrease of (b) (4) and (b) (4) the products to offset the addition of the (b) (4) and (b) (4) flavors. These differences are minor and not expected to significantly alter HPHC yields. In EX0001101, EX0001102, and EX0001106, (b) (4) is added, which leads to the addition of low quantities of (b) (4) mg/g, (b) (4) mg/g, (b) (4) µg/g, and (b) (4) µg/g). Due to the addition of the (b) (4) flavoring, there is a decrease in “(b) (4)” and (b) (4) to offset the addition of the (b) (4) flavoring. The (b) (4) flavoring is 92.2% (b) (4) and the quantities of (b) (4), (b) (4), and (b) (4) (b) (4) are minor; therefore, the differences are not expected to significantly affect smoke chemistry or HPHC yields. In EX0001104, EX0001105, and EX0001107, (b) (4) is added, which leads to addition of (b) (4) mg/g, (b) (4) mg/g, and (b) (4) mg/g). The applicant proposed to decrease (b) (4) flavor, which is comprised of (b) (4) (b) (4), and (b) (4) and (b) (4). These differences are very low and minor for any appreciable risk from exposures to these ingredients at the levels submitted by the applicant. In EX0001108-

EX0001110, (b) (4) " is added, which results in the addition of (b) (4) mg/g), (b) (4) mg/g, (b) (4) flavor), (b) (4) mg/g), (b) (4) mg/g), (b) (4) mg/g, (b) (4) flavor), and (b) (4) mg/g, (b) (4) flavor). Also, the quantities of (b) (4) ", which contain (b) (4) flavors, and (b) (4) decrease. These differences in flavors and additives are considered minor and not expected to significantly alter the smoke profile of the products. 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, research suggests that enjoyment of flavor has been associated with initiation and continued use of tobacco products (e.g., smokeless tobacco products), particularly among youth and young adults.^{a,b} Since the differences in flavor between the new and original tobacco products are not changed between non-characterizing and characterizing flavors, as indicated by the use of flavor descriptors in the new and original tobacco products, based on current scientific evidence, these changes in flavor descriptors are not of concern to FDA at this time. 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 EX0001098, EX0001099, EX0001101-EX0001110, as identified on the cover page of this review.

^a Couch ET, Darius EF, Walsh MM, Chaffee BW. ST product characteristics and relationships with perceptions and behaviors among rural adolescent males: a qualitative study. *Health Educ Res.* 2017;32(6):537-545.

^b Ben Taleb Z, Brel and A, Bahelah R, et al. Flavored Versus Nonflavored Waterpipe Tobacco: A Comparison of Toxicant Exposure, Puff Topography, Subjective Experiences, and Harm Perceptions. *Nicotine Tob Res.* 2019;21(9):1213-1219.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes		
Submission date	May 7, 2020	
Receipt date	May 7, 2020	
Applicant	Al Fakher Distribution USA, Inc.	
Product manufacturer	Al Fakher Tobacco Factory, F.Z.E.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001098	GF1908322
Product name	Al Fakher Citrus with Mint Flavour 1000 grams	Al Fakher Mint 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	Citrus with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) (b) (4) • Addition of complex purchased flavor (b) (4) (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) (b) (4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001099	GF1908319
Product name	Al Fakher Citrus with Mint Flavour 250 grams	Al Fakher Mint 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 grams	250 grams
Characterizing flavor	Citrus with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %

Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Addition of complex purchased flavor (b) (4) Addition of complex purchased flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Decreasing the quantity of (b) (4) Decreasing the quantity of complex purchased flavor (b) (4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001101	GF1908334
Product name	Al Fakher Grape with Berry Flavour 250 grams	Al Fakher Grape 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 grams	250 grams
Characterizing flavor	Grape with Berry	Grape
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Addition of complex purchased flavor “ (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Decreasing the quantity of (b) (4) Decreasing the quantity of complex purchased flavor (b) (4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001102	GF1908331
Product name	Al Fakher Grape with Berry Flavour 1000 grams	Al Fakher Grape 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	Grape with Berry	Grape
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives:	

	<ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) <p>(b) (4)</p> <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) <p>(b) (4)</p>	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001103	GF1908313
Product name	Al Fakher Citrus with Mint Flavour 50 grams	Al Fakher Mint 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 grams	50 grams
Characterizing flavor	Citrus with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) <p>(b) (4)</p> <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) <p>(b) (4)</p> <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) <p>(b) (4)</p>	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001104	GF1908313
Product name	Al Fakher Gum with Mint Flavour 50 grams	Al Fakher Mint 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 grams	50 grams
Characterizing flavor	Gum with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) <p>(b) (4)</p>	

	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Decreasing the quantity of (b) (4) Decreasing the quantity of complex purchased flavor (b) (4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001105	GF1908319
Product name	Al Fakher Gum with Mint Flavour 250 grams	Al Fakher Mint 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 grams	250 grams
Characterizing flavor	Gum with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Addition of complex purchased flavor “(b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Decreasing the quantity of (b) (4) Decreasing the quantity of complex purchased flavor (b) (4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001106	GF1908333
Product name	Al Fakher Grape with Berry Flavour 50 grams	Al Fakher Grape 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 grams	50 grams
Characterizing flavor	Grape with Berry	Grape
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Addition of complex purchased flavor “(b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Decreasing the quantity of (b) (4) Decreasing the quantity of complex purchased flavor (b) (4) 	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001107	GF1908322
Product name	Al Fakher Gum with Mint Flavour 1000 grams	Al Fakher Mint 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	Gum with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001108	GF1908322
Product name	Al Fakher Watermelon with Mint Flavour 1000 grams	Al Fakher Mint 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	Watermelon with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001109	GF1908319

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Product name	Al Fakher Watermelon with Mint Flavour 250 grams	Al Fakher Mint 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 grams	250 grams
Characterizing flavor	Watermelon with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 	
Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001110	GF1908313
Product name	Al Fakher Watermelon with Mint Flavour 50 grams	Al Fakher Mint 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 grams	50 grams
Characterizing flavor	Watermelon with Mint	Mint
Tobacco cut size	(b) (4) mm	(b) (4) mm
Additional Properties: Tobacco moisture	(b) (4) %	(b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Decreasing the quantity of (b) (4) • Decreasing the quantity of complex purchased flavor (b) (4) 	

Appendix B. Amendments

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Status	Brief Description
September 30, 2020	September 30, 2020	EX0001304	EX0001101 EX0001102 EX0001106	Yes	Active	Response to May 12, 2020 FDA Information Request