

**Technical Project Lead (TPL) Review of Exemption Requests:
EX0000978 – EX0000981**

Common Attributes of EX Requests		
Applicant	Al Fakher Distribution USA, Inc.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
EX Requests Included in this Review		
Tobacco Product	New	Original
Submission tracking number	EX0000978	GF1908310
Product name	Al Fakher Plum Flavour 250 grams	Al Fakher Plum Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	250 grams	250 grams
Characterizing flavor	Plum	Plum
Additional property:	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b)(4)%	Tobacco Moisture (b)(4)%
Product modifications	Addition/Deletion of tobacco additives:	
	<ul style="list-style-type: none"> • Deletion of multiple additives in the complex purchased flavor (b)(4) (b)(4) " (b)(4)) • Addition of multiple additives in the complex purchased flavor (b)(4) (b)(4) " (b)(4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> • Increasing in the quantity of multiple additives in the complex purchased flavor (b)(4) (b)(4) " (b)(4) • Decreasing in the quantity of multiple additives in the complex purchased flavor (b)(4) (b)(4) (b)(4) 	

Tobacco Product	New	Original
Submission tracking number	EX0000979	GF1908339
Product name	Al Fakher Golden Eskandarani Apple Flavour 250 grams	Al Fakher Golden Eskandarani Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	250 grams	250 grams
Characterizing flavor	Eskandarani Apple	Eskandarani
Additional property:	Tobacco Cut Size: (b)(4) Tobacco Moisture: (b)(4)%	Tobacco Cut Size: (b)(4) Tobacco Moisture: (b)(4)%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Deletion of (b)(4) from the complex purchased flavor (b)(4) (b)(4) (b)(4)) Addition of (b)(4) (b)(4) in the complex purchased flavor (b)(4) (b)(4) (b)(4)) 	
Tobacco Product	New	Original
Submission tracking number	EX0000980	GF1908348
Product name	Al Fakher Cherry with Mint Flavour 250 grams	Al Fakher Cherry Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	250 grams	250 grams
Characterizing flavor	Cherry with Mint	Cherry
Additional property:	Tobacco Cut Size: (b)(4) Tobacco Moisture: (b)(4)%	Tobacco Cut Size: (b)(4) Tobacco Moisture (b)(4)%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Addition of (b)(4) through the inclusion of a new complex purchased flavor (b)(4) (b)(4) (b)(4)) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increasing the quantity of (b)(4) in the tobacco filler Decreasing the quantity of the complex purchased flavor (b)(4) (b)(4) 	

(b)(4)

Tobacco Product	New	Original
Submission tracking number	EX0000981	GF1908338
Product name	Al Fakher Golden Strawberry Flavour 250 grams	Al Fakher Golden Strawberry Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Box	Box
Package quantity	250 grams	250 grams
Characterizing flavor	Strawberry	Strawberry
Additional property:	Tobacco Cut Size: (b)(4)	Tobacco Cut Size: (b)(4)
	Tobacco Moisture: (b)(4)%	Tobacco Moisture: (b)(4)%
Product modifications	Addition/Deletion of tobacco additives:	
	<ul style="list-style-type: none"> • Deletion of (b)(4) from the complex purchased flavor (b)(4) (b)(4) " (b)(4)) • Addition of (b)(4) in the complex purchased flavor (b)(4) (b)(4) (b)(4) • Deletion of multiple additives in the complex purchased flavor (b)(4) (b)(4) (b)(4) • Addition of multiple additives in the complex purchased flavor (b)(4) (b)(4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> • Increasing in the quantity of multiple additives in the complex purchased flavor (b)(4) " (b)(4) (b)(4) • Decreasing in the quantity of multiple additives in the complex purchased flavor (b)(4) (b)(4) (b)(4) 	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

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Date: 2020.03.31 09:11:35 -04'00'

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

Signatory Decision:

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S
Date: 2020.03.31 09:33:28 -04'00'

Matthew R. Holman, Ph.D.
Director
Office of Science

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The original tobacco products are waterpipe tobacco filler manufactured by the applicant as indicated on the cover page of this review.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 7, 2020, FDA received Exemption Requests EX0000978 - EX0000981 from Troutman Sanders LLP on behalf of Al Fakher Distribution USA, Inc. FDA issued an Acceptance letter for these Exemption Requests on February 27, 2020. On February 18, 2020, February 26, 2020, and March 4, 2020, FDA sent the applicant requests for information via email. On February 21, 2020, March 2, 2020, and March 9, 2020, FDA received three solicited amendments (EX0000993, EX0001005, EX0001013) containing clarification of the predicate tobacco product names and that the predicate tobacco products were not exclusively in a test market as of February 15, 2007.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

- deleting additives (multiple additives in the complex purchased flavor (b)(4) (b)(4) in EX0000978 and EX0000981
- adding additives (multiple additives in the complex purchased flavor (b)(4) (b)(4) in EX0000978 and EX0000981
- increasing the quantities of existing additives (multiple additives in the complex purchased flavor (b)(4) in EX0000978 and EX0000981
- decreasing the quantities of existing additives (multiple additives in the complex purchased flavor (b)(4)”) in EX0000978 and EX0000981
- deleting an additive (b)(4) in complex purchased flavor (b)(4) in EX0000979
- adding an additive (b)(4) in complex purchased flavor (b)(4) (b)(4) in EX0000979
- adding additives (b)(4) through the inclusion of a new complex purchased flavor (b)(4) in EX0000980
- increasing the quantity of an existing additive (b)(4) in tobacco filler) in EX0000980
- decreasing the quantity of an existing additive (complex purchased flavor (b)(4) (b)(4) in EX0000980
- deleting an additive (b)(4) in complex purchased flavor (b)(4) (b)(4) in EX0000981

- adding an additive (b)(4) in complex purchased flavor (b)(4) (b)(4) in EX0000981

2. REGULATORY REVIEW

Regulatory reviews were completed by Donna Cheung on February 27, 2020. The reviews conclude that the Exemption Requests are administratively complete.

3. 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 other than exclusively in test markets as of February 15, 2007. The OCE review dated March 13, 2020, concludes that the original tobacco products are grandfathered products. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A chemistry review was completed by Megan Mekoli on March 27, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives for all EX Requests and increasing and decreasing the quantity of existing tobacco additives in EX0000978, EX0000980, and EX0000981. Complex purchased flavors and (b)(4) are used in the manufacturing of the original tobacco products, and 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 Federal Food, Drug, and Cosmetic Act (FD&C Act).

For EX0000978 and EX0000981, multiple tobacco additives were deleted, added, decreased, and increased in the complex purchased flavor (b)(4) and are minor modifications. In EX0000979, (b)(4) was deleted and (b)(4) was added in the complex purchased flavor (b)(4) and are minor modifications. In EX0000980, (b)(4), and (b)(4) were added in the complex purchased flavor (b)(4), the quantity of the existing additive complex purchased flavor (b)(4) was decreased, and the quantity of the existing additive (b)(4) was increased in the waterpipe tobacco filler. These modifications for EX0000980 are minor modifications. For EX0000981, (b)(4) was deleted in the complex purchased flavor (b)(4) and (b)(4) was added in the complex purchased flavor (b)(4) and are minor modifications. In all of the above EX Requests, the changes 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

² 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.

³ EX0000980 only

any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Shannon Hanna on March 2, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 12, 2020. The FONSI was supported by an environmental assessment prepared by FDA on March 12, 2020.

6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modification compared to the corresponding original tobacco products:

- deleting additives (multiple additives in the complex purchased flavor (b)(4) (b)(4) ") in EX0000978 and EX0000981
- adding additives (multiple additives in the complex purchased flavor (b)(4) (b)(4) in EX0000978 and EX0000981
- increasing the quantities of existing additives (multiple additives in the complex purchased flavor (b)(4) in EX0000978 and EX0000981
- decreasing the quantities of existing additives (multiple additives in the complex purchased flavor (b)(4) ") in EX0000978 and EX0000981
- deleting an additive (b)(4) in complex purchased flavor (b)(4) in EX0000979
- adding an additive (b)(4) in complex purchased flavor (b)(4) (b)(4) in EX0000979
- adding additives (b)(4) and (b)(4) through the inclusion of a new complex purchased flavor (b)(4) ") in EX0000980
- increasing the quantity of an existing additive (b)(4) in tobacco filler) in EX0000980
- decreasing the quantity of an existing additive (complex purchased flavor (b)(4) (b)(4) in EX0000980
- deleting an additive (b)(4) in complex purchased flavor (b)(4) (b)(4) in EX0000981
- adding an additive (b) (4) in complex purchased flavor (b)(4) (b)(4) in EX0000981

I concur with the conclusion of the scientific review that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines 'additive' as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), . . ." I concur with the scientific review that the changes represent adding or deleting tobacco additives for all EX Requests and increasing and decreasing the quantity of existing tobacco additives in EX0000978, EX0000980, and EX0000981. In addition, I concur with the scientific reviews that the changes represent the addition, deletion,

increasing of existing tobacco additives, and/or decreasing of existing tobacco additives in complex purchased flavors. 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 protection of the public health. For EX0000978 and EX0000981, multiple tobacco additives were deleted, added, decreased, and increased in the complex purchased flavor (b)(4) " " and are minor modifications. In EX0000979, (b)(4) was deleted and (b)(4) was added in the complex purchased flavor (b)(4) " " and are minor modifications. In EX0000980, (b)(4) , and (b)(4) was added in the complex purchased flavor (b)(4) " , the quantity of the existing additive complex purchased flavor (b)(4) was decreased, and the quantity of the existing additive (b)(4) was increased in the waterpipe tobacco filler. These modifications for EX0000980 are minor modifications. For EX0000981, (b)(4) was deleted in the complex purchased flavor (b)(4) " and (b)(4) was added in the complex purchased flavor (b)(4) " and are minor modifications. 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, FDA finds, based on the information contained in the Exemption Requests and CTP's scientific understanding, 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 other than exclusively in test markets 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 EX0000978 – EX0000981, as identified on the cover page of this review.