

**Technical Project Lead (TPL) Review of Exemption Requests:
EX0001037, EX0001040, EX0001041, EX0001045, EX0001048 –
EX0001050, and EX0001053 – EX0001060**

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	EX0001037	GF1908361
Product name	Al Fakher Apple Flavour 1000 grams	Al Fakher Apple Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	1000 grams	1000 grams ¹
Characterizing flavor	Apple	Apple
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	

¹ The package quantity was stated as 1 Kg, which was converted to 1000 grams.

Tobacco Product	New	Original
Submission tracking number	EX0001040	GF1908359
Product name	Al Fakher Apple Flavour 50 grams	Al Fakher Apple Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing order 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	Apple	Apple
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001041	GF1908360
Product name	Al Fakher Apple Flavour 250 grams	Al Fakher Apple Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order 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	Apple	Apple
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001045	GF1908321
Product name	Al Fakher Mango Flavour 250 grams	Al Fakher Mango Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order 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	Mango	Mango
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001048	GF1908306
Product name	Al Fakher Strawberry Flavour 1000 grams	Al Fakher Strawberry Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic pouch
Package quantity	1000 grams	1000 grams ¹
Characterizing flavor	Strawberry	Strawberry
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) Addition of (b) (4) e in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001049	GF1908308
Product name	Al Fakher Strawberry Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing order 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	Strawberry	Strawberry
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001050	GF1908303
Product name	Al Fakher Strawberry Flavour 250 grams	Al Fakher 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	Plastic Pouch	Plastic pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Strawberry	Strawberry
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001053	GF1908324
Product name	Al Fakher Melon Flavour 250 grams	Al Fakher Melon Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order 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	Melon	Melon
Additional property:	Tobacco Cut Size: (b) (4) mm	Tobacco Cut Size: (b) (4) mm
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) Decreasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001054	GF1908323
Product name	Al Fakher Melon Flavour 1000 grams	Al Fakher Melon Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic pouch
Package quantity	1000 grams	1000 grams ¹
Characterizing flavor	Melon	Melon
Additional property:	Tobacco Cut Size: (b) (4) mm	Tobacco Cut Size: (b) (4) mm
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) Decreasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001055	GF1908345
Product name	Al Fakher Cocktail Flavour 1000 grams	Al Fakher Cocktail Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic pouch
Package quantity	1000 grams	1000 grams ¹
Characterizing flavor	Cocktail	Cocktail
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001056	GF1908325
Product name	Al Fakher Mango Flavour 1000 grams	Al Fakher Mango Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic pouch
Package quantity	1000 grams	1000 grams ¹
Characterizing flavor	Mango	Mango
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001057	GF1908342
Product name	Al Fakher Cocktail Flavour 250 grams	Al Fakher Cocktail Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order 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	Cocktail	Cocktail
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001058	GF1908301
Product name	Al Fakher Two Apples Flavour 250 grams	Al Fakher Two Apple Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order 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	Two Apples	Two Apples
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) Addition of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001059	GF1908305
Product name	Al Fakher Two Apples Flavour 1000 grams	Al Fakher Two Apple Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic pouch
Package quantity	1000 grams	1000 grams ¹
Characterizing flavor	Two Apples	Two Apples
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001060	GF1908302
Product name	Al Fakher Two Apples Flavour 50 grams	Al Fakher Two Apples Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing order 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	Two Apples	Two Apples
Additional property:	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 (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
Recommendation		
Issue Exempt (EX) order.		

Technical Project Lead (TPL):

Digitally signed by Jeannie H. Jeong-im -S
Date: 2020.06.23 14:08:51 -04'00'

Jeannie Jeong-Im, Ph.D.
Chemistry Branch Chief
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: 2020.06.23 14:20:59 -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 April 14, 2020, FDA received fifteen Exemption Requests (EX0001037, EX0001040, EX0001041, EX0001045, EX0001048 – EX0001050, and EX0001053 – EX0001060) from Troutman Sanders LLP, on behalf of Al Fakher Distribution USA, Inc. On April 29, 2020, FDA received amendment (EX0001068) with the updated certification statements as requested by FDA in a teleconference dated April 28, 2020. On May 5, 2020, FDA received an amendment (EX0001075) in response to OCE's request for information to complete 905(j)(3) status review for all EX Requests. On May 8, 2020, FDA issued an Acceptance letter. On May 12, 2020, FDA received an amendment (EX0001111) in response to OCE's request for additional information to complete 905(j)(3) status review for EX0001045. On May 13, 2020 FDA received an amendment (EX0001114) in response to a follow up request by OCE for additional information.

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 an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001037, EX0001040, EX0001041
- adding an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001037, EX0001040, EX0001041
- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001045 and EX0001056
- increasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4) in EX0001045 and EX0001056
- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001048 – EX0001050
- adding an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001048 – EX0001050
- decreasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4) in EX0001053 and EX0001054
- increasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4) in EX0001053 and EX0001054
- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001055 and EX0001057

- increasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4) in EX0001055 and EX0001057
- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001058 – EX0001060
- adding an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001058 – EX0001060

2. REGULATORY REVIEW

Regulatory reviews were completed by Kathryn Mueller on May 8, 2020. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews 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 reviews dated May 20, 2020, for EX0001037; May 22, 2020, for EX0001040, EX0001041, EX0001045, EX0001059, and EX0001060; May 23, 2020, for EX0001048- EX0001050, and EX0001053-EX0001057; and May 26, 2020, for EX0001058, conclude 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 Jikun Liu on June XX, 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 decreasing³ the quantity of existing tobacco additives in EX0001037, EX0001040, EX0001041, EX0001045, EX0001048 – EX0001050, and EX0001053 – EX0001060. Complex purchased flavors 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 EX0001037, EX0001040, and EX0001041, tobacco additives were deleted and added in the complex purchased flavor (b) (4). The applicant proposes to delete (b) (4) and add (b) (4) at the same quantity. (b) (4) the (b) (4) extracted from (b) (4), is widely used to flavor food. This complex purchased flavor is comprised of approximately 83% of (b) (4) and (b) (4) and (b) (4) appear to be interchangeable flavor ingredients. For EX0001058 – EX0001060, the applicant proposes to modify the original tobacco products by deleting (b) (4) from the complex flavor (b) (4) and adding an equal quantity of (b) (4) in the original tobacco

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 EX0001053 and EX0001054 only

products. These proposed product modifications result in a 20% increase in trans-anethole in the new tobacco products of EX0001037, EX0001040, EX0001041, and EX0001058 – EX0001060 compared to the original tobacco products, and deletion of other (b) (4) ingredients such as (b) (4), and (b) (4) from the new tobacco products. For EX0001045 and EX0001056, the proposed modification is the deletion of (b) (4) from a complex purchased flavor, (b) (4) and increasing (b) (4) in the new formula. (b) (4) is a natural flavor compound present in (b) (4), other (b) (4), and (b) (4) (b) (4) occurs in (b) (4) and (b) (4) and has a bland odor, but when combined with other fragrant (b) (4) helps to generate odor of some (b) (4) varieties. In EX0001048 – EX0001050, the applicant proposes substitution of (b) (4) from the complex purchased flavor (b) (4) with an equal quantity of (b) (4) in the new tobacco products. (b) (4) is one of the main volatile carbonyl species in the vapors of (b) (4), and (b) (4) and its characteristic odor is similar to (b) (4). For EX0001053 – EX0001054, the applicant proposes to modify the original tobacco products by decreasing the quantity of (b) (4) in the complex purchased flavor (b) (4) and increasing the level of (b) (4) by the same quantity, which is an increase of 1000%. However, the concentration of this complex flavor in the new products is (b) (4) g/g. Therefore, the increase in (b) (4) is only 0.11% or (b) (4) mg/g of the mass of the new products. In EX0001055 and EX0001057, the applicant proposes to delete (b) (4) with an equal quantity of (b) (4) by increasing the quantity of (b) (4) by 0.25% in the complex flavor additive (b) (4). 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 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 Dilip Venugopal on June 4, 2020.

The final environmental review found that the applicant did not provide: the marketing intention for the original products after receiving the marketing orders for the new products; a statement if the new products are intended to replace or substitute the other waterpipe tobacco products currently in the market; and a full environmental assessment with marketing of the proposed products on disproportionately high and adverse human health or environmental effects on low-income, minority or native/indigenous populations. Therefore, additional information is needed to determine whether to prepare an environmental impact statement (EIS) or finding of no significant impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

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

- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001037, EX0001040, EX0001041

- adding an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001037, EX0001040, EX0001041
- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001045 and EX0001056
- increasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4) in EX0001045 and EX0001056
- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001048 – EX0001050
- adding an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001048 – EX0001050
- decreasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4) in EX0001053 and EX0001054
- increasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4) in EX0001053 and EX0001054
- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001055 and EX0001057
- increasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4) in EX0001055 and EX0001057
- deleting an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001058 – EX0001060
- adding an additive (b) (4) in the complex purchased flavor (b) (4) in EX0001058 – EX0001060

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 in (b) (4)

(b) (4) complex flavors represent adding or deleting tobacco additives for all EX Requests and increasing or decreasing the quantity of existing tobacco additives. 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. The modifications are as follows: deletion of (b) (4) mg/g of (b) (4) and addition of (b) (4) mg/g of (b) (4) in the complex purchased flavor (b) (4) for EX0001037, EX0001040 and EX0001041; deletion of (b) (4) /g of (b) (4) and increasing (b) (4) mg/g of (b) (4) in the complex flavor additive (b) (4) for EX0001045 and EX0001056; deletion of (b) (4) mg/g of (b) (4) and addition of (b) (4) mg/g of (b) (4) in the complex purchased flavor (b) (4) for EX0001048 – EX0001050; decreasing (b) (4) mg/g of (b) (4) and increasing (b) (4) mg/g of (b) (4) in the complex purchased flavor (b) (4) for EX0001053 – EX0001054; deletion of (b) (4) mg/g of (b) (4) and increasing (b) (4) mg/g of (b) (4) in the complex flavor additive (b) (4) and deletion of (b) (4) mg/g of (b) (4) and addition of (b) (4) mg/g of (b) (4) in the complex purchased flavor (b) (4)

(b) (4) for EX0001058 – EX0001060. 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 these modifications are 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 these new tobacco products exempt from substantial equivalence and found that additional information is necessary to determine the impact of the action. Without this information, FDA may be precluded or delayed from issuing an EX order.

An Environmental Information Request letter should be issued requesting the following information:

1. All of your EX Requests lack information regarding marketing of the original tobacco products after receiving marketing orders for the new tobacco products. Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and original tobacco products. You stated that the original products are currently not marketed to consumers in the United States. Clarify whether the new and corresponding original tobacco products would be marketed simultaneously after receiving marketing orders for the new tobacco products, or if the original tobacco products will continue to not be marketed to consumers in the United States. If the original tobacco products will be marketed, provide the projected market volumes in the first and fifth years of marketing the new tobacco products. Table 1 may be used to provide this information, or you can submit this information using an alternative approach if it provides the first- and fifth-year market volume projections for the original tobacco products.

Table 1. Market volume projections for the original tobacco products

Original Tobacco Product	Unit	First Year	Fifth Year
Al Fakher Apple Flavour 1 Kg (GF1908361)			
Al Fakher Apple Flavour 50 grams (GF1908359)			
Al Fakher Apple Flavour 250 grams (GF1908360)			
Al Fakher Mango Flavour 250 grams (GF1908321)			

Al Fakher Strawberry Flavour 1 Kg (GF1908306)			
Al Fakher Strawberry Flavour 50 grams (GF1908308)			
Al Fakher Strawberry Flavour 250 grams (GF1908303)			
Al Fakher Melon Flavour 250 grams (GF1908324)			
Al Fakher Melon Flavour 1 Kg (GF1908323)			
Al Fakher Cocktail Flavour 1 Kg (GF1908345)			
Al Fakher Mango Flavour 1 Kg (GF1908325)			
Al Fakher Cocktail Flavour 250 grams (GF1908342)			
Al Fakher Two Apples Flavour 250 grams (GF1908301)			
Al Fakher Two Apples Flavour 1 Kg (GF1908305)			
Al Fakher Two Apples Flavour 50 grams (GF1908302)			

2. All of your EX Requests lack information regarding if the new tobacco products are intended to compete with or replace portions of other waterpipe tobacco products currently on the market. Provide a statement if the new tobacco products are intended to compete with or replace portions of other waterpipe tobacco products currently on the market. The information about marketing of the new tobacco products are used to assess the environmental impacts of the proposed actions.

3. All of your EX Requests provided an environmental assessment, however the environmental assessment does not address whether marketing of the proposed product is likely to have a disproportionately high and adverse human health or environmental effects on low- income, minority or native/indigenous populations. Provide an evaluation addressing the impacts of marketing of your proposed products regarding environmental justice and if applicable any proposed mitigation strategies. This information will support our assessment of environmental justice as it relates to impacts on low-income, minority, or native/indigenous populations. For more information on environmental justice please refer to: <https://www.epa.gov/environmentaljustice/environmental-justice-and-national-environmental-policy-act>.

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order should be issued for the new tobacco products in EX0001037, EX0001040, EX0001041, EX0001045, EX0001048 – EX0001050, and EX0001053 – EX0001060, as identified on the cover page of this review.