

Technical Project Lead (TPL) Review of Exemption Requests

New Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001329-PD1, EX0001330-PD1, EX0001331-PD1, EX0001332-PD1, EX0001333-PD1, EX0001334-PD1, EX0001335-PD1, EX0001339-PD1, EX0001340-PD1
Common Attributes	
Submission date	November 19, 2020
Receipt date	November 19, 2020
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 Jeffrey R. Ammann -S
Date: 2021.07.15 14:32:29 -04'00'

Jeffrey R. Ammann, Ph.D.
Chemistry Team Supervisor
Division of Product Science

Signatory Decision:

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S
Date: 2021.07.15 15:19:03 -04'00'

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

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1. BACKGROUND

1.1. NEW AND ORIGINAL PRODUCTS

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

1.2. REGULATORY ACTIVITY

See appendices for products and amendments.

1.3. SCOPE OF REVIEW

This review captures all compliance, regulatory, and scientific reviews completed for the new products that are the subject of this review.

Table 1. Disciplines reviewed

	Cycle 1	
Discipline	Reviewer(s)	Review Date
regulatory	Kaylene Charles	2/19/2021
chemistry	Jason Hsieh	6/10/2021
environmental science	Chad Baisden	6/3/2021

2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE review dated June 7, 2021 concludes that the evidence submitted by the applicant is adequate to demonstrate original products are grandfathered products. Therefore, the original products are eligible for modification under the Exemption Request pathway.¹

¹ Any 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. TOBACCO ADDITIVE MODIFICATION

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

- deleting a complex additive (b) (4) and adding a complex additive (b) (4), and increasing the quantity of (b) (4) in EX0001329-PD1, EX0001331-PD1, and EX0001332-PD1
- deleting a complex additive (b) (4) and adding a complex additive (b) (4), and increasing the quantity of (b) (4) in EX0001330-PD1, EX0001333-PD1, and EX0001334-PD1
- deleting a complex additive (b) (4), and adding two complex additives (b) (4) and (b) (4), and increasing the quantity of (b) (4) in EX0001335-PD1 and EX0001340-PD1
- deleting a complex additive (b) (4), and adding three complex additives (b) (4), and increasing the quantity of (b) (4) in EX0001339-PD1

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 products. The review concludes that the modifications are minor modifications of a 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 June 10, 2021. The FONSI was supported by an environmental assessment prepared by FDA on June 10, 2021.

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 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 products to be marketed would be appropriate for the protection of the public health. The applicant proposes to modify the original products of EX0001329-PD1, EX0001331-PD1, and EX0001332-PD1 by deleting (b) (4) mg/g of the complex purchased flavor (b) (4) and adding (b) (4) mg/g of the complex purchased flavor (b) (4) and increasing the quantity of (b) (4) by 7% (b) (4) mg/g) to the new products. The applicant provides the quantities of the single chemical compounds in the units of a percent (%) of the flavor supplied by the flavor manufacturer (b) (4) for (b) (4); (b) (4) for (b) (4). The applicant also provides the CAS numbers for the single chemical compounds in the flavors. The

[illegible]

^b Sá, Amanda Gomes Almeida, et al. "A review on enzymatic synthesis of aromatic esters used as flavor ingredients for food, cosmetics and pharmaceuticals industries." *Trends in Food Science & Technology* 69 (2017): 95-105.

(b) (4)

(b) (4)

(b) (4)

[†] Schubert, J., Hahn, J., Dettbarn, G., et al. "Mainstream smoke of the waterpipe: Does this environmental matrix reveal as significant source of toxic compounds?" *Toxicology Letters* 2011; 205(3), p279-284

EX0001329-PD1, EX0001330-PD1, EX0001331-PD1, EX0001332-PD1, EX0001333-PD1, EX0001334-PD1, EX0001335-PD1, EX0001339-PD1, EX0001340-PD1

for this modification is otherwise appropriate as required by section 905(j)(3)(A)(iii) of the FD&C Act. Therefore, the new products should be found exempt from the requirements of substantial equivalence under section 910(a)(3)(A) of the FD&C Act.

The original products are eligible for modification through the Exemption Request pathway because they can be legally marketed in the United States. The original 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 products exempt and made a finding of no significant impact.

An exempt order should be issued for the new products, as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original products

Common Attributes		
Submission date	November 19, 2020	
Receipt date	November 19, 2020	
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 Product	Original Product
STN	EX0001329	GF1908303
Product name	Al Fakher Blueberry Vanilla Ice Cream Flavour 250 grams ^g	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	Polyethylene Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Blueberry Vanilla Ice Cream	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) flavor (b) (4) • Addition of Blueberry Ice Cream flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	

^g Brand/sub-brand or other commercial name used in commercial distribution.

EX0001329-PD1, EX0001330-PD1, EX0001331-PD1, EX0001332-PD1, EX0001333-PD1, EX0001334-PD1, EX0001335-PD1, EX0001339-PD1, EX0001340-PD1

Attributes	New Product	Original Product
STN	EX0001330	GF1908308
Product name	Al Fakher Earl Grey Tea 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	Polyethylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Earl Grey Tea	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) flavor (b) (4) • Addition of (b) (4) flavor (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 Product	Original Product
STN	EX0001331	GF1908306
Product name	Al Fakher Blueberry Vanilla Ice Cream Flavour 1000 grams	Al Fakher Strawberry Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Blueberry Vanilla Ice Cream	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) flavor (b) (4) • Addition of Blueberry Ice Cream flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	

EX0001329-PD1, EX0001330-PD1, EX0001331-PD1, EX0001332-PD1, EX0001333-PD1, EX0001334-PD1, EX0001335-PD1, EX0001339-PD1, EX0001340-PD1

Attributes	New Product	Original Product
STN	EX0001332	GF1908308
Product name	Al Fakher Blueberry 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	Polyethylene Pouch	Plastic Pouch
Package quantity	250 g	50 g
Characterizing flavor	Blueberry Vanilla Ice Cream	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) flavor (b) (4) • Addition of Blueberry Ice Cream flavor (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 Product	Original Product
STN	EX0001333	GF1908303
Product name	Al Fakher Earl Grey Tea Flavour 250 grams	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	Polyethylene Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Earl Grey Tea	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) flavor (b) (4) • Addition of (b) (4) flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	

EX0001329-PD1, EX0001330-PD1, EX0001331-PD1, EX0001332-PD1, EX0001333-PD1, EX0001334-PD1, EX0001335-PD1, EX0001339-PD1, EX0001340-PD1

Attributes	New Product	Original Product
STN	EX0001334	GF1908306
Product name	Al Fakher Earl Grey Tea Flavour 1000 grams	Al Fakher Strawberry Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Earl Grey Tea	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) flavor (b) (4) • Addition of (b) (4) flavor (Tobacco Technology) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	
Attributes	New Product	Original Product
STN	EX0001335	GF1908308
Product name	Al Fakher Frosty Mint 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	Polyethylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Frosty Mint	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) flavor (b) (4) • Addition of (b) (4) flavor (b) (4) • Addition of (b) (4) flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	

EX0001329-PD1, EX0001330-PD1, EX0001331-PD1, EX0001332-PD1, EX0001333-PD1, EX0001334-PD1, EX0001335-PD1, EX0001339-PD1, EX0001340-PD1

Attributes	New Product	Original Product
STN	EX0001339	GF1908308
Product name	Al Fakher Frosty Two Apples 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	Polyethylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Frosty Two Apples	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) flavor (b) (4) • Addition of (b) (4) flavor (b) (4) • Addition of (b) (4) flavor (b) (4) • Addition of (b) (4) flavor (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 Product	Original Product
STN	EX0001340	GF1908306
Product name	Al Fakher Frosty Mint Flavour 1000 grams	Al Fakher Strawberry Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Frosty Mint	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) flavor (b) (4) • Addition of (b) (4) flavor (b) (4) • Addition of (b) (4) flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	