

# **Technical Project Lead (TPL) Review of Exemption Requests**

New Products Subject of this Review		
Submission tracking numbers (STNs)	EX0001353-PD1 - EX0001364-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):

For Jenna DuMond, Ph.D.

Chemistry Team Supervisior Division of Product Science

Signatory Decision: Concur with TPL recommendation and basis of recommendation

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	Kathryn Mueller	2/19/2021	
chemistry	Mona Shrestha	6/11/2021	
environmental	Thomas Creaven	6/8/2021	
science			

#### 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. The OCE review dated June 8, 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.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Any tobacco product that can be sold under 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 is the result of:

- adding an additive ((b) (4) ) in EX0001353-PD1 and EX0001355-PD1
- adding an additive ((b) (4) ) in EX0001353-PD1, EX0001355-PD1 and EX0001364-PD1
- adding an additive (b) (4) ) in EX0001354-PD1, EX0001359-PD1 and EX0001360-PD1
- adding an additive (b) (4) ) in EX0001356-PD1 EX0001358-PD1
- adding an additive (b) (4) ) in EX0001356-PD1 EX0001358-PD1
- adding an additive ((b) (4) ) in EX0001356-PD1 EX0001358-PD1 and EX0001364-PD1

) in EX0001361-PD1 – EX0001363-PD1

in EX0001364-PD1

) in EX0001364-PD1

- adding an additive (b) (4)
- adding an additive (b) (4
- adding an additive (b) (4)
- deleting an additive (b) (4) in all the EX Requests
  - deleting an additive (b) (4)(b) (4) ) in EX0001356-PD1 EX0001358-PD1
- increasing the quantity of an existing additive (b) (4) ) in all the EX Requests
- increasing the quantity of an existing additive (b) (4)
   PD1 and EX0001355-PD1

in EX0001353-

#### 4. SCIENTIFIC REVIEW

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The review finds these modified ingredients (see Section 3) as 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 products 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 17, 2021. The FONSI was supported by an environmental assessment prepared by FDA on June 17, 2021.

#### 6. CONCLUSION AND RECOMMENDATION

<b>(b) (4)</b> ", a	nd " <mark>(b) (4</mark> )	" (EX00013	856-PD1 – E	EX0001358-PD1),	"(b) (4)	"
	PD1 – EX00013	363-PD1), " <mark>(</mark> )	(4)	", " <mark>(b)</mark>	(4)	", " <mark>(b) (4)</mark>
, and "				. The additions of	f the complex pu	rchased flavors
have increase	ed ingredients	such as (b) (4)			, (b) (4)	
(b) (4) <sub>,</sub> (b)	(4)	,	(b) (4)	(b) (4) (b) (4	) I, <mark>(b) (</mark> 4	<b>4)</b> ,
(b) (4)	(b) (4)			(b) (4)		e, <mark>(b) (4)</mark>
, (b) (4)	, (b) (4)	,(b) (4)	, (b) (4)	and (b)	(4) . Sor	ne of these

ingredients, such as (b) (4) could be of concern, however, with normal waterpipe use only a small percentage of the (b) (4) degrades. All other ingredient differences are small enough that they are not expected by chemistry to affect HPHC smoke yields. There is also an increase in (b) (4)

in the new products of EX0001353-PD1 and EX001355-PD1. However, from a chemistry perspective, this small difference of is not expected to impact HPHC smoke yields. Furthermore, in all of the EX Requests, chemistry has determined that because the changes in the amounts of the ingredients are small, any modification on such a scale is not anticipated to have a measurable change in the waterpipe tobacco smoke yields. For all EX Requests there are increases in the humectant (b) (4) in the new products. There also are lower quantities of (b) (4) for all EX Requests in the new products. Therefore, for all EX Requests, the minor net change in humectants is not expected to result in a measurable change in the HPHC smoke yields. 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 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	EX0001353-PD1	GF1908308	
Product name	Al Fakher Magic Love Flavour 50	Al Fakher Strawberry Flavour 50	
r iouuci name	grams	grams	
Eligibility status	Not Applicable	Grandfathered	
Marketing authorization date	Not Applicable Not Applicable		
Abbreviated report date	Not applicable	Not Applicable	
Package type	Polypropylene Pouch Plastic Pouch		
Package quantity	50 grams (g) 50 g		
Characterizing flavor	Magic Love	Strawberry	
Additional Property	Tobacco cut size: (b) mm	Tobacco cut size: <sup>b</sup> mm	
	Tobacco moisture: <mark>(b</mark> %	Tobacco moisture: (b %	
Product modifications	Addition/Deletion of tobacco additives: • Addition of complex purchased flavor (b) (4) " (b) (4) (b) (4) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c		

Attributes	New Product	Original Product	
STN	EX0001354-PD1	GF1908308	
	Al Fakher Pina Colada Flavour 50	Al Fakher Strawberry Flavour 50	
Product name	grams	grams	
Eligibility status	Not Applicable	Grandfathered	
Marketing authorization	Not Applicable	Not Applicable	
date			
Abbreviated report date	Not applicable	Not Applicable	
Package type	Polypropylene Pouch	Plastic Pouch	
Package quantity	50 g	50 g	
Characterizing flavor	Pina Colada	Strawberry	
Additional Dranartics	Tobacco cut size: <mark>(b</mark> mm	Tobacco cut size: (b) mm	
Additional Properties	Tobacco moisture: (b)	Tobacco moisture: 0 %	
	Addition/Deletion of tobacco additive	es:	
	Addition of complex purchase	ed flavor " <mark>(b) (4)</mark> "	
	Deletion of complex purchase	ed flavor "(b) (4) " (b) (4)	
Product modifications			
	Increasing/Decreasing the quantity o	f existing tobacco additives:	
	• Increase in the quantity of (b) (4)		
Attributes	New Product	Original Product	
STN	EX0001355-PD1	GF1908306	
Product name	Al Fakher Magic Love 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 Kilogram (Kg)	
Characterizing flavor	Magic Love	Strawberry	
Additional Property	Tobacco cut size: (b mm	Tobacco cut size: (b mm	
Length	Tobacco moisture: <mark>0</mark> %	Tobacco moisture: 0 %	
	Addition/Deletion of tobacco additive	es:	
<ul> <li>Addition of complex purchased flavor "(b) (4)</li> <li>(b) (4)</li> <li>(b) (4)</li> <li>Addition of complex purchased flavor "(b) (4)</li> </ul>		ed flavor " <mark>(b) (4)</mark> " ( <mark>(b) (4)</mark>	
	<ul> <li>Deletion of complex purchased flavor "(b) (4)</li> <li>Increasing/Decreasing the quantity of existing tobacco additive</li> <li>Increase in the quantity of (b) (4)</li> <li>Increase in the quantity of (b) (4)</li> </ul>		

Attributes	New Product	Original Product
STN	EX0001356-PD1	GF1908303
Product name	Al Fakher Super Lemon Mint	Al Fakher Strawberry Flavour 250
rioddet name	Flavour 250 grams	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	Super Lemon Mint	Strawberry
Additional Property	Tobacco cut size: <mark>(b</mark> mm	Tobacco cut size: 🕩 mm
Length	Tobacco moisture: <mark>(</mark> %	Tobacco moisture: (b %
Product modifications	Addition/Deletion of tobacco additives: Addition of complex purchased flavor "(b) (4) " (b) (4)	

Attributes	New Product	Original Product
STN	EX0001357-PD1	GF1908308
Product name	Al Fakher Super Lemon Mint	Al Fakher Strawberry Flavour 50
	Flavour 50 grams	grams
Eligibility status	Not Applicable	Grandfathered
Marketing authorization date	Not Applicable	Not Applicable
Abbreviated report date	Not applicable	Not Applicable
Package type	Polypropylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Super Lemon Mint	Strawberry
Additional Property	Tobacco cut size: (b) mm	Tobacco cut size: 🕑 mm
Length	Tobacco moisture: <mark>(b</mark> %	Tobacco moisture: (b %
Product modifications	<ul> <li>Addition/Deletion of tobacco additives:</li> <li>Addition of complex purchased flavor "(b) (4) " (b) (4) "</li></ul>	

Attributes	New Product	Original Product	
STN	EX0001358-PD1	GF1908306	
Product name	Al Fakher Super 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	Super Lemon Mint	Strawberry	
Additional Property	Tobacco cut size: (b mm	Tobacco cut size: (b mm	
Length	Tobacco moisture: (b)	Tobacco moisture: (b)	
Product modifications	<ul> <li>Addition of complex purchased flavor "(b) (4) " (b) (4)</li> <li>Deletion of complex purchased flavor (b) (4) " (b) (4)</li> <li>Deletion of (b) (4) (4)</li> <li>Deletion of (b) (4) (4)</li> <li>Increasing/Decreasing the quantity of existing tobacco additives:</li> </ul>		
Attuileutee	Increase in the quantity of		
Attributes STN	New Product EX0001359-PD1	Original Product GF1908303	
Product name	Al Fakher Pina Colada 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	Pina Colada	Strawberry	
Additional Property	Tobacco cut size: (b mm	Tobacco cut size: <mark>b</mark> mm	
Length	Tobacco moisture: 10%	Tobacco moisture: 10%	
Product modifications	<ul> <li>Addition/Deletion of tobacco additives:</li> <li>Addition of complex purchased flavor "(b) (4) " (b) (4)</li> <li>Deletion of complex purchased flavor "(b) (4) " (b) (4)</li> <li>Increasing/Decreasing the quantity of existing tobacco additives:</li> <li>Increase in the quantity of (b) (4)</li> </ul>		

Attributes	New Product	Original Product	
STN	EX0001360-PD1	GF1908306	
Product name	Al Fakher Pina Colada 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	Pina Colada	Strawberry	
Additional Property	Tobacco cut size: (b mm	Tobacco cut size: (b mm	
Length	Tobacco moisture: <mark>(</mark> %	Tobacco moisture (b)	
Product modifications	<ul> <li>Addition of complex purchased flavor "(b) (4) "</li> <li>Deletion of complex purchased flavor "(b) (4) (b) (4) (b) (4) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c</li></ul>		
Attributes	New Product Original Product		
STN	EX0001361-PD1	GF1908308	
Product name	Al Fakher Sweet Passion Fruit 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	Sweet Passion Fruit	Strawberry	
Additional Property	Tobacco cut size: (b mm	Tobacco cut size: (b) mm	
Length	Tobacco moisture: (b)	Tobacco moisture: (b)	
Product modifications	<ul> <li>Addition/Deletion of tobacco additives:</li> <li>Addition of complex purchased flavor "(b) (4) " (b) (4)</li> <li>Deletion of complex purchased flavor "(b) (4) " (b) (4)</li> <li>Increasing/Decreasing the quantity of existing tobacco additives:</li> <li>Increase in the quantity of (b) (4)</li> </ul>		

New Product	Original Product	
EX0001362-PD1	GF1908306	
Al Fakher Sweet Passion Fruit	Al Fakher Strawberry Flavour 1 Kg	
Flavour 1000 grams		
Not Applicable	Grandfathered	
Not Applicable	Not Applicable	
Not applicable	Not Applicable	
Polyethylene Pouch	Plastic Pouch	
1000 g	1 Kg	
Sweet Passion Fruit	Strawberry	
Tobacco cut size: (b mm	Tobacco cut size: 🕑 mm	
Tobacco moisture: (b)	Tobacco moisture: (b)	
Addition/Deletion of tobacco additive	es:	
Addition of complex purchase	ed flavor "(b) (4) "(b) (4)	
)		
• Deletion of complex purchased flavor "(b) (4) " (b) (4)		
Increasing/Decreasing the quantity of	f existing tobacco additives:	
New Product Original Product		
EX0001363-PD1	GF1908303	
Al Fakher Sweet Passion Fruit	<b>GF1908303</b> Al Fakher Strawberry Flavour 250	
Al Fakher Sweet Passion Fruit	Al Fakher Strawberry Flavour 250	
Al Fakher Sweet Passion Fruit Flavour 250 grams	Al Fakher Strawberry Flavour 250 grams	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable	Al Fakher Strawberry Flavour 250 grams Grandfathered	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable	Al Fakher Strawberry Flavour 250 grams Grandfathered	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Not applicable	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Not Applicable	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Not applicable Polyethylene Pouch	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Not applicable Polyethylene Pouch 250 g	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch 250 g	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Not applicable Polyethylene Pouch 250 g Sweet Passion Fruit	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch 250 g Strawberry	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Polyethylene Pouch 250 g Sweet Passion Fruit Tobacco cut size:	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch 250 g Strawberry Tobacco cut size: b mm Tobacco moisture: (b)	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Not applicable Polyethylene Pouch 250 g Sweet Passion Fruit Tobacco cut size: Dmm Tobacco moisture: DMM	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch 250 g Strawberry Tobacco cut size: b mm Tobacco moisture: b	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Polyethylene Pouch 250 g Sweet Passion Fruit Tobacco cut size:	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch 250 g Strawberry Tobacco cut size: mm Tobacco moisture: D	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Polyethylene Pouch 250 g Sweet Passion Fruit Tobacco cut size: (b) Addition/Deletion of tobacco additive Addition of complex purchase	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch 250 g Strawberry Tobacco cut size: [b] mm Tobacco moisture: [b] es: ed flavor "(b) (4) " (b) (4)	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Not applicable Polyethylene Pouch 250 g Sweet Passion Fruit Tobacco cut size: Dmm Tobacco moisture: DMM	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch 250 g Strawberry Tobacco cut size: (b mm Tobacco moisture: (b) es: ed flavor "(b) (4) " (b) (4)	
Al Fakher Sweet Passion Fruit Flavour 250 grams Not Applicable Not Applicable Polyethylene Pouch 250 g Sweet Passion Fruit Tobacco cut size: (b) Addition/Deletion of tobacco additive Addition of complex purchase	Al Fakher Strawberry Flavour 250 grams Grandfathered Not Applicable Plastic Pouch 250 g Strawberry Tobacco cut size: (b) mm Tobacco moisture: (b) es: ed flavor "(b) (4) " (b) (4)	
	EX0001362-PD1 Al Fakher Sweet Passion Fruit Flavour 1000 grams Not Applicable Not Applicable Not applicable Polyethylene Pouch 1000 g Sweet Passion Fruit Tobacco cut size: b mm Tobacco moisture: b Addition/Deletion of tobacco additive Addition of complex purchase Deletion of complex purchase () Increasing/Decreasing the quantity of Increase in the quantity of New Product	

Attributes	New Product	Original Product
STN	EX0001364-PD1	GF1908306
Product name	Al Fakher Iced Raspberry 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	Iced Raspberry Mint	Strawberry
Additional Property	Tobacco cut size:(b) mm	Tobacco cut size: <mark>b</mark> mm
Length	Tobacco moisture: <mark>(b</mark> %	Tobacco moisture: (b %
Product modifications	Tobacco moisture:       %       Tobacco moisture:       %         Addition/Deletion of tobacco additives:       •       Addition of complex purchased flavor "(b) (4)       "         •       Addition of complex purchased flavor (b) (4)       "       "       (b) (4)       "         •       Addition of complex purchased flavor (b) (4)       "       "       (b) (4)       "         •       Addition of complex purchased flavor "(b) (4)       "       "       (b) (4)       "       (b) (4)         •       Addition of complex purchased flavor "(b) (4)       "       "       (b) (4)       (b) (4)       "       (b) (4)       "       (b) (4)	