

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 Supervisor
 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 science	Thomas Creaven	6/8/2021

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. 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.¹

¹ 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.

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 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	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: (b) mm
	Tobacco moisture: (b) %	Tobacco moisture: (b) %
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)) • Deletion of complex purchased flavor (b) (4) " (b) (4)) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) • Increase in the quantity of (b) (4) 	

Attributes	New Product	Original Product
STN	EX0001354-PD1	GF1908308
Product name	Al Fakher Pina Colada 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	Polypropylene Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Pina Colada	Strawberry
Additional Properties	Tobacco cut size: (b) mm	Tobacco cut size: (b) mm
	Tobacco moisture: (b) %	Tobacco moisture: (b) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4) ” • Deletion of complex purchased flavor “(b) (4) ” (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	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: (b) %	Tobacco moisture: (b) %
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) • Deletion of complex purchased flavor “(b) (4) ” (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) • Increase in the quantity of (b) (4) 	

Attributes	New Product	Original Product
STN	EX0001356-PD1	GF1908303
Product name	Al Fakher Super Lemon Mint 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	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	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)” • Addition of complex purchased flavor “(b) (4) (b) (4)” • Deletion of complex purchased flavor “(b) (4) (b) (4)” • Deletion of (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	EX0001357-PD1	GF1908308
Product name	Al Fakher Super Lemon 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	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: (b) mm
Length	Tobacco moisture: (b) %	Tobacco moisture: (b) %
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • 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)” • Deletion of complex purchased flavor “(b) (4) (b) (4)” • Deletion of (b) (4)(b) (4) <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	

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	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)” • Addition of complex purchased flavor “(b) (4) (b) (4)” • Deletion of complex purchased flavor “(b) (4) (b) (4)” • Deletion of (b) (4) (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	EX0001359-PD1	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: (b) mm
Length	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4) (b) (4)” • Deletion of complex purchased flavor “(b) (4) (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	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: (b) %	Tobacco moisture: (b) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4) (b) (4)” • Deletion of complex purchased flavor “(b) (4) (b) (4) (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	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	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Addition of complex purchased flavor “(b) (4) (b) (4)” (b) (4) • Deletion of complex purchased flavor “(b) (4) (b) (4)” (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	EX0001362-PD1	GF1908306
Product name	Al Fakher Sweet Passion Fruit 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	Sweet Passion Fruit	Strawberry
Additional Property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
Length	Tobacco moisture: (b) (4)	Tobacco moisture: (b) (4)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Addition of complex purchased flavor "(b) (4) (b) (4) (b) (4)" Deletion of complex purchased flavor "(b) (4) (b) (4) (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	EX0001363-PD1	GF1908303
Product name	Al Fakher Sweet Passion Fruit 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	Sweet Passion Fruit	Strawberry
Additional Property	Tobacco cut size: (b) (4) mm	Tobacco cut size: (b) (4) mm
Length	Tobacco moisture: (b) (4)	Tobacco moisture: (b) (4)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> Addition of complex purchased flavor "(b) (4) (b) (4) (b) (4)" Deletion of complex purchased flavor "(b) (4) (b) (4) (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	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: (b) mm
Length	Tobacco moisture: (b) %	Tobacco moisture: (b) %
Product modifications	<p>Addition/Deletion of tobacco additives:</p> <ul style="list-style-type: none"> • 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))” • Addition of complex purchased flavor “(b) (4) (b) (4))” • Deletion of complex purchased flavor “(b) (4) (b) (4))” <p>Increasing/Decreasing the quantity of existing tobacco additives:</p> <ul style="list-style-type: none"> • Increase in the quantity of (b) (4) 	