

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

<b>New Tobacco Products Subject of this Review</b>	
Submission tracking numbers (STNs)	EX0001139, EX0001140, EX0001142, EX0001145, EX0001147-EX0001150, EX0001153, EX0001155, EX0001158, EX0001161, EX0001163, EX0001167, and EX0001168
<b>Common Attributes</b>	
Submission date	June 12, 2020
Receipt date	June 12, 2020
Applicant	Al Fakher Distribution USA, Inc.
Product manufacturer	Al Fakher Tobacco Factory, F.Z.E.
Product category	Waterpipe Tobacco Products
Product subcategory	Waterpipe Tobacco Filler
<b>Cross-Referenced Submissions</b>	
All EX Requests	None
<b>Supporting FDA Memoranda Relied Upon in this Review</b>	
All EX Requests	None
<b>Recommendation</b>	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

**Technical Project Lead (TPL):**

Digitally signed by Jeannie H. Jeong-im -S  
Date: 2021.01.19 11:21:38 -05'00'

Jeannie Jeong-Im, Ph.D.  
Chemistry Branch Chief  
Division of Product Science

**Signatory Decision:**

Concur with TPL recommendation and basis of recommendation

Digitally signed by Todd L. Cecil -S  
Date: 2021.01.19 13:15:57 -05'00'

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

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## 1. BACKGROUND

### 1.1. NEW AND ORIGINAL TOBACCO PRODUCTS

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

### 1.2. REGULATORY ACTIVITY

See appendices for tobacco products and amendments.

### 1.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new tobacco products subject of this review.

**Table 1. Disciplines reviewed**

Discipline	Cycle 1: Reviewer(s)	Review Date
regulatory (EX0001139, EX0001140, EX0001142, EX0001145, EX0001147 - EX0001150, EX0001153, and EX0001155)	Kathryn Mueller	6/18/2020
regulatory (EX0001158, EX0001161, EX0001163, EX0001167, and EX0001168)	Ranjeeta Gupta	6/19/2020
chemistry	Robert Gahl	12/9/2020
environmental science	Sang Ki Park	12/7/2020

## 2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco products in EX0001139, EX0001140, EX0001142, EX0001145, EX0001147 – EX0001150, EX0001153, EX0001155, EX0001158, EX0001161, EX0001163, EX0001167, and EX0001168 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 December 15, 2020, concludes that the evidence submitted by the applicant is adequate to demonstrate original tobacco products are grandfathered products.

Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.<sup>1</sup>

<sup>1</sup> 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. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive (b)(4) in EX0001142, EX0001145, EX0001147, EX0001149, EX0001153, EX0001155, EX0001158, EX0001161, EX0001163, and EX0001168
- increasing the quantity of an existing additive (b)(4) in tobacco filler) in EX0001142, EX0001145, EX0001147, EX0001149, EX0001153, EX0001155, EX0001158, EX0001161, EX0001163, and EX0001168
- decreasing the quantity of an existing additive (b)(4) in the tobacco filler) in EX0001139, EX0001140, EX0001148, EX0001150, and EX0001167
- decreasing the quantity of an existing additive (b)(4) in EX0001139, EX0001140, EX0001148, EX0001150, and EX0001167
- adding an additive (b)(4) in EX0001139 and EX0001140
- adding an additive (b)(4) in EX0001142
- adding an additive (b)(4) in EX0001145 and EX0001147
- adding additives (b)(4) in EX0001148-EX0001150
- adding additives (b)(4) in EX0001153 and EX0001155
- adding an additive (b)(4) in EX0001158 and EX0001161
- adding additives (b)(4) in EX0001163
- adding an additive (b)(4) in EX0001167
- adding an additive (b)(4) in EX0001168

### 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 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 FD&C Act.

### 5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Luis Valerio, Ph.D. on December 14, 2020. The FONSI was supported by an environmental assessment prepared by FDA on December 7, 2020

### 6. CONCLUSION AND RECOMMENDATION

I concur with the conclusion of the scientific review that these modifications (see Section 3) are minor modifications of a tobacco 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 tobacco products to be marketed would be appropriate for the protection of the public health.

The applicant proposes to modify the original tobacco products of EX0001142, EX0001145, EX0001147, EX0001149, EX0001153, EX0001155, EX0001158, EX0001161, EX0001163, and EX0001168 by deleting (b)(4) of the complex purchased flavor (b)(4) from the tobacco filler. Deletion of (b)(4) is accompanied by an addition of: (b)(4) (b)(4) in EX0001142, (b)(4) in EX0001145 and EX0001147, (b)(4) (b)(4) and (b)(4) in EX0001149, (b)(4) (b)(4) and (b)(4) in EX0001153 and EX0001155, (b)(4) (b)(4) in EX0001158 and EX0001161, (b)(4) and (b)(4) in EX0001163, and (b)(4) in EX0001168. All of these added flavors are mixtures of essential oils and carbonyl compounds that are present in less than 2% weight of the new tobacco products and is not anticipated to have measurable changes in the waterpipe tobacco smoke. In addition to these changes, there are 8-23% increases in the single chemical substance, glycerine. The primary component in (b)(4) and (b)(4) are (b)(4). An increase in humectants in waterpipe tobacco such as (b)(4) and (b)(4) may lead to greater quantities of HPHCs (e.g., acrolein, formaldehyde, acetaldehyde) in mainstream waterpipe smoke. After comparison of differences in levels of (b)(4) and (b)(4) (b)(4) in (b)(4) and (b)(4) the difference of is very small (b)(4) in the new tobacco products compared to their corresponding original tobacco products and are not expected to significantly alter HPHC yields. The applicant proposes to decrease the quantities of the complex purchased flavor (b)(4) and (b)(4) (b)(4) and add complex purchased flavors (b)(4) for EX0001139 and EX0001140, (b)(4) and (b)(4) for EX0001148 and EX0001150, and (b)(4) for EX0001167. (b)(4) and (b)(4) may lead to greater quantities of HPHCs (e.g., acrolein, formaldehyde, acetaldehyde) in mainstream waterpipe smoke. The primary component is (b)(4) in (b)(4) in EX0001139 and EX0001140. The difference of is very small (b)(4) in the new tobacco product compared to the original tobacco product. The other ingredients in (b)(4) are essential oils, carbonyl compound, and alcohols that are present at <1.6% weight of the new product and are not expected to significantly alter HPHC yields. (b)(4) are a mixture of flavors with (b)(4) (b)(4) as the primary component, respectively, that is present at 2.3% weight of the new products of EX0001148, EX0001150, and EX0001167. Therefore, these are minor modifications. These differences in flavors and additives are considered minor and not expected to significantly alter the smoke profile of the products. For all 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, research suggests that enjoyment of flavor has been associated with initiation and continued use of tobacco products (e.g., smokeless tobacco products), particularly among youth and young adults.<sup>2,3</sup> Since the differences in flavor between the new and original tobacco products are not changed between non-characterizing and characterizing flavors, as indicated by the use of flavor descriptors in the new and original tobacco products, based on current scientific evidence, these changes in flavor descriptors are not of concern to FDA at this time. Additionally, the modifications are not expected to materially affect any other characteristic (materials, ingredients, design,

<sup>2</sup> Couch ET, Darius EF, Walsh MM, Chaffee BW. ST product characteristics and relationships with perceptions and behaviors among rural adolescent males: a qualitative study. *Health Educ Res.* 2017;32(6):537-545.

<sup>3</sup> Ben Taleb Z, Breland A, Bahelah R, et al. Flavored Versus Nonflavored Waterpipe Tobacco: A Comparison of Toxicant Exposure, Puff Topography, Subjective Experiences, and Harm Perceptions. *Nicotine Tob Res.* 2019;21(9):1213-1219.

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 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 EX0001139, EX0001140, EX0001142, EX0001145, EX0001147-EX0001150, EX0001153, EX0001155, EX0001158, EX0001161, EX0001163, EX0001167, and EX0001168 as identified on the cover page of this review.

**7. APPENDICES**

**Appendix A. New and original tobacco products**

<b>Common Attributes</b>		
Submission date	June 12, 2020	
Receipt date	June 12, 2020	
Applicant	Al Fakher Distribution USA, Inc.	
Product manufacturer	Al Fakher Tobacco Factory, F.Z.E.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
<b>Attributes</b>	<b>New Tobacco Product</b>	<b>Original Tobacco Product</b>
<b>STN</b>	EX0001139	GF1908322
Product name	Al Fakher Fresh Flavour 1000 grams (g)	Al Fakher Mint Flavour 1 Kilogram (Kg)
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Fresh	Mint
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Decrease in the quantity of (b)(4) in the tobacco filler</li> <li>Decrease in the quantity of the complex purchased flavor (b)(4)</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001140	GF1908319
Product name	Al Fakher Fresh Flavour 250 grams	Al Fakher Mint 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 Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Fresh	Mint
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Decrease in the quantity of (b)(4) in the tobacco filler</li> <li>Decrease in the quantity of the complex purchased flavor (b)(4)</li> </ul>	
STN	EX0001142	GF1908308
Product name	Al Fakher Cinnamon 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 Plastic Pouch	Polypropylene Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Cinnamon	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Deletion of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	



EX0001139, EX0001140, EX0001142, EX0001145, EX0001147-EX0001150, EX0001153, EX0001155, EX0001158, EX0001161, EX0001163, EX0001167, and EX0001168

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001145	GF1908303
Product name	Al Fakher Bubble Gum 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 Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Bubble Gum	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Deletion of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	
STN	EX0001147	GF1908308
Product name	Al Fakher Bubble Gum 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 Plastic Pouch	Polypropylene Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Bubble Gum	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Deletion of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001148	GF1908319
Product name	Al Fakher Grapefruit with Mint Flavour 250 grams	Al Fakher Mint 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 Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Grapefruit with mint	Mint
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Addition of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Decrease in the quantity of (b)(4) in the tobacco filler</li> <li>Decrease in the quantity of the complex purchased flavor (b)(4)</li> </ul>	
STN	EX0001149	GF1908306
Product name	Al Fakher Grapefruit 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 Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Grapefruit	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Deletion of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001150	GF1908313
Product name	Al Fakher Grapefruit with Mint Flavour 50 grams	Al Fakher Mint 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 Plastic Pouch	Polypropylene Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Grapefruit with mint	Mint
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Addition of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Decrease in the quantity of (b)(4) in the tobacco filler</li> <li>Decrease in the quantity of the complex purchased flavor (b)(4)</li> </ul>	
STN	EX0001153	GF1908308
Product name	Al Fakher Grenadine 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 Plastic Pouch	Polypropylene Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Grenadine	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Deletion of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001155	GF1908303
Product name	Al Fakher Grenadine 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 Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Grenadine	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of the complex purchased flavor (b)(4)</li> <li>• Addition of the complex purchased flavor (b)(4)</li> <li>• Deletion of the complex purchased flavor (b)(4)</li> </ul>	
	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	
STN	EX0001158	GF1908306
Product name	Al Fakher Guava 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 Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Guava	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of the complex purchased flavor (b)(4)</li> <li>• Deletion of the complex purchased flavor (b)(4)</li> </ul>	
	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001161	GF1908308
Product name	Al Fakher Guava 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 Plastic Pouch	Polypropylene Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Guava	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives:	
	<ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Deletion of the complex purchased flavor (b)(4)</li> </ul>	
Additional property	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> <li>Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	
STN	EX0001163	GF1908306
Product name	Al Fakher Gum with Cinnamon 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 Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Gum with Cinnamon	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives:	
	<ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Deletion of the complex purchased flavor (b)(4)</li> </ul>	
Additional property	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> <li>Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001167	GF1908322
Product name	Al Fakher Mojito Flavour 1000 grams	Al Fakher Mint 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 Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Mojito	Mint
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Decrease in the quantity of (b)(4) in the tobacco filler</li> <li>Decrease in the quantity of the complex purchased flavor (b)(4)</li> </ul>	
STN	EX0001168	GF1908306
Product name	Al Fakher Vanilla Flavour 1000 grams	Al Fakher Strawberry Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Polyethylene Plastic Pouch	Polyethylene Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Vanilla	Strawberry
Additional property	Tobacco cut size: (b)(4)	Tobacco cut size: (b)(4)
	Tobacco moisture: 10%	Tobacco moisture: 10%
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b)(4)</li> <li>Deletion of the complex purchased flavor (b)(4)</li> </ul> Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> <li>Increase in the quantity of (b)(4) in the tobacco filler</li> </ul>	

**Appendix B. Amendments**

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Status	Brief Description
December 3, 2020	December 3, 2020	EX0001372	EX0001139, EX0001140, EX0001142, EX0001145, EX0001147- EX0001150, EX0001153, EX0001155, EX0001158, EX0001161, EX0001163, EX0001167 EX0001168	Yes	Active	Response to December 1, 2020 FDA Information Request
December 4, 2020	December 4, 2020	EX0001373	EX0001145	Yes	Active	Response to December 3, 2020 FDA Information Request