

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

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001082, EX0001083, EX0001087-EX0001089, EX0001092-EX0001094, EX0001120-EX0001125, and EX0001208
Common Attributes	
Submission date	May 5, 2020, <sup>1</sup> May 21, 2020, <sup>2</sup> and July 6, 2020 <sup>3</sup>
Receipt date	May 5, 2020, <sup>1</sup> May 21, 2020, <sup>2</sup> and July 6, 2020 <sup>3</sup>
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
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 Jeannie H. Jeong-im -S  
Date: 2020.12.15 14:26:31 -05'00'

Jeannie Jeong-Im  
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: 2020.12.15 22:44:37 -05'00'

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

<sup>1</sup> For EX0001082, EX0001083, EX0001087-EX0001089, and EX0001092-EX0001094

<sup>2</sup> For EX0001120-EX0001125

<sup>3</sup> For EX0001208

**TABLE OF CONTENTS**

**1. BACKGROUND..... 3**  
    1.1. NEW AND ORIGINAL TOBACCO PRODUCTS ..... 3  
    1.2. REGULATORY ACTIVITY ..... 3  
    1.3. SCOPE OF REVIEW..... 3

**2. COMPLIANCE REVIEW..... 3**

**3. TOBACCO ADDITIVE MODIFICATION..... 4**

**4. SCIENTIFIC REVIEW..... 4**

**5. ENVIRONMENTAL DECISION..... 5**

**6. CONCLUSION AND RECOMMENDATION..... 5**

**7. APPENDICES..... 7**

## 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 (EX0001082- EX0001083, EX0001087-EX0001089, EX0001092-EX0001094)	Kathryn Mueller	5/14/2020
regulatory (EX0001120- EX0001125)	Ranjeeta Gupta	5/28/2020
regulatory (EX0001208)	Ravi Choudhuri	7/13/2020
chemistry	Robert Gahl	11/16/2020
environmental science	Sang Ki Park	11/12/2020

## 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 EX0001082, EX0001083, EX0001087-EX0001089, EX0001092-EX0001094, and EX0001120-EX0001125 are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE review dated November 17, 2020 for EX0001082, EX0001083, EX0001087, EX0001088, EX0001092 concludes that the evidence submitted by the applicant is adequate to demonstrate original tobacco products are grandfathered products. The OCE review dated November 18, 2020 for EX0001093, EX0001094, EX0001120-EX0001125 concludes that the evidence submitted by the applicant is adequate to demonstrate original tobacco products are grandfathered products. The OCE review dated November 23, 2020 for EX0001089 concludes that the evidence submitted by the applicant is adequate to demonstrate that the original tobacco product is a grandfathered product.

The original tobacco product in EX0001208 was determined to be substantially equivalent and in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) by FDA.

Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.<sup>4</sup>

### 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:

- adding an additive (b) (4) in EX0001082, EX0001083, EX0001087-EX0001089, and EX0001092-EX0001094
- increasing the quantity of an existing additive (b) (4) in tobacco filler) in EX0001082, EX0001083, and EX0001089
- decreasing the quantity of an existing additive (b) (4) in EX0001082
- decreasing the quantity of an existing additive (b) (4) in EX0001083 and EX0001089
- decreasing the quantity of an existing additive ((b) (4) in the tobacco filler) in EX0001087, EX0001088, EX0001092-EX0001094, and EX0001120-EX0001125
- decreasing the quantity of an existing additive (b) (4) in EX0001087 and EX0001088
- increasing the quantity of an existing additive (b) (4) in EX0001087 and EX0001088
- deleting an additive, (b) (4), in an existing additive (b) (4) in EX0001092
- adding an additive, (b) (4) in an existing additive (b) (4) in EX0001092
- decreasing the quantity an existing additive (b) (4) in EX0001092
- decreasing the quantity an existing additive (b) (4) in EX0001093, EX0001094, EX0001122, and EX0001123
- decreasing the quantity an existing additive (b) (4) in EX0001093, EX0001094, EX0001122, and EX0001123
- adding an additive (b) (4) in EX0001120-EX0001125
- decreasing the quantity of an existing additive (b) (4) in EX0001120 and EX0001121
- decreasing the quantity of an existing additive (b) (4) in EX0001124 and EX0001125
- deleting multiple additives in (b) (4) in EX0001208
- adding multiple additives in (b) (4) in EX0001208

### 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

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<sup>4</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.

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 November 17, 2020. The FONSI was supported by an environmental assessment prepared by FDA on November 17, 2020.

## 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 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.

In EX0001082, EX0001083, EX0001087-EX0001089, EX0001093-EX0001094, <(b) mg/g of (b) (b) (4) is added, which results in the addition of (b) (4) .To offset this small addition, there are decreases of: (b) (4) in EX0001082; (b) (4) (b) (4) in EX0001083 and EX0001089; (b) (4) in both EX0001087 and EX0001088; (b) (4) (b) (4) in EX0001092; and (b) (4) and (b) (4) in both EX0001093 and EX0001094. (b) (4) is increased in EX0001087 and EX0001088, but the major ingredient is (b) (4) that increased by less than (b) (4) mg/g. There are also decreases of (b) (4) % of (b) (4) in the original tobacco products of EX0001087, EX0001088, and EX0001092-EX0001094 and increases of 1-2% in the original tobacco products of EX0001082, EX0001083, and EX0001089. These differences are minor and not expected to significantly alter HPHC yields. In EX0001120-EX0001125, (b) (4) mg/g of (b) (4) is added to the tobacco filler. To offset this addition, there are decreases in: (b) (4) in EX0001120 and EX0001121; (b) (4) and (b) (4) in EX0001122 and EX0001123; and (b) (4) in EX0001124 and EX0001125. There are also decreases of 1-7% in the single chemical substance, (b) (4) in the original tobacco products of EX0001120-EX0001125. Since (b) (4) is approximately 82% (b) (4) , the addition is (b) (4) mg/g, and the addition is offset by decreasing other flavorings, the differences are not expected to significantly affect smoke chemistry or HPHC yields. In EX0001092, (b) (4) mg/g of (b) (4) (b) (4) in complex flavoring (b) (4) is deleted and (b) (4) mg/g of (b) (4) is added as the commercially available formulation has changed. Also, (b) (4) is approximately 83% (b) (4) (b) (4) . Therefore, the ingredients are similar and this is a minor modification. In EX0001208, (b) (4) in the original tobacco product has been reformulated by the supplier. Multiple ingredients in (b) (4) are added/deleted/increased/decreased, but the same quantity of (b) (4) mg/g is present in both the new and original tobacco products. Therefore, this is a minor modification. These differences in flavors and additives are considered minor and not expected to significantly alter the smoke profile of the products. 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, 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>5,6</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, 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 as of February 15, 2007 or previously found SE and in compliance with the FD&C Act by FDA.

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 EX0001082, EX0001083, EX0001087-EX0001089, EX0001092-EX0001094, EX0001120-EX0001125, and EX0001208, as identified on the cover page of this review.

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<sup>5</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>6</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.

**7. APPENDICES**

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

<b>Common Attributes</b>		
Submission date	May 5, 2020 <sup>1</sup> , May 21, 2020 <sup>2</sup> , and July 6, 2020 <sup>3</sup>	
Receipt date	May 5, 2020 <sup>1</sup> , May 21, 2020 <sup>2</sup> , and July 6, 2020 <sup>3</sup>	
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>	EX0001082	GF1908347
Product name	Al Fakher Cherry with Mint Flavour 1000 grams	Al Fakher Cherry Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>7</sup>	Plastic Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Cherry with Mint	Cherry
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
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>Increase in the quantity of (b) (4)</li> <li>Decrease in the quantity of the complex purchased flavor (b) (4)</li> </ul>	

<sup>7</sup> Polyethylene pouch

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001083	GF1908331
Product name	Al Fakher Grape with Mint Flavour 1000 grams	Al Fakher Grape Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>7</sup>	Plastic Pouch	Plastic Pouch
Package quantity	1000g	1 Kg
Characterizing flavor	Grape with Mint	Grape
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b) (4) (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)</li> <li>Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4)</li> </ul>	
STN	EX0001087	GF1908332
Product name	Al Fakher Lemon with Mint Flavour 1000 grams	Al Fakher Lemon Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>7</sup>	Plastic Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Lemon with Mint	Lemon
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of the complex purchased flavor (b) (4) (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)</li> <li>Decrease in the quantity of complex purchased flavor (b) (4) (b) (4)</li> <li>Increase in the quantity of complex purchased flavor (b) (4) (b) (4)</li> </ul>	

<sup>8</sup> Page 4 of EX0001087 and EX0001088 describe changes to the complex purchased ingredient (b) (4) rather than (h) (4) as listed in Exhibit C in these EX Requests. This is presumably a typographical error by the applicant and (b) (4) is used in this review to describe modifications of the new and original tobacco products of EX0001087 and EX0001088.



Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001088	GF1908326
Product name	Al Fakher Lemon with Mint Flavour 50 grams	Al Fakher Lemon Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>9</sup>	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Lemon with Mint	Lemon
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
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>Increase in the quantity of complex purchased flavor (b) (4)</li> <li>Decrease in the quantity of (b) (4)</li> <li>Decrease in the quantity of complex purchased flavor (b) (4)</li> <li></li> </ul>	
STN	EX0001089	GF1908333
Product name	Al Fakher Grape with Mint Flavour 50 grams	Al Fakher Grape Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>9</sup>	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Grape with Mint	Grape with Mint
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
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>Increase in the quantity of (b) (4)</li> <li>Decrease in the quantity of complex purchased flavor (b) (4)</li> </ul>	

<sup>9</sup> Polypropylene pouch

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001092	GF1908305
Product name	Al Fakher Two Apples with Mint Flavour 1000 grams	Al Fakher Two Apple Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>7</sup>	Plastic Pouch	Plastic Pouch
Package quantity	1000 g	1 Kg
Characterizing flavor	Two Apples with Mint	Two Apple
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of anise star oil in the complex flavor ingredient (b) (4)</li> <li>• Addition of (b) (4) in the complex flavor ingredient (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)</li> <li>• Decrease in the quantity of complex purchased flavor (b) (4)</li> </ul>	
STN	EX0001093	GF1908315
Product name	Al Fakher Orange with Mint Flavour 250 grams	Al Fakher Orange Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>7</sup>	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Orange with Mint	Orange
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
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)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4)</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001094	GF1908318
Product name	Al Fakher Orange with Mint Flavour 50 grams	Al Fakher Orange Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>9</sup>	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Orange with Mint	Orange
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
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)</li> <li>Decrease in the quantity of complex purchased flavor (b) (4)</li> <li>Decrease in the quantity of complex purchased flavor (b) (4)</li> </ul>	
STN	EX0001120	GF1908313
Product name	Al Fakher Mint with Cream 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 <sup>9</sup>	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Mint with Cream	Mint
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
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)</li> <li>Decrease in the quantity of the complex purchased flavor (b) (4)</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001121	GF1908319
Product name	Al Fakher Mint with Cream 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 <sup>7</sup>	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Mint with Cream	Mint
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of the complex purchased flavor (b) (4) (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)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4)</li> </ul>	
STN	EX0001122	GF1908315
Product name	Al Fakher Orange with Cream Flavour 250 grams	Al Fakher Orange Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>7</sup>	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Orange with Cream	Orange
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of the complex purchased flavor (b) (4) (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)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4)</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001123	GF1908318
Product name	Al Fakher Orange with Cream Flavour 50 grams	Al Fakher Orange Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>9</sup>	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Orange with Cream	Orange
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of the complex purchased flavor (b) (4) (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)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4)</li> </ul>	
STN	EX0001124	GF1908303
Product name	Al Fakher Strawberry with Cream 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 <sup>7</sup>	Plastic Pouch	Plastic Pouch
Package quantity	250 g	250 g
Characterizing flavor	Strawberry with Cream	Strawberry
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of the complex purchased flavor (b) (4) (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)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4) (b) (4)</li> </ul>	

Attributes	New Tobacco Product	Original Tobacco Product
STN	EX0001125	GF1908308
Product name	Al Fakher Strawberry with Cream 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 <sup>9</sup>	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Strawberry with Cream	Strawberry
Additional property	Tobacco cut size: 11 mm Tobacco moisture: 10%	Tobacco cut size: 11 mm 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)</li> <li>• Decrease in the quantity of the complex purchased flavor (b) (4)</li> </ul>	
STN	EX0001208	SE0015700
Product name	Al Fakher Plum Flavour 50 grams	Al Fakher Plum Flavour 50 grams
Eligibility status	Not applicable	Previously found SE
Marketing authorization date	Not applicable	6/30/2020
Abbreviated report date	Not applicable	Not applicable
Package type <sup>9</sup>	Plastic Pouch	Plastic Pouch
Package quantity	50 g	50 g
Characterizing flavor	Plum	Plum
Additional property	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %	Tobacco cut size: (b) (4) mm Tobacco moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of multiple additives in the complex purchased flavor (b) (4)</li> <li>• Addition of multiple additives in the alternate complex purchased (b) (4)</li> </ul>	

**Appendix B. Amendments**

Submission Date	Receipt Date	Amendment	Applications being amended	Reviewed	Status	Brief Description
November 3, 2020	November 3, 2020	EX0001317	EX0001082- EX0001083, EX0001087- EX0001089, EX0001092- EX0001094, EX0001120- EX0001125	Yes	Active	Response to October 29, 2020 FDA Information Request
November 19, 2020	November 19, 2020	EX0001365	EX0001089	Yes	Active	Response to November 18, 2020 email request from OCE
November 20, 2020	November 20, 2020	EX0001366	EX0001089	Yes	Active	Response to November 20, 2020 email request