

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

New Tobacco Products Subject of this Review	
Submission tracking numbers (STNs)	EX0001096, EX0001097, EX0001100
Common Attributes	
Submission date	May 7, 2020
Receipt date	May 7, 2020
Applicant	Al Fakher Distribution USA, Inc.
Product manufacturer	Al Fakher Tobacco Factory, F.Z.E., UAE
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: 2021.02.17 16:31:48 -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: 2021.02.18 07:50:33 -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		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
regulatory	Kathryn Muller	5/15/2020	Not Assigned	N/A
chemistry	Jason Hsieh	10/29/2020	Jason Hsieh	1/21/2021
environmental science	Hermes Reyes Caballero	10/2/2020	Hermes Reyes Caballero	1/19/2021

## 2. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed a review to determine whether the applicant established that the original tobacco products are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE reviews dated September 21, 2020 for EX0001096 and September 28, 2020 for EX0001097 and EX0001100 conclude 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>

## 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 all the EX Requests
- decreasing the quantities of existing additives (b)(4) in all the EX Requests

<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.

#### 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 February 3, 2021. The FONSI was supported by an environmental assessment prepared by FDA on February 3, 2021.

#### 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. In all EX Reports, the applicant proposed to add an additive (b)(4) and offset the addition by decreasing the quantities of additives (b)(4). (b)(4) is the largest single chemical ingredient in (b)(4). Although (b)(4) increases, (b)(4) decreases by twice the amount. Both (b)(4) and (b)(4) are expected to lead to the same the harmful and potentially harmful constituents (HPHC) during use (e.g., acrolein, formaldehyde, acetaldehyde); therefore, the increase in (b)(4) is considered minor. Also, the flavoring (b) contains (b)(4) (b)(4) mg/g) is added to the new tobacco products. However, the flavoring (b) which contains (b)(4) that is composed mainly of (b)(4), decreases in the new tobacco products by more than (b) mg/g. All other flavoring ingredients were below 1 mg/g and the proposed changes are considered minor and are not anticipated to have a measurable effect on the tobacco smoke. 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, composition, heating source, or other features) of the tobacco products. Lastly, I find that an exemption for these modifications 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.

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<sup>2</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.

<sup>3</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.

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.

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 EX0001096, EX0001097, and EX0001100 as identified on the cover page of this review.

7. APPENDICES

Appendix A. New and original tobacco products

Common Attributes		
Submission date	May 7, 2020	
Receipt date	May 7, 2020	
Applicant	Al Fakher Distribution USA, Inc.	
Product manufacturer	Al Fakher Tobacco Factory, F.Z.E., UAE	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
Attributes	<b>New Tobacco Product</b>	<b>Original Tobacco Product</b>
STN	EX0001096	GF1908322
Product name	Al Fakher Blueberry with Mint Flavour 1000 grams	Al Fakher Mint Flavour 1Kg
Eligibility status	Not applicable	Grandfathered
Marketing authorization date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type <sup>4</sup>	Pouch	Pouch
Package quantity	1 Kg	1 Kg
Characterizing flavor	Blueberry with Mint	Mint
Additional property	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>Addition of (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) (b)(4) (b)(4)</li> <li>Decrease in the quantity of (b)(4)</li> </ul>	

<sup>4</sup> Polyethylene

STN	EX0001097	GF1908319
Product name	Al Fakher Blueberry 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 <sup>4</sup>	Pouch	Pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Blueberry with Mint	Mint
Additional property	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of (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) (b)(4) (b)(4)</li> <li>• Decrease in the quantity of (b)(4)</li> </ul>	
STN	EX0001100	GF1908313
Product name	Al Fakher Blueberry 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 <sup>4</sup>	Pouch	Pouch
Package quantity	50 grams	50 grams
Characterizing flavor	Blueberry with Mint	Mint
Additional property	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)	Tobacco cut size: (b)(4) Tobacco moisture: (b)(4)
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Addition of (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) (b)(4) (b)(4)</li> <li>• Decrease in the quantity of (b)(4)</li> </ul>	

**Appendix B. Amendments**

<b>Submission Date</b>	<b>Receipt Date</b>	<b>Applications being amended</b>	<b>Reviewed</b>	<b>Brief Description</b>
November 25, 2020	November 25, 2020	All STNs	Yes	Response to October 30, 2020 Deficiency Letter