

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

New Products Subject of this Review <sup>1</sup>	
STNs	EX0002185.PD1-EX0002187.PD1
Common Attributes	
Submission date	July 26, 2021
Receipt date	July 26, 2021
Applicant	AIR Distribution USA Inc.
Product manufacturer	Al Fakher Tobacco Factory, F.Z.E.
Product category	Waterpipe
Product subcategory	Waterpipe Tobacco Filler
Cross-Referenced Submissions	
All new STNs	None
Supporting FDA Memoranda Relied Upon in this Review	
All new STNs	None
Recommendation	
Issue Exempt (EX) orders for the new tobacco products subject of this review.	

**Technical Project Lead (TPL):**

Digitally signed by Tricia L. Johnson -S  
Date: 2022.08.15 08:39:29 -04'00'

Tricia L. Johnson, M.A.  
Supervisory Chemist  
Division of Product Science

**Signatory Decision:**

Concur with TPL recommendation and basis of recommendation

**Todd L. Cecil -S** Digitally signed by Todd L. Cecil -S  
Date: 2022.08.15 08:47:58 -04'00'

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

<sup>1</sup> Product details, amendments, and dates provided in the Appendix. EX means exemption (request) from substantial equivalence. STN means submission tracking number.

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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.

### 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**

Discipline	Cycle 1	
	Reviewer(s)	Review Date
Regulatory	Noor-UI-Huda Dawood	7/14/2022
Chemistry	Kyle Ferguson	6/29/2022
Environmental science	Carla Figueroa	6/21/2022

## 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 (i.e., were commercially marketed in the United States as of February 15, 2007). The OCE review dated, June 22, 2022, 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>2</sup>

## 3. TOBACCO ADDITIVE MODIFICATION

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

- deleting an additive (b) (4) in all the EX Requests
- adding an additive (b) (4) in all the EX Requests
- adding an additive (b) (4) in all the EX Requests
- adding an additive (b) (4) in all the EX Requests
- increasing the quantity of an existing additive (b) (4) in all the EX Requests

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<sup>2</sup> Any 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 products. The review concludes that the modifications are minor modifications of a 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 June 22, 2022. The FONSI was supported by an environmental assessment prepared by FDA on June 22, 2022.

#### 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 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 products to be marketed would be appropriate for the protection of the public health.

For all EX Requests, the applicant proposed modifying all the original products by deleting a complex flavor additive, “(b) (4)” (all EX Requests), from the waterpipe tobacco filler in the corresponding new products, adding the complex flavor additives, (b) (4), to the waterpipe tobacco filler in the corresponding new products, and increasing the quantity of an existing additive, (b) (4), to the waterpipe tobacco filler in the corresponding new products. The applicant claims that the complex flavor additive, (b) (4), is no longer commercially available, and therefore the addition of the complex flavor additives, (b) (4) are used in the new products to maintain manufacturing consistency between all the new and corresponding original products. The finished new and corresponding original products contain 50 grams (EX0002185.PD1), 1000 grams (EX0002186.PD1) and 250 grams (EX0002187.PD1), with a container closure system (CCS) consisting of a polypropylene pouch (new product: EX0002185.PD1), polyethylene pouch (new products: EX0002186.PD1 and EX0002187.PD1), and a plastic pouch (corresponding original products). The outer packaging in all the new and corresponding original products is a box. The (b) (4), and design parameters (i.e., tobacco cut size, moisture content) are identical in all the new and corresponding original products. The applicant claims that both the new and corresponding original products contain characterizing flavors (i.e., “Magic Love” (new products) and “Strawberry” (original products)).

The complex flavor, (b) (4) which is deleted from the waterpipe tobacco filler in all the new products, consists of (b) (4) and other ingredients in nanogram and microgram quantities. The complex flavor, (b) (4) which is added to the waterpipe tobacco filler in all the new products, contains a mixture of (b) (4). The deletion of the complex flavor, (b) (4) and the addition of the

complex flavor, (b) (4) resulted in the following single ingredient quantity differences between the new and corresponding original products: (b) (4)

(b) (4) Pyrolysis of (b) (4) and (b) (4) is shown to yield certain mainstream smoke yields, such as carbonyls and other toxicants. The complex flavor, (b) (4) represents (b) (4) [(b) (4) g (EX0002185.PD1), (b) (4) g (EX0002186.PD1), and (b) (4) g (EX0002187.PD1)] of the total weight in all the original products and the complex flavor, (b) (4) ", represents (b) (4) [(b) (4) g (EX0002185.PD1), (b) (4) g (EX0002186.PD1), and (b) (4) g (EX0002187.PD1)] of the total weight in the corresponding new products. Although the percent quantity differences between the two complex flavors appear large, the absolute quantity differences on a gram per gram basis are significantly small, relative to the total waterpipe tobacco filler weight in all the new products.

The complex flavors, (b) (4) are added to the waterpipe tobacco filler in all the new products. The complex flavor, (b) (4) contains (b) (4) (b) (4) is a complex natural ingredient, composed of mostly (b) (4) , and under pyrolysis may yield benzo[α]pyrene, phenol, and other toxicants. The complex flavor, (b) (4) contains mostly (b) (4) (b) (4) ther toxicants. However, waterpipe tobacco typically burns at a lower temperature than cigarettes, which minimizes the formation of certain HPHCs. The complex flavor, (b) (4) of the total waterpipe tobacco filler weight in all the new products.

Increasing the quantity of an existing additive, (b) (4) , resulted in a (b) (4) addition to the waterpipe tobacco filler in all the new products compared to the corresponding original products. (b) (4) is primarily used as a humectant and humectants (i.e., (b) (4) ) are found in the total particulate matter phase in waterpipe tobacco smoke, producing acetaldehyde, acrolein, and formaldehyde under certain pyrolysis conditions. Overall, glycerine quantity represents (b) (4) , of the total weight in the new products. However, the total humectant quantity change represents (b) (4) (b) (4) g (EX0002185.PD1), (b) (4) g (EX0002186.PD1), and (b) (4) g (EX0002187.PD1)] of the total weight in the new products compared to the corresponding original products. This ingredient change is small in the new products compared to the corresponding original products and is not anticipated to have a measurable impact on the mainstream smoke yields, from a chemistry perspective.

Collectively, the proposed modifications to the original products in EX0002185.PD1-EX0002187.PD1 are minor modifications in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Lastly, I find that an exemption for these modifications are 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<sup>3</sup>

Common Attributes		
Submission date	July 26, 2021	
Receipt date	July 26, 2021	
Applicant	AIR Distribution USA Inc.	
Product manufacturer	Al Fakher Tobacco Factory, F.Z.E.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
Attributes	New Product	Original Product
STN	EX0002185	GF1908308
Static Product ID	PD1	
Product Name	Al Fakher Magic Love Flavour 50 grams	Al Fakher Strawberry Flavour 50 grams
Package Type	Polypropylene pouch	Plastic pouch
Package Quantity	50 grams (g)	50 g
Characterizing Flavor	Magic Love	Strawberry
Eligibility status	Not Applicable (N/A)	N/A
Marketing authorization date	N/A	N/A
Abbreviated report	N/A	N/A
Tobacco cut size	11 millimeters (mm)	11 mm
Tobacco moisture	10%	10%
Product Modification	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> </ul> Increasing the quantity of existing tobacco additive: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	

<sup>3</sup> Brand/sub-brand or other commercial name used in commercial distribution.

Attributes	New Product	Original Product
STN	EX0002186	GF1908306
Static Product ID	PD1	
Product Name	Al Fakher Magic Love Flavour 1000 grams	Al Fakher Strawberry Flavour 1 Kg
Package Type	Polyethylene pouch	Plastic Pouch
Package Quantity	1000 g	1000 g <sup>4</sup>
Characterizing Flavor	Magic Love	Strawberry
Eligibility status	N/A	N/A
Marketing authorization date	N/A	N/A
Abbreviated report	N/A	N/A
Tobacco cut size	11 mm	11 mm
Tobacco moisture	10%	10%
Product modification	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> </ul> Increasing the quantity of existing tobacco additive: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	
STN	EX0002187	GF1908303
Static Product ID	PD1	
Product Name	Al Fakher Magic Love Flavour 250 grams	Al Fakher Strawberry Flavour 250 grams
Package Type	Polyethylene pouch	Plastic Pouch
Package Quantity	250 g	250 g
Characterizing Flavor	Magic Love	Strawberry
Eligibility status	N/A	N/A
Marketing authorization date	N/A	N/A
Abbreviated report	N/A	N/A
Tobacco cut size	11 mm	11 mm
Tobacco moisture	10%	10%
Product modification	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> <li>• Deletion of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> <li>• Addition of (b) (4)</li> </ul> Increasing the quantity of existing tobacco additive: <ul style="list-style-type: none"> <li>• Increase in the quantity of (b) (4)</li> </ul>	

<sup>4</sup> 1000 grams = 1 Kilogram