

## Technical Project Lead (TPL) Review: SE0015696 – SE0015701

<b>SE0015696: Al Fakher Melon Flavour 50 grams</b>	
Package Type	Plastic Pouch
Package Quantity	50 grams (g)
Characterizing Flavor <sup>1</sup>	Melon
Additional Property	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE0015697: Al Fakher Pineapple Flavour 50 grams</b>	
Package Type	Plastic Pouch
Package Quantity	50 g
Characterizing Flavor <sup>1</sup>	Pineapple
Additional Property	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE0015698: Al Fakher Coconut Flavour 50 grams</b>	
Package Type	Plastic Pouch
Package Quantity	50 g
Characterizing Flavor <sup>1</sup>	Coconut
Additional Property	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE0015699: Al Fakher Mango Flavour 50 grams</b>	
Package Type	Plastic Pouch
Package Quantity	50 g
Characterizing Flavor <sup>1</sup>	Mango
Additional Property	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE0015700: Al Fakher Plum Flavour 50 grams</b>	
Package Type	Plastic Pouch
Package Quantity	50 g
Characterizing Flavor <sup>1</sup>	Plum
Additional Property	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE0015701: Al Fakher Cocktail Flavour 50 grams</b>	
Package Type	Plastic Pouch
Package Quantity	50 g
Characterizing Flavor <sup>1</sup>	Cocktail
Additional Property	Tobacco moisture: 10% Tobacco cut size: (b) (4)

<sup>1</sup> As provided by the applicant's certification statement. For Product Quantity Change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

Common Attributes of SE Reports	
Applicant	Al Fakher Distribution USA, Inc.
Report Type	Regular Product Quantity Change
Product Category	Waterpipe Tobacco Product
Product Sub-Category	Waterpipe Tobacco Filler
Recommendation	
Issue Substantially Equivalent (SE) orders.	

**Technical Project Lead (TPL):**

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Date: 2020.06.30 13:33:18 -04'00'

Colleen K. Rogers, Ph.D.  
Director  
Division of Product Science  
Office of Science

**Signatory Decision:**

- Concur with TPL recommendation and basis of recommendation
- Concur with TPL recommendation with additional comments (see separate memo)
- Do not concur with TPL recommendation (see separate memo)

Digitally signed by Matthew R. Holman -S  
Date: 2020.06.30 13:44:40 -04'00'

Matthew R. Holman, Ph.D.  
Director  
Office of Science

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**1. BACKGROUND**

**1.1. PREDICATE TOBACCO PRODUCTS**

The applicant submitted the following predicate tobacco products:

<b>SE001 S696: Al Fakher Melon Flavour 50 grams</b>	
<b>Product Name</b>	Al Fakher Melon Flavour 250 grams
<b>Package Type</b>	Plastic Pouch
<b>Package Quantity</b>	250 g
<b>Characterizing Flavor<sup>1</sup></b>	Melon
<b>Additional Property</b>	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE001 S697: Al Fakher Pineapple Flavour 50 grams</b>	
<b>Product Name</b>	Al Fakher Pineapple Flavour 250 grams
<b>Package Type</b>	Plastic Pouch
<b>Package Quantity</b>	250 g
<b>Characterizing Flavor<sup>1</sup></b>	Pineapple
<b>Additional Property</b>	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE001 S698: Al Fakher Coconut Flavour 50 grams</b>	
<b>Product Name</b>	Al Fakher Coconut Flavour 250 grams
<b>Package Type</b>	Plastic Pouch
<b>Package Quantity</b>	250 g
<b>Characterizing Flavor<sup>1</sup></b>	Coconut
<b>Additional Property</b>	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE001 S699: Al Fakher Mango Flavour 50 grams</b>	
<b>Product Name</b>	Al Fakher Mango Flavour 250 grams
<b>Package Type</b>	Plastic Pouch
<b>Package Quantity</b>	250 g
<b>Characterizing Flavor<sup>1</sup></b>	Mango
<b>Additional Property</b>	Tobacco moisture: 10% Tobacco cut size: (b) (4)
<b>SE001 S700: Al Fakher Plum Flavour 50 grams</b>	
<b>Product Name</b>	Al Fakher Plum Flavour 250 grams
<b>Package Type</b>	Plastic Pouch
<b>Package Quantity</b>	250 g
<b>Characterizing Flavor<sup>1</sup></b>	Plum
<b>Additional Property</b>	Tobacco moisture: 10% Tobacco cut size: (b) (4)

SE0015701: Al Fakher Cocktail Flavour 50 grams	
Product Name	Al Fakher Cocktail Flavour 250 grams
Package Type	Plastic Pouch
Package Quantity	250 g
Characterizing Flavor <sup>1</sup>	Cocktail
Additional Property	Tobacco moisture: 10% Tobacco cut size: (b) (4)

The predicate tobacco products are waterpipe tobacco filler manufactured by Al Fakher Distribution USA, Inc.

### 1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On February 7, 2020, FDA received six Product Quantity Change (PQ) Substantial Equivalence (SE) Reports (SE0015696 - SE0015701) from Troutman Sanders LLP, on behalf of Al Fakher Distribution USA, Inc. On February 26, 2020, FDA issued an Acceptance letter. On March 2, 2020, March 9, 2020, and March 16, 2020, FDA received amendments (SE0015750, SE0015761, and SE0015778, respectively) in response to requests for information. On May 14, 2020, FDA received an amendment (SE0016609) providing an updated certification statement as requested in a teleconference dated May 13, 2020. FDA issued a Deficiency letter to the applicant on June 17, 2020, for SE0015696, SE0015699-SE0015701. On June 26, 2020, FDA received an amendment (SE0016742) responding to the Deficiency letter for SE0015696, SE0015699-SE0015701.

Product Name	SE Report	Amendments
Al Fakher Melon Flavour 50 grams	SE0015696	SE0015750 SE0015761 SE0015778 SE0016609 SE0016742
Al Fakher Pineapple Flavour 50 grams	SE0015697	SE0015750 SE0015761
Al Fakher Coconut Flavour 50 grams	SE0015698	SE0015778 SE0016609
Al Fakher Mango Flavour 50 grams	SE0015699	SE0015750 SE0015761
Al Fakher Plum Flavour 50 grams	SE0015700	SE0015778 SE0016609
Al Fakher Cocktail Flavour 50 grams	SE0015701	SE0016742

### 1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these SE Reports.

## **2. REGULATORY REVIEW**

Regulatory reviews were completed by Donna Cheung on February 24, 2020, and Kathryn Mueller on May 22, 2020.

The final reviews conclude that the SE Reports are administratively complete.

## **3. COMPLIANCE REVIEW**

OCE completed reviews to determine whether the applicant established that the predicate 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). The OCE reviews dated March 17, 2020 (SE0015696 – SE0015698) and March 19, 2020 (SE0015699 – SE0015701), conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are grandfathered and, therefore, are eligible predicate tobacco products.

OCE also completed a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see section 910(a)(2)(A)(i)(II) of the FD&C Act). The OCE review dated April 10, 2020, concludes that the new tobacco products are in compliance with the FD&C Act.

## **4. SCIENTIFIC REVIEW**

Scientific review was not initiated by the Office of Science (OS) because the product characteristics of the new and corresponding predicate tobacco products are identical except for a change in product quantity. OS prepared memoranda<sup>2</sup> summarizing its current thinking on product quantity changes. Existing data on product quantity changes are limited and do not address the size threshold (i.e., how much of a change in product quantity) necessary to raise different questions of public health. With respect to product quantity decreases, even though some of the currently available scientific evidence is specific to tobacco products, the studies do not separate out the effect of reduced price from size on consumption or initiation. Thus, based upon the currently available science and CTP's experience in reviewing SE Reports, product quantity changes do not cause new tobacco products to raise different questions of public health. Therefore, scientific review is unnecessary.

## **5. ENVIRONMENTAL DECISION**

An environmental review was completed by Dilip Venugopal on March 16, 2020.

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on March 16, 2020. The FONSI was supported by an environmental assessment prepared by FDA on March 16, 2020.

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<sup>2</sup> See memorandum on product quantity changes, dated December 7, 2017, and addendum for deemed tobacco products, dated December 30, 2019.

## **6. CONCLUSION AND RECOMMENDATION**

The product characteristics of the new and corresponding predicate tobacco products are identical except for a decrease in product quantity from 250 grams to 50 grams (↓80%).

The OS memoranda<sup>2</sup> conclude that based on OS' experience and the currently available evidence, the difference in product quantity does not cause the new tobacco products to raise different questions of public health. I concur with this conclusion.

The predicate tobacco products in SE0015696 – SE0015701 meet statutory requirements because it was determined that they are grandfathered products (i.e., were commercially marketed in the United States other than exclusively in test markets as of February 15, 2007).

The new tobacco products are currently in compliance with the FD&C Act.

FDA examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0015696 – SE0015701, as identified on the cover page of this review.