

**Technical Project Lead (TPL) Review of Exemption Requests:
EX0001036, EX0001038, EX0001039, EX0001042 – EX0001044,
EX0001046, EX0001047, EX0001051, and EX0001052**

Common Attributes of EX Requests		
Applicant	Al Fakher Distribution USA, Inc.	
Product category	Waterpipe Tobacco Products	
Product subcategory	Waterpipe Tobacco Filler	
EX Requests Included in this Review		
Tobacco Product	New	Original
Submission tracking number	EX0001036	GF1908358
Product name	Al Fakher Apricot Flavour 1000 grams	Al Fakher Apricot Flavour 1Kg ¹
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	1000 grams	1000 grams
Characterizing flavor	Apricot	Apricot
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives:	
	<ul style="list-style-type: none"> • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

¹ The package quantity was stated as 1 Kg, which was converted to 1000 grams.

Tobacco Product	New	Original
Submission tracking number	EX0001038	GF1908354
Product name	Al Fakher Banana Flavour 250 grams	Al Fakher Banana Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Banana	Banana
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives:	
	<ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001039	GF1908357
Product name	Al Fakher Banana Flavour 1000 grams	Al Fakher Banana Flavour 1Kg ¹
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	1000 grams	1000 grams
Characterizing flavor	Banana	Banana
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives:	
	<ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001042	GF1908356
Product name	Al Fakher Apricot Flavour 50 grams	Al Fakher Apricot Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	50 grams	50 grams
Characterizing flavor	Apricot	Apricot
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001043	GF1908355
Product name	Al Fakher Apricot Flavour 250 grams	Al Fakher Apricot Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Apricot	Apricot
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001044	GF1908352
Product name	Al Fakher Banana Flavour 50 grams	Al Fakher Banana Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	50 grams	50 grams
Characterizing flavor	Banana	Banana
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives:	
	<ul style="list-style-type: none"> Deletion of (b) (4) in the complex purchased flavor (b) (4) 	
Product modifications	Increasing/Decreasing the quantity of existing tobacco additives:	
	<ul style="list-style-type: none"> Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001046	GF1908307
Product name	Al Fakher Rose Flavour 250 grams	Al Fakher Rose Flavour 250 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	250 grams	250 grams
Characterizing flavor	Rose	Rose
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001047	GF1908312
Product name	Al Fakher Rose Flavour 50 grams	Al Fakher Rose Flavour 50 grams
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	50 grams	50 grams
Characterizing flavor	Rose	Rose
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) 	
	Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	

Tobacco Product	New	Original
Submission tracking number	EX0001051	GF1908311
Product name	Al Fakher Rose Flavour 1000 grams	Al Fakher Rose Flavour 1 Kg ¹
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	1000 grams	1000 grams
Characterizing flavor	Rose	Rose
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Addition of (b) (4) in the complex purchased flavor (b) (4) Increasing/Decreasing the quantity of existing tobacco additives: <ul style="list-style-type: none"> • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) • Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4) 	
Tobacco Product	New	Original
Submission tracking number	EX0001052	GF1908316
Product name	Al Fakher Plum Flavour 1000 grams	Al Fakher Plum Flavour 1 Kg
Eligibility status	Not applicable	Grandfathered
Marketing order date	Not applicable	Not applicable
Abbreviated report date	Not applicable	Not applicable
Package type	Plastic Pouch	Plastic Pouch
Package quantity	1000 grams	1000 grams
Characterizing flavor	Plum	Plum
Additional properties	Tobacco Cut Size: (b) (4)	Tobacco Cut Size: (b) (4)
	Tobacco Moisture: (b) (4) %	Tobacco Moisture: (b) (4) %
Product modifications	Addition/Deletion of tobacco additives: <ul style="list-style-type: none"> • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex purchased flavor (b) (4) • Deletion of (b) (4) in the complex purchased flavor (b) (4) 	

	<ul style="list-style-type: none">• Increasing the quantity of (b) (4) in the complex purchased flavor “Sabrina 16070701-D HF” (Hertz Flavors GmbH & Co. KG)• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)• Increasing the quantity of (b) (4) in the complex purchased flavor (b) (4)
Recommendation Issue Exempt (EX) order.	

Technical Project Lead (TPL):

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Date: 2020.06.18 15:46:01 -04'00'

Matthew J. Walters, Ph.D., MPH
CDR, US Public Health Service
Deputy Director
Division of Product 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: 2020.06.18 16:55:56 -04'00'

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

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1. BACKGROUND

1.1. ORIGINAL TOBACCO PRODUCTS

The original tobacco products are waterpipe tobacco filler manufactured by the applicant as indicated on the cover page of this review.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

On April 14, 2020, FDA received ten Exemption Requests (EX0001036, EX0001038-EX0001039, EX0001042-EX0001044, EX0001046-EX0001047, EX0001051-EX0001052) from Troutman Sanders LLP, on behalf of Al Fakher Distribution USA, Inc. On April 28, 2020, FDA conducted a teleconference to request the applicant provide updated certification statements. On April 29, 2020, FDA received an amendment (EX0001068) including the updated certification statements. On May 5, 2020, FDA received an amendment (EX0001075) in response to OCE's request for information to complete 905(j)(3) status review for all EX requests. On May 8, 2020, FDA issued an Acceptance letter. On May 12, 2020, FDA received an amendment (EX0001111) in response to OCE's request for additional information to complete 905(j)(3) status review for EX0001042 and EX0001044. On May 13, 2020 FDA received an amendment (EX0001114) in response to a follow up request by OCE for additional information.

1.3. SCOPE OF REVIEW

This review captures all regulatory, compliance, and scientific reviews completed for these Exemption Requests.

1.4. TOBACCO ADDITIVE MODIFICATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

For EX0001036, EX0001042, EX0001043:

- adding additives (b) (4) deleting additives (b) (4) and increasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4)

For EX0001038, EX0001039, EX0001044:

- deleting an additive (b) (4) increasing the quantities of existing additives (b) (4) in the complex purchased flavor (b) (4)

For EX0001046, EX0001047, and EX0001051:

- deleting additives (b) (4) adding an additive (b) (4) increasing the quantities of existing additives (b) (4) in the complex purchased flavor (b) (4)

For EX00001052:

- adding additives (b) (4)
[REDACTED]
[REDACTED] in the complex purchase flavor (b) (4)
- deleting additives (b) (4)
[REDACTED]
[REDACTED] in in the complex purchase flavor (b) (4)
- decreasing the quantity of an existing additive (b) (4) in the complex purchase flavor (b) (4)
- increasing the quantities of existing additives (b) (4)
[REDACTED]
[REDACTED] in in the complex purchase flavor (b) (4)

2. REGULATORY REVIEW

Regulatory reviews were completed by Kathryn Mueller on May 8, 2020. The reviews conclude that the Exemption Requests are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that 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). The OCE reviews dated May 20, 2020 for EX0001036 and EX0001038; May 21, 2020 for EX0001039 and EX0001043; May 22, 2020 for EX0001042, EX0001044, EX0001046; and May 23, 2020 for EX0001047, EX0001051 and EX0001052 conclude that the original tobacco products are grandfathered products. Therefore, the original tobacco products are eligible for modification under the Exemption Request pathway.²

4. SCIENTIFIC REVIEW

A chemistry review was completed by Jason Hseih on June 18, 2020.

The review states that the new tobacco products have been modified by adding or deleting tobacco additives for all EX Requests and increasing and decreasing the quantity of existing tobacco additives in all EX Requests. Complex purchased flavors are used in the manufacturing of the original tobacco

² 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.

products, and 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 Federal Food, Drug, and Cosmetic Act (FD&C Act).

In EX0001036, EX0001042, EX0001043, (b) (4), and (b) (4) was added, (b) (4) (b) (4) and (b) (4) was deleted, and the quantity of (b) (4) was increased in the complex purchased flavor (b) (4) and are minor modifications. In EX0001038, EX0001039, EX0001044, (b) (4) was deleted and the quantities of (b) (4) and (b) (4) was increased in the complex purchased flavor (b) (4) and are minor modifications. In EX0001046, EX0001047, and EX0001051, (b) (4) and (b) (4) was deleted, (b) (4) was added, and the quantities of (b) (4) and (b) (4) were increased in the complex purchased flavor (b) (4) and are minor modifications. For EX0001052, multiple additives were added or deleted, and multiple existing additives were increased or decreased in the complex purchase flavor (b) (4) and are minor modifications. In all of the above EX Requests, the changes 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, the modifications are not expected to materially affect any other characteristic (materials, ingredients, design, composition, heating source, or other features) of the tobacco products.

5. ENVIRONMENTAL DECISION

An environmental review was completed by Dilip Venugopal on May 22, 2020.

The review found that the applicant did not provide information regarding marketing of the original tobacco products and information regarding if the new products are intended to compete with or replace portions of other waterpipe tobacco products currently on the market. Therefore, additional information is needed to determine whether to prepare an environmental impact statement (EIS) or finding of no significant impact (FONSI).

6. CONCLUSION AND RECOMMENDATION

The new tobacco products contain the following modifications compared to the corresponding original tobacco products:

For EX0001036, EX0001042, EX0001043:

- adding additives (b) (4) deleting additives (b) (4) and (b) (4), and increasing the quantity of an existing additive (b) (4) in the complex purchased flavor (b) (4)

For EX0001038, EX0001039, EX0001044:

- deleting an additive (b) (4) increasing the quantities of existing additives (b) (4) in the complex purchased flavor (b) (4)

For EX0001046, EX0001047, and EX0001051:

- deleting additives (b) (4) adding an additive (b) (4) increasing the quantities of existing additives ((b) (4) and (b) (4)) in the complex purchased flavor (b) (4)

For EX00001052:

- adding additives ((b) (4), (b) (4), (b) (4), and (b) (4)) in the complex purchase flavor (b) (4)
- deleting additives (b) (4) (b) (4), (b) (4), and (b) (4)) in in the complex purchase flavor (b) (4)
- decreasing the quantity of an existing additive (b) (4) in the complex purchase flavor (b) (4)
- increasing the quantities of existing additives (b) (4) in in the complex purchase flavor (b) (4)

I concur with the conclusion of the scientific review that these modifications are minor modifications of a tobacco product in accordance with section 905(j)(3)(A)(i) of the FD&C Act. Section 900(1) of the FD&C Act defines ‘additive’ as “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), . . .” I concur with the scientific review that the changes represent adding or deleting tobacco additives for all EX Requests and increasing and decreasing the quantity of existing tobacco additives in all EX Requests. In addition, I concur with the scientific reviews that the changes represent the addition, deletion, increasing of existing tobacco additives, and/or decreasing of existing tobacco additives in complex purchased flavors. 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 protection of the public health. In EX0001036, EX0001042, EX0001043, (b) (4) (b) (4), and (b) (4) was added, (b) (4) and (b) (4) was deleted, and the quantity of (b) (4) was increased in the complex purchased flavor (b) (4) and are minor modifications. In EX0001038, EX0001039, EX0001044, (b) (4) was deleted and the quantities of ben (b) (4) and (b) (4) was increased in the complex purchased flavor (b) (4) and are minor modifications. In EX0001046, EX0001047, and EX0001051, (b) (4) and (b) (4) was deleted, (b) (4) was added, and the quantities of (b) (4) and (b) (4) were increased in the complex purchased flavor (b) (4) and are minor modifications. For EX0001052, multiple additives were added or deleted, and multiple existing additives were increased or decreased in the complex purchase

flavor (b) (4) and are minor modifications. 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, 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, FDA finds, based on the information contained in the Exemption Requests and CTP’s scientific understanding, 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 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 these new tobacco products exempt from substantial equivalence and found that additional information is necessary to determine the impact of the action. Without this information, FDA may be precluded or delayed from issuing an EX order.

An Environmental Information Request letter should be issued requesting the following information:

1. Your EX Requests lack information regarding marketing of the original tobacco products after receiving marketing orders for the new tobacco products. Marketing information is used to assess the cumulative environmental impacts of concurrent manufacturing, use, and disposal of the new and original tobacco products. You stated that the original products were currently not marketed to consumers in the United States. Clarify whether the new and corresponding original tobacco products would be marketed simultaneously after receiving marketing orders for the new tobacco products, or if the original tobacco products will continue to not be marketed to consumers in the United States. If the original tobacco products will be marketed, provide the projected market volumes in the first and fifth years of marketing the new tobacco products. Table 1 can be used to provide this information, or you can submit this information using an alternative approach if it provides the first- and fifth-year market volume projections for the original tobacco products.

Table 1. Market volume projections for the original tobacco products

Original Tobacco Product	Unit	First Year	Fifth Year
Al Fakher Apricot Flavour 1 Kg (GF1908361)			
Al Fakher Banana Flavour 250 grams (GF1908354)			
Al Fakher Banana Flavour 1 Kg (GF1908357)			
Al Fakher Apricot Flavour 50 grams (GF1908356)			

Al Fakher Apricot Flavour 250 grams (GF1908355)			
Al Fakher Banana Flavour 50 grams (GF1908352)			
Al Fakher Rose Flavour 250 grams (GF1908307)			
Al Fakher Rose Flavour 50 grams (GF1908312)			
Al Fakher Rose Flavour 1 Kg (GF1908311)			
Al Fakher Plum Flavour 1 Kg (GF1908316)			

2. Your EX Requests lack information regarding if the new tobacco products are intended to compete with or replace portions of other waterpipe tobacco products currently on the market. Provide a statement if the new tobacco products are intended to compete with or replace portions of other waterpipe tobacco products currently on the market. The information about marketing of the new tobacco products are used to assess the environmental impacts of the proposed actions.

If the applicant adequately responds to the request and an EIS or FONSI is completed, an EX order should be issued for the new tobacco products in EX0001036, EX0001038, EX0001039, EX0001042 – EX0001044, EX0001046, EX0001047, EX0001051, and EX0001052, as identified on the cover page of this review.