

**Programmatic Environmental Assessment for Marketing
Orders for New Waterpipe Tobacco Products Manufactured
by Al Fakher Distribution USA, Inc.**

**Prepared by Center for Tobacco Products
U.S. Food and Drug Administration**

November 17, 2020

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1. Applicant and Manufacturer Information

Applicant Name:	Al Fakher Distribution USA, Inc.
Applicant Address:	14931 Gwenchris Court Paramount, CA 90723
Manufacturer Name:	Al Fakher Tobacco Factory, F.Z.E.
Product Manufacturing Location:	P.O. Box 20037, Free Zone Gate No. 4 Ajman, United Arab Emirates

2. Product Information

New Tobacco Product Names, Submission Tracking Numbers (STN), and Original Tobacco Product Names

New Tobacco Product		Original Tobacco Product	
Name	STN	Name	STN
Al Fakher Cherry with Mint Flavour 1000 grams	EX0001082	Al Fakher Cherry Flavour 1 Kg	GF1908347
Al Fakher Grape with Mint Flavour 1000 grams	EX0001083	Al Fakher Grape Flavour 1 Kg	GF1908331
Al Fakher Lemon with Mint Flavour 1000 grams	EX0001087	Al Fakher Lemon Flavour 1Kg	GF1908332
Al Fakher Lemon with Mint Flavour 50 grams	EX0001088	Al Fakher Lemon Flavour 50 grams	GF1908326
Al Fakher Grape with Mint Flavour 50 grams	EX0001089	Al Fakher Grape Flavour 50 grams	GF1908333
Al Fakher Two Apples with Mint Flavour 1000 grams	EX0001092	Al Fakher Two Apple Flavour 1Kg	GF1908305
Al Fakher Orange with Mint Flavour 250 grams	EX0001093	Al Fakher Orange Flavour 250 grams	GF1908315
Al Fakher Orange with Mint Flavour 50 grams	EX0001094	Al Fakher Orange Flavour 50 grams	GF1908318
Al Fakher Mint with Cream Flavour 50 grams	EX0001120	Al Fakher Mint Flavour 50 grams	GF1908313
Al Fakher Mint with Cream Flavour 250 grams	EX0001121	Al Fakher Mint Flavour 250 grams	GF1908319
Al Fakher Orange with Cream Flavour 250 grams	EX0001122	Al Fakher Orange Flavour 250 grams	GF1908315
Al Fakher Orange with Cream Flavour 50 grams	EX0001123	Al Fakher Orange Flavour 50 grams	GF1908318
Al Fakher Strawberry with Cream Flavour 250 grams	EX0001124	Al Fakher Strawberry Flavour 250 grams	GF1908303
Al Fakher Strawberry with Cream Flavour 50 grams	EX0001125	Al Fakher Strawberry Flavour 50 grams	GF1908308
Al Fakher Plum Flavour 50 grams	EX0001208	Al Fakher Plum Flavour 50 grams	SE0015700

Product Identification

Product Category:	Waterpipe Tobacco
Product Subcategory:	Waterpipe Tobacco Filler
Product Number per Retail Unit:	Product quantity includes 50, 250, and 1000 grams
Product Package:	An outer box with inner polypropylene pouch containing waterpipe tobacco filler.

3. The Need for the Proposed Actions

The proposed actions, requested by the applicant, are for the Food and Drug Administration (FDA) to issue exemptions from substantial equivalence (SE) reporting for marketing orders under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for 15 waterpipe tobacco products. A tobacco product that is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, may be considered for exemption from demonstrating substantial equivalence if (1) the product is a modification of another tobacco product and the modification is minor, (2) the modifications are to a tobacco product that may be legally marketed under the FD&C Act, (3) an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health, (4) the modified tobacco product is marketed by the same organization as the original product, and (5) an exemption is otherwise appropriate.

The new tobacco products are newly deemed waterpipe tobaccos that according to the applicant are currently manufactured for commercial distribution in the United States. The applicant wishes to continue to market the new tobacco products in the United States. The applicant must obtain written notification that FDA has granted the products exemptions from demonstrating substantial equivalence under section 905(j)(3) before submitting an abbreviated report. Ninety days after FDA receipt of the abbreviated report, the applicant may introduce or deliver for introduction into interstate commerce for commercial distribution the new products for which the applicant has obtained exemptions from demonstrating substantial equivalence.

The original products are grandfathered products commercially marketed in the United States as of February 15, 2007, except the one for EX0001208, which is a product previously found SE. The new products are made by modifying the corresponding original products. These modifications are to the flavor additives (Confidential Appendix 1).

4. Alternatives to the Proposed Actions

The no-action alternative is FDA does not issue marketing orders for the new tobacco products.

5. Potential Environmental Impacts of the Proposed Actions and Alternatives – Manufacturing the New Tobacco Products

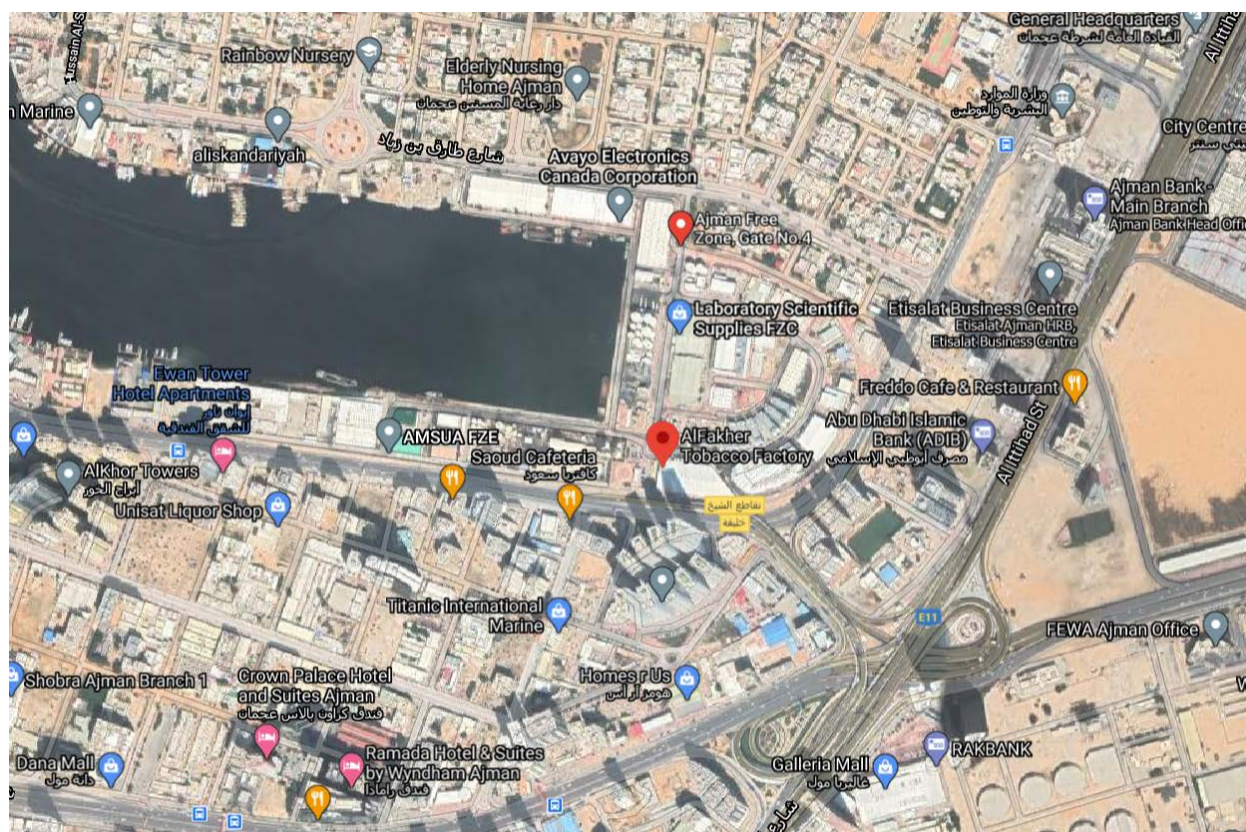
The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new products and found no significant impacts based on the Agency-gathered information and the following applicant-submitted information:

- The new tobacco products are currently marketed in the United States.
- No facility expansion or new construction is expected due to manufacturing the new products.
- Components of the new products are commonly used in other products manufactured at the facility.

5.1 Affected Environment

The affected environment includes human and natural environments surrounding the facility. The new products would be manufactured at the address listed in section 1 of this document (Figure 1).

Figure 1. Location of the Manufacturing Facility¹



The manufacturing facility is located in Ajman, United Arab Emirates. The facility is located in a densely populated mixed industrial, commercial, and residential area. A harbor is located to the west, which opens to the Persian Gulf. The facility is located on a major highway.

5.2 Air Quality

The Agency does not anticipate that manufacturing the new products would cause the release of any new chemicals or new type of emissions into the environment. The applicant stated that manufacturing the new products would not require additional environmental controls for air emissions.

¹ Google (2020). Map of Google maps. Available at: www.google.com/maps. accessed October 26, 2020.

5.3 Water Resources

The Agency does not anticipate that manufacturing the new products would cause the discharge of any new chemicals into water. The new products are intended to replace similar tobacco products currently manufactured at the facility. The applicant stated that manufacturing the new products would not require any additional environmental controls for water discharges.

5.4 Soil, Land Use, and Zoning

The Agency does not anticipate that manufacturing the new products would lead to changes in soil, land use, or zoning. The applicant stated that there would be no expected facility expansion or new construction due to manufacturing the new products. Therefore, there would be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.

5.5 Biological Resources

The Agency does not anticipate that manufacturing the new products would jeopardize the continued existence of any listed species or result in the destruction or adverse modification of the habitat of any such species identified under the Endangered Species Act (ESA) though the facility is outside of the United States. The applicant stated that the manufacturing facility is not within close proximity to any critical habitat of a threatened or endangered species.

5.6 Regulatory Compliance

The applicant stated that the manufacturing facility complies with all applicable environmental regulations.

The applicant also stated that the facility complies with the ESA and the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

5.7 Socioeconomics and Environmental Justice

No changes on socioeconomics are anticipated due to manufacturing the new products. The Agency does not anticipate any impacts on employment, revenue, or taxes because the new products are intended to replace similar tobacco products currently manufactured at the facility.

5.8 Solid Waste and Hazardous Materials

The Agency does not foresee that the introduction of the new products would notably affect the current manufacturing waste generated from the facility production of all waterpipe tobacco. The Agency anticipates the waste generated due to manufacturing the new products would be released to the environment and disposed of in landfills in the same manner as any other waste generated from any other products manufactured in the same facility. The applicant stated that manufacturing the new products would not require any additional environmental controls for solid waste disposal. Therefore, no new or revised waste permit or construction of new waste management facility is expected.

5.9 Floodplains, Wetlands, and Coastal Zones

There would be no facility expansion due to manufacturing the new products and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.

5.10 Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing waterpipe tobacco at the listed facility, as many similar tobacco products would continue to be manufactured.

6. Potential Environmental Impacts of the Proposed Actions and Alternatives – Use of the New Tobacco Products

The Agency considered potential impacts to resources in the environment that could be affected by use of the new products and found no significant impacts based on Agency-gathered information and the applicant's submitted information. Included in the information the Agency considered were the projected market volumes for the new products (Confidential Appendix 2).

6.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

6.2. Air Quality

The impacts from use of waterpipe tobacco products include exposure to secondhand smoke (SHS) produced from burned tobacco at homes, hookah bars, lounges, or anywhere else they are used. Particles emitted by smoking may remain on surfaces, be re-emitted back into the gas phase, or react with oxidants and other compounds in the environment to yield secondary pollutants, thirdhand smoke (THS). These pollutants coexist in mixtures in the environment alongside SHS (Burton, 2011; Matt et al., 2011). While these studies focus on SHS from cigarette smoking, research suggests that SHS from waterpipe smoking may be worse due to higher concentrations of carcinogens, carbon monoxide, and other chemicals (Daher et al., 2010; Weitzman et al., 2016). Carbon monoxide poisoning has been reported for users of waterpipe tobacco products as well as non-users in environments where waterpipe tobacco was being consumed (Kocak et al., 2017), raising concerns for employees and non-smoking patrons of establishments where waterpipe tobacco is consumed.

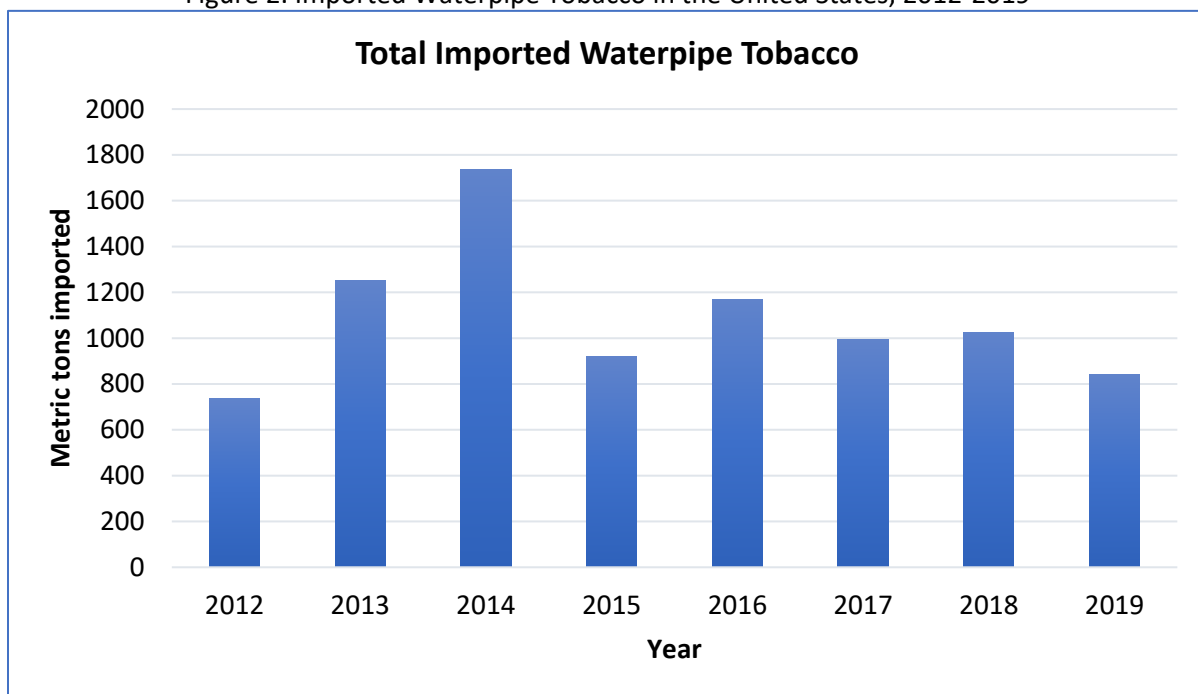
There is no safe level of exposure to SHS (U.S. Department of Health and Human Services, 2006a and 2006b). Even low levels of SHS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30% (U.S. Department of Health and Human Services, 2014).
- Exposure to SHS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. It can cause coughing, wheezing, phlegm, and breathlessness (U.S. Department of Health and Human Services, 2006a and 2006b).

- SHS causes more than 40,000 deaths a year (U.S. Department of Health and Human Services, 2014).

Although overall use of waterpipe tobacco does not appear to be changing based on import data since 2012² (Figure 2), use of waterpipe by youth and young adults is increasing (Grinberg, 2015). Researchers believe this increase is due to the belief that waterpipe tobacco smoking is less addictive and harmful than cigarette smoking (Primack et al., 2008). Waterpipe tobacco smoking exposes users to nicotine, carbon monoxide, polycyclic aromatic hydrocarbons, volatile aldehydes, phenols, heavy metals and other constituents (Primack et al., 2016). Comparisons between cigarette smoking and waterpipe tobacco smoking suggests that users of waterpipe inhale as much as 120 times the tobacco smoke than cigarette users in a single session with increased concentrations of many components found in cigarette smoke. Waterpipe tobacco smoking is associated with various respiratory diseases, cancer, low birthweight, cardiovascular disease, and other health related issues (Waziry et al., 2017). This is especially concerning considering the prevalence of youth use (Primack et al. 2016).

Figure 2. Imported Waterpipe Tobacco in the United States, 2012-2019



As of March 2020, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2020). Such laws are expected to reduce the levels of non-user exposure to SHS and THS.

The Agency does not anticipate that new chemicals would be released into the environment as a result of use of the new products, relative to chemicals released into the environment due to use of other waterpipe tobacco products already on the market because (1) the combustion products from the new products would be released in the same manner as the combustion products of the original products and any other marketed waterpipe tobacco products; and (2) the new products are already currently on

² U.S. International Trade Commission (ITC) statistical data available at: <https://dataweb.usitc.gov/trade/search/Import/HTS>. Accessed February 28, 2020.

the market; and (3) the ingredients in the new products are used in other currently marketed tobacco products.

6.3. Environmental Justice

No new emissions are expected due to use of the new products. Therefore, there would be no disproportionate impacts on minority or low-income populations.

6.4. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of waterpipe tobacco, as many similar tobacco products would continue to be used in the United States.

7. Potential Environmental Impacts of the Proposed Actions and Alternatives – Disposal of the New Tobacco Products

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new products. Based on the applicant's submitted information, including market volume projections for the new products, the Agency found no significant impacts.

7.1. Affected Environment

The affected environment includes human and natural environments in the United States because the marketing orders would allow for the new tobacco products to be sold to consumers in the United States.

7.2. Air Quality

The Agency does not anticipate disposal of the new products or the packaging material would lead to the release of new or increased chemicals into the air.

No changes in air quality are anticipated from disposal of the new products. The chemicals in the new products are commonly used in other currently marketed waterpipe tobacco. Because the new products are anticipated to compete with or replace other currently marketed waterpipe tobacco, the waste generated from the new products would replace the same type of waste. Therefore, the fate and effects of any materials emitted into the air from disposal of the new products are anticipated to be the same as any materials from other waterpipe tobacco disposed of in the United States.

No changes in air quality from disposal of the new products' package materials would be expected because (1) the paper and plastic components of the packages are more likely to be recycled, or at least a portion of the packaging waste is likely to be recycled, (2) the packaging materials are commonly used in the United States, and (3) the waste generated due to disposal of the new products' packaging is a minuscule portion of the municipal solid waste (U.S. Environmental Protection Agency, 2019) per FDA's experience in evaluating the packaging waste generated from tobacco products.

7.3. Biological Resources

The proposed actions are not expected to change the continued existence of any endangered species or result in the destruction or adverse modification of the habitat of any such species, as prohibited under the U.S. ESA. The new products are not expected to change disposal conditions as (1) the disposal of the

new products would be the same as the disposal of other waterpipe tobacco products that are currently marketed in the United States, and (2) there would be no anticipated increase in amount of waterpipe tobacco being disposed of as the new products are already on the market and anticipated to compete with similar marketed waterpipe tobacco.

7.4. Water Resources

No changes in any impacts on water resources are expected due to disposal of the waterpipe tobacco and packaging from the new products because the chemicals in the new products would be used in currently marketed waterpipe tobacco. Furthermore, the new products are already on the market and would compete with other waterpipe tobacco on the market.

Information on environmental impacts of disposal of water from waterpipe smoking is scarce. However, users who smoke waterpipe tobacco at home discard the water waste in various places including down the drain and in storm drains (Kaseem et al., 2019). This is concerning considering the various compounds that may leach out of the discarded water after disposal including remaining heavy metals (Al-Kazwini et al., 2015).

Waterpipe tobacco contains ingredients used in cigarettes. While waterpipe tobacco is mainly heated but not combusted during use, similar types of toxic chemicals of discarded waterpipe water may leach out to the environment as cigarette butts. Discarded cigarette butts are known to leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015). Individually, marketing these products is not expected to increase overall consumption of waterpipe tobacco and waterpipe tobacco imports (Confidential Appendix 2).

7.5. Solid Waste

Information on environmental impacts of disposal of tobacco from waterpipe smoking is scarce. However, users who smoke waterpipe tobacco at home discard the waste in various places including trashcans, down the drain, in potted plants, in their yard, and in storm drains (Kaseem et al., 2019). This is concerning considering the various compounds that may leach out of the discarded tobacco, water, and charcoal after disposal including remaining heavy metals (Al-Kazwini et al., 2015).

Waterpipe tobacco contains ingredients used in cigarettes. While waterpipe tobacco is mainly heated but not combusted during use, similar types of toxic chemicals of discarded waterpipe tobacco and water may leach out to the environment as cigarette butts. Discarded cigarette butts are known to leach out into water, potentially threatening human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015).

The Agency does not foresee the introduction of the new products would notably affect the current waterpipe tobacco and packaging waste generated from all waterpipe tobacco products. The waste generated due to disposal of the new products would be handled in the same manner as any other waste generated from any other waterpipe tobacco products marketed in the United States. The amount of waterpipe tobacco generated would be equivalent to the market projections (Confidential Appendix 2).

7.6. Socioeconomics and Environmental Justice

The Agency does not anticipate changes in impacts on socioeconomic conditions or environmental justice from disposal of the new products. The waste generated due to disposal of the new products

would be handled in the same manner as the waste generated from disposal of other waterpipe tobacco products in the United States. No new emissions are expected due to disposal of the new products; therefore, there would be no disproportionate impacts on minority or low-income populations.

7.7. Impacts of the No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of disposal of waterpipe tobacco and packaging, as many other similar tobacco products would continue to be disposed of in the United States.

8. List of Preparers

The following individuals were primarily responsible for preparing and reviewing this programmatic environmental assessment:

Preparer:

Sang Ki Park, Ph.D., D.A.B.T., Center for Tobacco Products
Education: M.S. in Biochemistry and Ph.D. in Toxicology
Experience: 12 years in regulatory toxicology review at FDA
Expertise: Chemical risk assessment

Reviewer:

Hoshing Chang, Ph.D., Center for Tobacco Products
Education: M.S. in Environmental Science and Ph.D. in Biochemistry
Experience: 12 years in FDA-related NEPA review
Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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CONFIDENTIAL APPENDIX 1. Modifications: New Tobacco Products as Compared with the Corresponding Original Tobacco Products

STN	Components	Modification
EX0001082	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Increase in (b) (4) • Decrease in purchased complex flavor (b) (4)
EX0001083	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Increase in (b) (4) • Decrease in purchased complex flavor (b) (4)
EX0001087 EX0001088	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Decrease in (b) (4) • Increase in purchased complex flavor (b) (4) • Decrease in purchased complex flavor (b) (4)
EX0001089	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Increase in (b) (4) • Decrease in purchased complex flavor (b) (4)
EX0001092	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Deletion of (b) (4) and addition of (b) (4) in purchased complex flavor (b) (4) • Decrease in (b) (4) • Decrease in purchased complex flavor (b) (4)
EX0001093 EX0001094	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Decrease in (b) (4) • Decrease in purchased complex flavor (b) (4) • Decrease in purchased complex flavor (b) (4)
EX0001120 EX0001121	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Decrease in purchased complex flavor (b) (4) • Decrease in (b) (4)
EX0001122 EX0001123	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Decrease in purchased complex flavor (b) (4) • Decrease in purchased complex flavor (b) (4) • Decrease in (b) (4)
EX0001124 EX0001125	Tobacco Additives	<ul style="list-style-type: none"> • Addition of purchased complex flavor (b) (4) • Decrease in purchased complex flavor (b) (4) • Decrease in (b) (4)
EX0001208	Tobacco Additives	<ul style="list-style-type: none"> • Reformulation of a complex purchased flavor (b) (4) resulting in the deletion, addition, decrease and increase in the amounts of various additives.

CONFIDENTIAL APPENDIX 2. Current Market Volumes and First- and Fifth-Year Market Volume Projections for the New and Corresponding Original Products and Percentage of Waterpipe Tobacco Imported to be Attributed to the New Products

Current market volume and first- and fifth-year market volume projections of the new products were compared to the total imported waterpipe tobacco into the United States³. For all EX requests except EX0001208, the applicant stated that both the new and original products are manufactured for commercial distribution in the United States. For EX0001208, the applicant stated that only the new product is manufactured for commercial distribution in the United States.

STN		Market Volume				
		Current Year		Projected Volume		
		Tobacco Product (metric tons)	Product as a Percent of Total Imported Waterpipe Tobacco ⁴	First-Year		Fifth-Year
Tobacco Product (metric tons)	Product as a Percent of Total Imported Waterpipe Tobacco ⁵			New Product (metric tons)	Product as a Percent of Total Imported Waterpipe Tobacco ⁶	
EX000-1082	New	(b) (4)				
	Original					
EX000-1083	New					
	Original					
EX000-1087	New					
	Original					
EX000-1088	New					
	Original					
EX000-1089	New					
	Original					
EX000-1092	New					
	Original					
EX000-1093	New					
	Original					
EX000-1094	New					
	Original					
EX000-1120	New					
	Original					

³ The Agency used historical data regarding total import of waterpipe tobacco from 2012 to 2019 to mathematically estimate the total amount of waterpipe tobacco used in the United States. Using an average of the import data from 2012-2019, the forecasted use of waterpipe tobacco is 1084.8 metric tons.

⁴ Projected Market Occupation of the Product in the United States (%) = $\frac{\text{Projected Market Volume of the Product (metric tons of waterpipe tobacco)}}{\text{Projected Import of Waterpipe Tobacco in United States (metric tons)}} \times 100$

⁵ Ibid

⁶ Ibid

EX000-1121	New
	Original
EX000-1122	New
	Original
EX000-1123	New
	Original
EX000-1124	New
	Original
EX000-1125	New
	Original
EX000-1208	New
	Original*
Total	
Total (New)	
Total (Original)	



* The original tobacco product for EX0001208 is not currently on the market.