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

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

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1. Applicant and Manufacturer Information

Applicant Name:	Al Fakher Distribution USA, Inc
Applicant Address:	14931 Gwenchris Court Paramount, California 90723
Manufacturer Name:	Al Fakher Tobacco Factory, F.Z.E.
Product Manufacturing Location:	(b) (4)

2. Products Information

New Product Names, Submission Tracking Numbers (STNs), and Original Product Names

New Product Names	STNs	Original Product Names	STNs
Al Fakher Blueberry Vanilla Ice Cream Flavour 250 grams	EX0001329/PD1	Al Fakher Strawberry Flavour 250 grams	GF1908303
Al Fakher Earl Grey Tea Flavour 50 grams	EX0001330/PD1	Al Fakher Strawberry Flavour 50 grams	GF1908308
Al Fakher Blueberry Vanilla Ice Cream Flavour 1000 grams	EX0001331/PD1	Al Fakher Strawberry Flavour 1 Kg	GF1908306
Al Fakher Blueberry Vanilla Ice Cream Flavour 50 grams	EX0001332/PD1	Al Fakher Strawberry Flavour 50 grams	GF1908308
Al Fakher Earl Grey Tea Flavour 250 grams	EX0001333/PD1	Al Fakher Strawberry Flavour 250 grams	GF1908303
Al Fakher Earl Grey Tea Flavour 1000 grams	EX0001334/PD1	Al Fakher Strawberry Flavour 1 Kg	GF1908306
Al Fakher Frosty Mint Flavour 50 grams	EX0001335/PD1	Al Fakher Strawberry Flavour 50 grams	GF1908308
Al Fakher Frosty Two Apples Flavour 50 grams	EX0001339/PD1	Al Fakher Strawberry Flavour 50 grams	GF1908308
Al Fakher Frosty Mint Flavour 1000 grams	EX0001340/PD1	Al Fakher Strawberry Flavour 1 Kg	GF1908306

Product Identification

Product Category:	Waterpipe	
Product Subcategory:	Waterpipe Tobacco Filler	
Product Number per Retail Unit:	EX0001329, EX0001333:	250 grams per polyethylene pouch
	EX0001331, EX0001334, EX0001340:	1000 grams per polyethylene pouch
	EX0001330, EX0001332, EX0001335, EX0001339:	50 grams per polyethylene pouch
Product Package:	Outer box with inner polyethylene pouch containing 50, 250, or 1000g, waterpipe tobacco.	

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 nine 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 applicant wishes to introduce the new tobacco products into interstate commerce for commercial distribution 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 new products are made by modifying the corresponding original products. These modifications are to the flavor additives (Confidential Appendix 1).

4. Alternative 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 Alternative – Manufacturing the New Products

The manufacturing facility is located outside of the United States. Therefore, environmental impacts associated with manufacturing at this facility will not be discussed.

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

The Agency considered potential impacts to resources in the environment that could be affected by use of the new tobacco 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 (Confidential Appendix 2) for the new products.

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. 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).

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 use of cigarettes in the United States is declining[1], 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). However, 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).

As of December 2020, 28 states and the District of Columbia have implemented comprehensive smoke-free laws (American Lung Association, 2021). 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; (2) the new products are expected to compete

[1] U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) statistical data available at: https://www.ttb.gov/tobacco/tobacco-stats.shtml. Accessed March 7, 2021.

with, or replace, other currently marketed waterpipe tobacco; 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 Alternative – Disposal of the New 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. 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. Endangered Species Act. 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 the amount of waterpipe tobacco being disposed of as the new products are anticipated to compete with similar marketed waterpipe tobacco products.

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 are used in currently marketed waterpipe tobacco. Furthermore, the new products would compete with or replace other waterpipe tobacco currently on the market.

7.5. Solid Waste

Information on disposal of tobacco and water 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 (Kassem et al., 2019). This is concerning considering the various compounds that may leech out of the discarded tobacco, water, and charcoal after disposal including remaining heavy metals (Al-Kazwini et al., 2015). Similar to waterpipe tobacco, discarded cigarette butts are known to leech out into water, potentially affecting human health and the environment, especially marine ecosystems (Kadir and Sarani, 2015).

Like cigarette butts, the environmental toxicity of discarded waterpipe tobacco is not well studied. The chemicals in discarded tobacco can be the original chemicals in the unsmoked tobacco or the pyrolysis and distillation products produced during use. Airborne emissions from used tobacco after disposal depend on the environmental conditions and the chemicals in the used tobacco. These emissions can be influenced by several factors, such as the brand, flavorings and other ingredients in the tobacco filler, types of tobacco, and extent of use. Emissions from disposal of the charcoal are unlikely to be of concern since the majority of charcoal will be used up in the smoking process. Additionally, air emissions from the disposed waterpipe water seem unlikely as those chemicals would likely remain in the water.

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 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) and a portion of that would be littered.

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 environmental assessment:

Preparer:

Chad Baisden, MS, Center for Tobacco Products
Education: MS in Natural Resources
Experience: Five years in various scientific activities
Expertise: Environmental risk assessment, regulatory compliance

Reviewer:

Shannon K. Hanna, Ph.D., Center for Tobacco Products
Education: Ph.D. in Environmental Science and Management
Experience: Four years in environmental science, three years in toxicology
Expertise: Ecotoxicology of new substances and materials, bioaccumulation of chemicals including heavy metals, soil/sediment and water quality

9. A Listing of Agencies and Persons Consulted

Not applicable.

10. References

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

STN	Modification
EX0001329	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) • Increase in the level of (b) (4)
EX0001330	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) • Increase in the level of (b) (4)
EX0001331	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) • Increase in the level of (b) (4)
EX0001332	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) • Increase in the level of (b) (4)
EX0001333	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) • Increase in the level of (b) (4)
EX0001334	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) • Increase in the level of (b) (4)
EX0001335	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) and "(b) (4) • Increase in the level of (b) (4)
EX0001339	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) "(b) (4) and "(b) (4) • Increase in the level of (b) (4)
EX0001340	• Deletion of complex purchased flavor "(b) (4) • Addition of complex purchased flavors "(b) (4) and "(b) (4) • Increase in the level of (b) (4)

CONFIDENTIAL APPENDIX 2. First- and Fifth-Year Market Volume Projections for the New Products and Percentage of Cigarette Use in the United States Projected to be Attributed to the New Products

Current market volume and first- and fifth-year market volume projections of the new and original products. The applicant stated that if the EX request is granted, only the new products will be manufactured for commercial distribution in the United States.

STN	Projected Market Volume	
	First-Year	Fifth-Year
	New Product (metric tons)	New Product (metric tons)
EX0001329	(b) (4)	
EX0001330		
EX0001331		
EX0001332		
EX0001333		
EX0001334		
EX0001335		
EX0001339		
EX0001340		
Total		