

# FINDING OF NO SIGNIFICANT IMPACT FOR

## Product Marketing Order for

**Al Fakher Melon Flavour 50 grams, Al Fakher Pineapple Flavour 50 grams, Al Fakher Coconut Flavour 50 grams, Al Fakher Mango Flavour 50 grams, Al Fakher Plum Flavour 50 grams, Al Fakher Cocktail Flavour 50 grams**

**Manufactured by Al Fakher Distribution USA, Inc.**

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts of this action and has concluded that this action will not have significant effects on the quality of the human environment. Therefore, an environmental impact statement is not required.

Al Fakher Distribution USA, Inc. wishes to introduce six new waterpipe tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA six substantial equivalence reports to obtain a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared a programmatic environmental assessment (EA), dated March 13, 2020, in accordance with the Council on Environmental Quality's regulations (40 CFR 1500–1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40) to support the finding of no significant impact. The evidence supporting this finding is contained in the attached PEA, which is available to the public upon request.

The PEA evaluates potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impacts due to manufacturing are anticipated. The Agency does not foresee that use of the new products would result in new or different environmental impacts. The Agency believes that the disposal of the new products is the same as the disposal conditions of other waterpipe tobacco products that are currently marketed in the United States. Therefore, the Agency does not foresee adverse impacts to the environment due to the proposed action as a result of the manufacturing, use, and disposal of the new products.

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Approved by

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