

# FINDING OF NO SIGNIFICANT IMPACT

## Marketing Orders for

**Al Fakher Cherry with Mint Flavour 1000 grams, Al Fakher Grape with Mint Flavour 1000 grams, Al Fakher Lemon with Mint Flavour 1000 grams, Al Fakher Lemon with Mint Flavour 50 grams, Al Fakher Grape with Mint Flavour 50 grams, Al Fakher Two Apples with Mint Flavour 1000 grams, Al Fakher Orange with Mint Flavour 250 grams, Al Fakher Orange with Mint Flavour 50 grams, Al Fakher Mint with Cream Flavour 50 grams, Al Fakher Mint with Cream Flavour 250 grams, Al Fakher Orange with Cream Flavour 250 grams, Al Fakher Orange with Cream Flavour 50 grams, Al Fakher Strawberry with Cream Flavour 250 grams, Al Fakher Strawberry with Cream Flavour 50 grams, and Al Fakher Plum 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 these actions and has concluded that this action will not have significant effects on the quality of the human environment. Therefore, environmental impact statements are not required.

Al Fakher Distribution USA Inc. wishes to introduce 15 new waterpipe tobacco products fillers into interstate commerce for commercial distribution in the United States and submitted to FDA 15 requests for exemption from substantial equivalence to obtain marketing orders under the provisions of section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated November 17, 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 the new tobacco products are anticipated. The Agency does not foresee that use of the new tobacco products would result in new or different environmental impacts. The Agency believes that the disposal of the new tobacco products is the same as the disposal conditions of other combusted cigarettes that are currently marketed in the United States. Therefore, the Agency does not foresee significant adverse impacts to the environment due to the proposed actions as a result of the manufacturing, use, and disposal of the new tobacco products.

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Approved by

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