

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

Al Fakher Citrus with Mint Flavour 1000 grams, Al Fakher Citrus with Mint Flavour 250 grams, Al Fakher Grape with Berry Flavour 250 grams, Al Fakher Grape with Berry Flavour 1000 grams, Al Fakher Citrus with Mint Flavour 50 grams, Al Fakher Gum with Mint Flavour 50 grams, Al Fakher Gum with Mint Flavour 250 grams, Al Fakher Grape with Berry Flavour 50 grams, Al Fakher Gum with Mint Flavour 1000 grams, Al Fakher Watermelon with Mint Flavour 1000 grams, Al Fakher Watermelon with Mint Flavour 250 grams, Al Fakher Watermelon with Mint 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 these actions 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 12 new waterpipe tobacco filler products into interstate commerce for commercial distribution in the United States and submitted to FDA 12 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 September 29, 2020, in accordance with the Council on Environmental Quality's regulations (40 CFR 1500–508) 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 products 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 filler products 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 products.

Approved by Digitally signed by Luis G. Valerio -S
Date: 2020.10.14 14:14:13 -04'00'

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