

FINDING OF NO SIGNIFICANT IMPACT

Marketing Order for

Al Fakher Berry Flavour 1000 grams, Al Fakher Grapefruit Flavour 50 grams*, Al Fakher Gum with Cinnamon Flavour 250 grams, Al Fakher Vanilla Flavour 50 grams, Al Fakher Kiwi Flavour 1000 grams, Al Fakher AF 07 Flavour 250 grams, Al Fakher AF 08 Flavour 250 grams, Al Fakher AF 24 Flavour 250 grams, Al Fakher AF 04 Flavour 250 grams, Al Fakher AF 22 Flavour 250 grams, Al Fakher AF 05 Flavour 250 grams, Al Fakher AF 03 Flavour 250 grams, Al Fakher AF 86 Flavour 250 grams, Al Fakher AF 66 Flavour 250 grams, and Al Fakher AF 51 Flavour 250 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 fifteen new Waterpipe tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA fifteen requests for exemption from substantial equivalence reporting to obtain marketing orders under the provisions of Section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared a programmatic environmental assessment (PEA), dated November 16, 2020, in accordance with the Council on Environmental Quality's regulations (40 CFR Part 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 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 cigarettes that are currently marketed in the United States. Therefore, the Agency does not foresee adverse impacts to the environment due to the proposed actions as a result of manufacturing, use, and disposal of the new products.

Approved by _____
Digitally signed by Luis G. Valerio -S
Date: 2020.11.16 13:55:18 -05'00'

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