

FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

Al Fakher Plum Flavour 250 gram, Al Fakher Golden Eskandarani Apple Flavour 250 grams, Al Fakher Cherry with Mint Flavour 250 grams, Al Fakher Golden Strawberry 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 four new waterpipe tobacco filler products into interstate commerce for commercial distribution in the United States and submitted to FDA four 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 March 12, 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 Kimberly A. Benson -S
Date: 2020.03.12 10:20:47 -04'00'

Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration