

FINDING OF NO SIGNIFICANT IMPACT

Product Marketing Orders for

Complete Full Flavor Deluxe 100s Box, Complete Full Flavor Deluxe Kings Box, Complete High Air Filter Deluxe 100s Box, Complete High Air Filter Deluxe Kings Box, Complete Menthol Deluxe 100s Box, Complete Menthol Deluxe Kings Box, Complete Menthol High Air Filter Deluxe 100s Box, Complete Menthol High Air Filter Deluxe Kings Box, Complete Non-Filter Deluxe Kings Box, Complete Ultra High Air Filter Deluxe 100s Box, Complete Ultra High Air Filter Deluxe Kings Box

Manufactured by Skookum Creek Tobacco Company, 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.

Skookum Creek Tobacco Company, Inc. wishes to introduce ten new filtered and one new non-filtered, combusted cigarettes into interstate commerce for commercial distribution in the United States and submitted eleven requests to FDA 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 June 10, 2019, 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 filtered and non-filtered, combusted 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 the manufacturing, use, and disposal of the new products.

Approved by Digitally signed by Kimberly A. Benson -S
Date: 2019.06.10 14:02:28 -04'00'

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