

FINDING OF NO SIGNIFICANT IMPACT FOR

Marketing Orders for

“Elements Red Single Wide” and “Rawblack Single Wide”

Manufactured by BBK Tobacco & Foods, LLP

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.

BBK Tobacco & Foods, LLP wishes to introduce two roll-your-own tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence reports to obtain marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated June 3, 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 roll-your-own tobacco products 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
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