FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

Elements 1 1/4 Elements 1 ½ **Elements SW DF Elements Three Hundred 20 CT Box** Elements 1 ¼ Perfect Fold

Manufactured by

BBK Tobacco & Foods, LLP Company d/b/a HBI International

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 five new roll-your-own (RYO) tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA five 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 April 20, 2020, in accordance with the Council on Environmental Quality's regulations (40 CFR Part 1500) 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 these findings is contained in the attached EA, which is available to the public upon request.

The EA evaluates potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impact due to manufacturing are anticipated. The Agency does not foresee use of the new products would result in new or different environmental impacts. The Agency believes that the disposal of the new product is the same as the disposal conditions of other Rolling Paper products that are currently marketed in the United States. Therefore, the Agency does not foresee adverse impacts to the environment due to the proposed action as a result of manufacturing, use, and disposal of the new products.

Digitally signed by Kimberly A. Benson -S Date: 2020.04.21 10:12:44 -04'00'

Approved by

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