FINDING OF NO SIGNIFICANT IMPACT

Marketing Order for

"RAW AUTO BOX 79 MM"

by BBK Tobacco & Foods, LLP Company dba HBI International

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts of this action and has concluded that this action will not have significant effects on the quality of the human environment. Therefore, an environmental impact statement is not required.

BBK Tobacco & Foods, LLP Company dba HBI International wishes to introduce one new roll-your-own (RYO) rolling box into interstate commerce for commercial distribution in the United States and submitted to FDA a request for exemption from substantial equivalence to obtain a marketing order under the provisions of section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the environmental assessment (EA), dated December 9, 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 EA, which is available to the public upon request.

The EA evaluates potential environmental effects due to manufacturing, use, and disposal of the new product. No increased or new types of environmental impacts due to manufacturing the new product are anticipated. The Agency does not foresee that use of the new product 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 RYO rolling boxes 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 product.

Approved by

Digitally signed by Kimberly A. Benson -S
Date: 2019.12.09 13:29:48 -05'00'

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