FINDING OF NO SIGNIFICANT IMPACT

Marketing Orders for

Top McClintock Menthol King Size, Top McClintock Blue King Size, and Top McClintock Blue 100mm

Manufactured by Republic Tobacco, LP

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.

Republic Tobacco wishes to introduce three new roll-your-own filtered cigarette tubes into interstate commerce for commercial distribution in the United States and submitted to FDA three substantial equivalence report to obtain a marketing order 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 this finding is contained in the attached PEA, 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 impacts 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 products is the same as the disposal conditions of other roll-your-own filtered cigarette tubes 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 manufacturing, use, and disposal of the new products.

Approved by

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

For      Digitally signed by Luis G. Valerio -S
Date: 2020.04.20 16:05:06 -04'00'