FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for

Top McClintock Blue King Size
LP's Top McClintock Regular 100MM
Top McClintock Menthol King Size
Top McClintock Regular King Size
Top McClintock Blue 100MM
LP's Top McClintock Blue King Size

Manufactured by Republic Tobacco LP

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

Republic Tobacco LP wishes to introduce six new roll-your-own (RYO) tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA six substantial equivalence report to obtain a marketing order under the provisions of sections 910 and 905(j) of the FD&C Act.

The Agency prepared the environmental assessment (EA), dated August 29, 2018, 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 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 would be the same as the disposal conditions of other RYO tobacco products that are currently marketed. Therefore, the Agency does not foresee adverse impacts to the environment as a result of manufacturing, use, or disposal of the new products.

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Approved by

Date: 2018.08.30 12:15:06 -04'00'

Kimberly Benson, Ph.D.

Director

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Center for Tobacco Products
U.S. Food and Drug Administration