## FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for Republic El Rey Regular 100MM, Republic El Rey Menthol King Size, Republic El Rey Regular 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 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 LP wishes to introduce three new roll-your-own (RYO) tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA three substantial equivalence reports to obtain marketing orders under the provisions of sections 910 and 905(j) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated July 20, 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 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 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.

Approved by

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