

# **FINDING OF NO SIGNIFICANT IMPACT FOR**

**Product Marketing Order for**

**Bull Durham Blue 100 MM**

**Bull Durham Regular King Size**

**Marketed 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 two new roll-your-own tobacco products into interstate commerce for commercial distribution in the United States and submitted two substantial equivalence reports to FDA to obtain marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared an programmatic environmental assessment (PEA), dated May 27, 2020, 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 product. No increased or new types of environmental impacts due to manufacturing 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 roll-your-own tobacco 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 the manufacturing, use, and disposal of the new product.

**Digitally signed by Luis G. Valerio -S**

**Date: 2020.05.27 13:59:36 -04'00'**

Approved by

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Luis Valerio Jr., Ph.D., ATS.  
Associate Director  
Division of Nonclinical Science  
Office of Science  
Center for Tobacco Products  
U.S. Food and Drug Administration