

FINDING OF NO SIGNIFICANT IMPACT

Product Marketing Orders for

OCB Ultimate 1-1/2, OCB Ultimate 1-1/4, OCB Ultimate Single Wide, OCB Ultimate Slim

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 four new roll-your-own (RYO) rolling papers into interstate commerce for commercial distribution in the United States and submitted to FDA four substantial equivalence reports to obtain marketing orders 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 June 25, 2019, 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 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 are the same as the disposal conditions of other RYO rolling papers 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.

Digitally signed by Kimberly A. Benson -S
Date: 2019.06.25 15:29:25 -04'00'

Approved by

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