

# FINDING OF NO SIGNIFICANT IMPACT FOR

## Marketing Orders for

**HIGH CARD Regular 12 oz. Large Bag, HIGH CARD Menthol 12 oz. Large Bag, HIGH CARD Gold 12 oz. Large Bag, and HIGH CARD Menthol 5 oz. Medium Bag**

**Manufactured by Top 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 a significant effect on the quality of the human environment. Therefore, environmental impact statements are not required.

Top Tobacco, LP wishes to introduce four pipe tobacco fillers 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 September 6, 2019, in accordance with the Council on Environmental Quality's regulations (40 CFR Part 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 the new products 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 pipe tobacco fillers 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

Digitally signed by Hans M. Rosenfeldt -S  
Date: 2019.09.06 11:18:39 -04'00'

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