

# **FINDING OF NO SIGNIFICANT IMPACT FOR**

**Product Marketing Orders for  
Native Full Flavor 100's Hard Pack (2016)  
Native Full Flavor 100's Soft (2016)  
Native Full Flavor King Hard Pack (2016)  
Native Full Flavor King Soft (2016)  
Native Menthol 100's Hard Pack (2016)  
Native Menthol 100's Soft (2016)  
Native Menthol King Hard Pack (2016)  
Native Menthol King Soft (2016)**

**Manufactured by Native Trading Associates**

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

Native Trading Associates wishes to introduce eight new combusted filtered cigarette tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence reports to obtain market authorizations under the provisions of sections 910 and 905(j) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated October 20, 2017, under the Council on Environmental Quality's regulations (40 CFR 1500–1508) implementing the National Environmental Policy Act and in accordance with 21 CFR 25.41 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 provides an environmental effects assessment due to manufacturing, use, and disposal after use of the new products. The PEA also provides analysis of energy and resource use as a result of marketing the new products.

To evaluate the potential environmental impacts of the proposed actions due to manufacturing the new products, the Agency evaluated information provided by the applicant stating that no additional manufacturing capacity would be required. No additional or new types of emissions due to manufacturing are anticipated, and no new pollution control practices are anticipated.

To evaluate the potential environmental impacts of the proposed actions due to use of the new products, the Agency utilized historical data on use of RYO tobacco products from 1984–2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau's *Tobacco Statistical Release Reports* to forecast the number of cigarettes consumed and found the projection for use of cigarettes is declining. The Agency

does not foresee new substances or additional air emissions to be released into the environment as a result of use of the new products.

The Agency believes that the disposal of the new products resembles the disposal conditions of other cigarette products that are currently marketed. The waste generated from the new products may be disposed of into the environment as litter or as municipal solid waste (MSW) in the same manner as the waste generated from other cigarette products used in the United States. The projected total waste due to disposal of the new products is a miniscule fraction of the MSW generated in the United States based on information in the U.S. Environmental Protection Agency's report *Advancing Sustainable Materials Management: Facts and Figures 2014*. Therefore, construction of new MSW facilities is not anticipated as a result of the proposed actions. Furthermore, the Agency does not foresee adverse impacts from additional air emissions released into the environment as a result of disposal of the new products.

No significant environmental impacts are expected from marketing the new products because no new control practices of air emission, water discharge, or solid waste disposal are foreseen; and no release of new substances, no expansion of the manufacturing facility, no additional use of resources and energy, and no impact on endangered or threatened species or critical habitat due to marketing the new products is anticipated.

Approved by

Digitally signed by Kimberly A. Benson -S

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