

## **FINDING OF NO SIGNIFICANT IMPACT FOR**

### **Product Marketing Orders for Hot Rod Regular King Size 100 Count and Hot Rod Menthol King Size 100 Count**

#### **Manufactured by Great Midwest Tube**

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.

Midwest Tobacco Tube Inc. dba Great Midwest Tube wishes to introduce two new roll-your-own (RYO) tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA 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 June 22, 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 use of the new products to 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 similar RYO tobacco products that are currently marketed. 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.

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Approved by

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