

## **FINDING OF NO SIGNIFICANT IMPACT**

for

Product Marketing Order for

“Hot Rod Regular King 100 Count”

Manufactured by Midwest Tobacco Tube, Inc.

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of this action and has concluded that this action 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. wishes to introduce a new filtered roll-your-own (RYO) tobacco product into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence (SE) reports to obtain a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug and Cosmetic Act (FD&C Ac).

The Agency prepared the environmental assessment (EA), dated October 10, 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 EA, which is available to the public upon request.

The EA provides an environmental effect analysis due to manufacturing, use, and disposal after use of the new product. The new product is manufactured in the United States.

To evaluate the potential environmental impacts of the proposed action due to manufacturing the new product, the Agency evaluated the projected market volume in the first and fifth year of marketing the new product and found it to comprise a fraction of the combined manufacturing of RYO tobacco and cigarettes in the United States. The agency also evaluated the differences between the new product and the predicate product and concluded that the ingredient change would not result in the release of any new substances or emissions into the environment. Because the new product is expected to compete with other marketed RYO products, the Agency would not anticipate an expansion of the manufacturing facility or any release of new substances or new type of emissions into the environment as a result of manufacturing the new product. No anticipated additional resources with new control measures for air emission, water discharge, or solid waste disposal would be required for manufacturing the new product. In addition, there would be no anticipated net increase in energy use.

To evaluate the potential environmental impacts of the proposed action due to use of the new product, the Agency utilized historical data for the use of RYO and cigarettes from 2008 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau Statistical Release reports to forecast the number of products consumed and found the projection for use of RYO tobacco and cigarettes is declining. Also, 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 product since changing the supplier would not lead to release of new chemicals.

The Agency believes that the disposal of the new product resembles the disposal conditions of RYO tobacco products that are currently marketed. The waste generated from the product may be disposed of as litter or as municipal solid waste (MSW) in the same manner as the waste generated from other RYO tobacco products used in the United States. The projected total waste due to disposal of the new product is a minute fraction of the MSW generated in the United States, based on information presented in the U.S. Environmental Protection Agency's Report "*Advancing Sustainable Materials Management: Facts and Figures 2014*". Therefore, no construction of new MSW management facilities is anticipated as a result of the proposed action. Furthermore, no additional air emissions associated with MSW is anticipated.

No significant environmental impacts are expected from marketing the new product because no new control practices of air emission, water discharge, or solid waste disposal are foreseen; no additional use of resources and energy due to marketing the new product is anticipated. The applicant also provided evidence of their compliance with relevant federal, state, and local environmental laws and regulations.

Approved by Digitally signed by Kimberly A. Benson -S  
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