

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Order for

Bugler Leaf .65 oz Pouch

Manufactured by Scandinavian Tobacco Group Lane, Ltd

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.

Scandinavian Tobacco Group Lane, Ltd wishes to introduce a new roll-your-own (RYO) tobacco product into interstate commerce for commercial distribution in the United States and submitted to FDA a substantial equivalence (SE) report to obtain a marketing order under the provisions of section 910 and 905(j) of the FD&C Act.

The Agency prepared the environmental assessment (EA), dated April 17, 2018, 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 assessment due to manufacturing, use, and disposal of the new product. The EA also provides analysis on energy and resource use as a result of marketing the new product.

To evaluate the potential environmental impacts of the proposed action due to the manufacturing of the new product, the Agency used a qualitative assessment and concluded that no new types of emissions due to manufacturing are reported and anticipated, and no new pollution control practices are anticipated.

To evaluate the potential environmental impacts of the proposed action due to the use of the new product, the Agency utilized historical data of the use of RYO tobacco products from 2008 to 2016 from the Alcohol and Tobacco Tax and Trade Bureau's Statistical Release reports and the number of RYO tobacco products consumed and found the trend for use of RYO tobacco products 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.

The Agency believes that the disposal of the new product is the same as the disposal conditions of other RYO tobacco products that are currently marketed. The waste generated from the new product may undergo two scenarios of disposal into the environment, 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 minuscule 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 action.

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 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 product is anticipated.

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Approved by

Kimberly Benson, Ph.D.

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Director

Division of Nonclinical Science

Office of Science

Center for Tobacco Products

U.S. Food and Drug Administration