

FINDING OF NO SIGNIFICANT IMPACT

For

Product Market Authorization Orders for

Wave Menthol King Size and Wave Full Flavor King Size
Manufactured by Japan Tobacco International USA, Inc.

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.

Japan Tobacco International USA, Inc. (JTI USA) wishes to introduce two new combusted cigarette products into interstate commerce for commercial distribution in the United States (U.S.) and submitted to FDA substantial equivalence (SE) reports to obtain market authorizations pursuant to Section 910(a)(3)(A)(ii) and Section 910(b) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated August 2, 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 (FONSI). The evidence supporting this finding is contained in the attached PEA, which is available to the public upon request.

The PEA provides an environmental effect assessment due to manufacturing, use, and disposal after use of the new products. The PEA also provides analyses on energy and resource use, well as impacts on endangered or threatened species or critical habitats, as a result of marketing the new products. The new products are manufactured in Turkey, and used and disposed of in the U.S.

To evaluate the environmental introduction for the proposed actions due to the manufacturing of the new products, the Agency used historical data from 2008 to 2016 from the U.S. International Trade Commission (USITC) to forecast the amount of combusted cigarette products imported to the U.S. from Turkey. No new types of emissions due to manufacturing are anticipated, and no new pollution control practices are anticipated.

To evaluate the environmental introduction for the proposed actions due to the use of the new products, the Agency utilized historical data of the use of combusted cigarette products from 2000 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports to forecast the number of combusted cigarette products consumed and found the projection for use of these products is declining. Also, the Agency does not foresee new substances or additional greenhouse gas 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 as a result of use of the products will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from other

cigarette products used in the U.S. The amount of projected total waste due to use and disposal of the new products is a minute fraction of the forecasted tobacco product waste generated in the U.S., based on information presented in the U.S. Environmental Protection Agency's report "*Advancing Sustainable Materials Management: Facts and Figures 2014*". Also, it is a negligible fraction of municipal solid waste generated in the U.S., based on information presented in this report. Therefore, construction of new POTWs and landfills are not anticipated as a result of the proposed actions. Furthermore, no additional control of greenhouse gas emissions is anticipated in the existing landfills.

The Agency does not anticipate the market volume for combusted cigarette products to be noticeably changed based on the provided information because the new products will completely replace the predicate products. Consequently, no additional use of resources and energy due to marketing the new products is anticipated.

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; 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.

The applicant also provided evidence of their compliance with relevant Turkish federal, regional, and local environmental laws and regulations.

Approved by Digitally signed by Kimberly A. Benson -S
Date: 2017.08.03 13:53:28 -04'00'
Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
Food and Drug Administration