

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for
Marlboro Southern Cut 100's Box
Manufactured by Philip Morris USA 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.

Philip Morris USA Inc wishes to introduce a new cigarette 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 sections 910 and 905(j) of the FD&C Act.

The Agency prepared the environmental assessment (EA), dated December 22, 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 EA, which is available to the public upon request.

The EA provides an environmental effect assessment due to manufacturing, use, and disposal after use of the new product. The EA also provides analyses on energy and resource use as a result of marketing the new product.

To evaluate the environmental introduction for the proposed action due to the manufacturing of the new product, the Agency used historical data from 2009-2016 from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau Tobacco Statistics to analyze cigarette manufacturing in the U.S. 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 action due to the use of the new product, the Agency utilized historical data for the use of cigarettes from 2004 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports to forecast the number of cigarettes consumed and found the projection for use of 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.

The Agency believes that the disposal of the new product will resemble the disposal conditions of other tobacco products that are currently marketed. The waste generated from use of the product may be disposed of into the environment as litter, transferred to publicly owned treatment works (POTW), and disposed of in landfills in the same manner as the waste generated from other tobacco products used in the United States. The amount of projected tobacco waste and packaging materials waste due to use and disposal of the new product will be a minute fraction of the forecasted tobacco product waste generated due to use of all tobacco products. Also, it will be a negligible fraction of municipal solid

waste 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, construction of new POTW and landfills is not anticipated as a result of the proposed actions.

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 are anticipated.

Approved by Digitally signed by Kimberly A. Benson -S
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