FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for

"Marlboro Soft Pack, Marlboro 100's Soft Pack, and Marlboro 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 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.

Philip Morris USA Inc. wishes to introduce new cigarettes into interstate commerce for commercial distribution in the United States and submitted to FDA six substantial equivalence (SE) 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 May 21, 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 (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 products. The EA also provides analyses on energy and resource use as a result of marketing the new products.

To evaluate the environmental introduction for the proposed actions due to the manufacturing of the new products, the Agency used the U.S. Environmental Protection Agency's (EPA) Toxic Release Inventory (TRI) and the applicant's submitted information to assess the facility's chemical emissions. Because the components in the new products are similar to that of the corresponding predicate products and other cigarettes currently on the market, the Agency would not anticipate an expansion of the manufacturing facility, or the release of any new types of emissions into the environment as a result of manufacturing the new products. No anticipated new pollution control measures for air emission, water discharge, or solid waste disposal would be required for manufacturing the new products.

To evaluate the environmental introduction for the proposed actions due to the use of the new products, the Agency utilized historical data for the use of cigarettes from 2001 to 2017 from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) tobacco statistical reports to forecast the number of cigarettes consumed. The Agency found the projection for use of cigarettes is declining. Furthermore, 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 products.

The Agency believes that the disposal of the new products will resemble the disposal conditions of other tobacco products that are currently marketed. The waste generated from use of the products 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 products will be a negligible fraction of municipal solid waste generated in the United States, based on information presented in the U.S. EPA'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 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 are anticipated.

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Approved by _____

For Kimberly Benson, Ph.D.
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