FINDING OF NO SIGNIFICANT IMPACT

Product Marketing Orders for

Merit Blue Pack 100's Box Marlboro Black Label Box L&M Turkish Blend Box L&M Turkish Blend 100's Box

Manufactured by Philip Morris USA Inc

The Centers for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts of these actions and has concluded that these actions will not have a significant effect on the quality of the human environment. Therefore, environmental impacts statements are not required.

Philip Morris USA Inc wishes to introduce four filtered cigarette products into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence reports to obtain marketing orders under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated January 24, 2019, in accordance with the Council on Environmental Quality's regulations (40 CFR 1500–1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40) to support the finding of no sigificant impacts. The evidence supporting this finding is contained in the attached PEA, which is available to the public upon request.

The PEA evaluates potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impacts due to manufacturing are anticipated. The Agency does not foresee that use of the new products would result in new or different environmental impacts. The Agency believes that the disposal of the new products would be the same as the disposal conditions of similar cigarette products that are currently marketed. Therefore, the Agency does not foresee significant adverse impacts to the environment due to the proposed actions as a result of manufacturing, use, and disposal of the new products.

Digitally signed by Kimberly A. Benson -S Date: 2019.01.24 14:19:07 -05'00'

Approved by

Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration