

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for

“Eclipse and Eclipse Menthol”

Manufactured by R.J. Reynolds Tobacco Company

The Center 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, an environmental impact statement is not required.

R.J. Reynolds Tobacco Company wishes to introduce two new filtered, non-combusted cigarettes into interstate commerce for commercial distribution in the United States and submitted to FDA two substantial equivalence 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 July 17, 2018, 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). 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 use of the new products to result in new or different environmental impacts. The Agency believes that the disposal of the new products are similar the disposal conditions of filtered, combusted cigarettes that are currently marketed in the United States. Therefore, the Agency does not foresee adverse impacts to the environment due to the proposed actions as a result of the manufacturing, use and disposal of the new products.

Approved by

Digitally signed by Kimberly A. Benson -S
Date: 2018.07.17 12:19:21 -04'00'

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