

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for

“Newport Kings, Newport Box, and Newport Box 100s”

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 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.

R.J. Reynolds Tobacco Company wishes to introduce three combusted, filtered cigarette products into interstate commerce for commercial distribution in the United States and submitted to FDA requests for exemption from substantial equivalence (SE) to obtain marketing orders under section 905(j)(3) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated October 13, 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 as well as impacts on endangered or threatened species or critical habitat as a result of marketing the new products.

To evaluate the potential environmental impacts of the proposed actions due to manufacturing the new products, the Agency evaluated information provided by the applicant stating that the manufacturing facility would not need to be expanded in order to produce the new products. The only differences between the new products and the corresponding original products for EX0000189, EX0000190, and EX0000191 is the use of an alternate fire standards compliant paper and a change in name. The new products will also replace their corresponding original products. Therefore, the Agency anticipates no new substances or new type of emissions to be released into the environment, and no new pollution control practices are anticipated as a result of manufacturing the new products.

To evaluate the potential environmental impacts of the proposed actions due to the use of the new products, the Agency utilized historical data of the use of combusted cigarette products from 2004 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports to forecast the number of combusted cigarettes consumed and found the projection for use of these products is declining. During use, the new products, like other cigarette products, are usually burned to ash, carbon dioxide, and water vapor, as well as products of incomplete combustion such as carbon

monoxide. These combustion products are released in a similar manner from the new products as they are from the original products and other combusted, filtered cigarettes. The released substances during use of the new products are negligible compared to the original products, from the environmental viewpoint.

The Agency believes that the disposal of the new products resembles the disposal conditions of other cigarettes 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 combusted tobacco products used in the United States. The amount of projected tobacco waste and packaging materials waste, including paper, due to use and disposal of the new products is a minute fraction of the forecasted tobacco product waste generated due to use of cigarette products. Also, it is 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 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.

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Date: 2017.10.13 14:27:30 -04'00'

Approved by

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