

FINDING OF NO SIGNIFICANT IMPACT FOR

Marketing Order for

“Kent III Silver Soft Pack”

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 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.

R.J. Reynolds Tobacco Company wishes to introduce a new combusted, filtered cigarette product into interstate commerce for commercial distribution in the United States and submitted to FDA a request for exemption from substantial equivalence to obtain marketing orders under section 905(j)(3) of the Food, Drug, and Cosmetic Act.

The Agency prepared the environmental assessment (EA), dated January 12, 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. 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 analysis due to manufacturing, use, and disposal after use of the new product. The EA 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 product.

To evaluate the potential environmental impacts of the proposed action due to manufacturing the new product, the Agency evaluated information provided by the applicant stating that the manufacturing facility would not need to be expanded to produce the new product. Based on the information in the Exemption Request, the new product and the original product are manufactured in a similar manner and the changes related to the deletion of a tobacco additive, the increase in quantity of two existing tobacco additive ingredients and the substitution of a tobacco additive of the tipping paper for the new product are minor changes that would not be expected to release new air emissions. The new product will also replace the original product. 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 product.

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 in the United State from 2008 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau Statistical Release reports to forecast the number of cigarettes consumed and found the projection for use of cigarettes to be declining. During use, the new product, 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 product as they are from the original product and other combusted, filtered cigarettes. The substances released during use of the new product are negligible compared to substances released during use of cigarettes in the United States, from the environmental viewpoint. Also, the Agency does not foresee new substances 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 resembles the disposal conditions of cigarettes that are currently marketed. The waste generated as a result of use of the product will be released to the environment, transferred to publicly owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from other cigarettes used in the United States. The amount of projected total waste as a result of disposal of the new product following use is a minute fraction of the forecasted tobacco product 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 POTWs and landfills are not anticipated as a result of the proposed action.

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 additional use of resources and energy due to marketing the new product is anticipated. The applicant also provided evidence of their compliance with relevant federal, state, and local environmental laws and regulations.

Approved by Digitally signed by Kimberly A. Benson -S
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