

FINDING OF NO SIGNIFICANT IMPACT FOR

Marketing Orders for

“Pall Mall Menthol Green Filter and Pall Mall Menthol Green Filter 100”

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 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 two new combusted, filtered cigarette products into interstate commerce for commercial distribution in the United States and submitted to FDA two requests 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 programmatic environmental assessment (PEA), dated April 25, 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 PEA, which is available to the public upon request.

The PEA provides an environmental effect analysis 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 to produce the new products. Based on the information in the Exemption Request, the new products and the corresponding original products are manufactured in a similar manner and the changes related to the deletion of a tobacco additive, in the tipping paper, and the addition of a tobacco additive, in the tipping paper are minor changes that would not be expected to release new air emissions. The new products will also replace the 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 environmental introduction for the proposed actions due to the use of the new products, the Agency utilized historical data for the use of cigarettes in the United State from 2002 to

2017 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 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 the same manner from the new products as they are from the original products and other combusted, filtered cigarettes. The substances released during use of the new products 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 products.

The Agency believes that the disposal of the new products will be the same as the disposal conditions of cigarettes that are currently marketed. The waste generated as a result of use of the new products 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 products 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 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 additional use of resources and energy due to marketing the new products is anticipated. The applicant also provided evidence of their compliance with relevant federal, state, and local environmental laws and regulations.

Approved by _____
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