

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

Monarch Red 100's Soft Pack
Monarch Gold 100's Soft Pack
Monarch Blue 100's Soft Pack
Monarch Red Box
Monarch Gold Box
GPC Non-Filter 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 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 six combusted, filtered cigarette products into interstate commerce for commercial distribution in the U.S. and submitted to FDA an application for exemption from substantial equivalence (SE) reports to obtain market authorizations under section 905(j)(3) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated August 29, 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.

The new products are manufactured, used and disposed of in the U.S. The only differences between the new products and the original product are the deletion of a complex tobacco additive and increase in an existing tobacco additive. Therefore, the Agency anticipates no new substances or new type of emissions to be released into the environment as a result of manufacturing the new products.

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 product, from the environmental viewpoint.

To evaluate the environmental introduction for the proposed action due to the manufacturing the new products, the first- and fifth-year projections of market share for the new products were provided. No new types of emissions due to manufacturing are anticipated, and no new pollution control practices are anticipated.

To evaluate the environmental introduction for the proposed action due to the use of the new products, the Agency utilized historical data of the use of combusted cigarette products from 2008 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. Also, the Agency does not foresee new substances or additional greenhouse gas emissions 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 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 U.S. 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 U.S., 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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