

# FINDING OF NO SIGNIFICANT IMPACT

for

Product Marketing Orders for

Filtered Cigarette Tubes “Altesse<sup>®</sup> Regular King Size, Gambler<sup>®</sup> Menthol King Size, and Gambler<sup>®</sup> Tubecut<sup>®</sup> Menthol King Size”

Manufactured by Republic Tobacco, LP

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.

Republic Tobacco, LP wishes to introduce three new roll-your-own (RYO) tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence (SE) reports to obtain marketing orders pursuant to the provisions of sections 905(j) and 910 of the Federal Food, Drug and Cosmetic Act (FD&C Ac).

The Agency prepared the programmatic environmental assessment (PEA), dated February 28, 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 of the new products. The PEA also provides analyses on energy and resource use as a result of marketing the new products.

To evaluate the potential environmental impacts of the proposed actions due to the manufacturing of the new products, the Agency evaluated the differences between the new products and the predicate products and concluded that the chemistry of the ingredient change would not result in the release of any new substances or emissions into the environment. Because the predicate products will compete with the corresponding predicate products and with other similar marketed tobacco products, the Agency would not anticipate an expansion of the manufacturing facility or release of any new type of emissions into the environment as a result of manufacturing the new products. No anticipated additional resources with new control measures for air emission, water discharge, or solid waste disposal would be required for manufacturing the new products. In addition, there would be no anticipated net increase in energy use.

To evaluate the potential environmental impacts of the proposed actions due to use of the new products, the Agency utilized historical data for the use of RYO and cigarettes from 2008 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau Statistical Release reports; the data indicate that RYO tobacco use is declining. Also, the Agency does not foresee new substances or increased air emissions to be released into the environment as a result of use of the new products since changing the

supplier, and the changes in the ingredients due to this change, would not lead to release of new chemicals.

The Agency believes that the disposal of the new products would be the same as the disposal conditions of other RYO tobacco products that are currently marketed. The waste generated from using the new products will be released to the environment and disposed of in landfills as litter or as municipal solid waste (MSW) in the same manner as the waste generated from other RYO tobacco products used in the United States. The projected total waste due to disposal of the new products is a miniscule fraction of the MSW 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 MSW facilities 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 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.

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