

FINDING OF NO SIGNIFICANT IMPACT

Product Marketing Orders for

Top Silver 100 MM
Gambler Tubecut Silver King Size
Gambler Silver King Size

Gambler Tubecut Silver 100 MM
Gambler Silver 100 MM
TOP Silver 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 six roll-your-own (RYO) tobacco filtered cigarette tube products into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence (SE) reports to obtain marketing orders under the provisions of sections 905(j) and 910 of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated October 31, 2017, and prepared in accordance with regulations of the Council on Environmental Quality's (40 CFR 1500-1508) and FDA (21 CFR Part 25) implementing the National Environmental Policy Act to support this finding of no significant impact (FONSI). The evidence supporting this finding is contained in the attached EA, which is available to the public upon request.

The new products are manufactured in Canada, and used, and disposed of in the United States. The only difference between the new products and the predicate products is a reduction in the amount of ink used in the products. The manufacturer is in compliance with all local, provincial, and federal environmental laws. 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 RYO products, are usually burned to ash, carbon dioxide, water vapor, and products of incomplete combustion such as carbon monoxide. These combustion products are released in a similar manner from the new and predicate products, as well as from other filtered cigarettes. The predicate products will be discontinued after the new products are authorized.

The Agency believes that the disposal of the new products resembles the disposal conditions of RYO cigarette tubes that are currently marketed. The waste generated from use of the products will be released to the environment as litter and disposed of in landfills in the same manner as the waste generated from other RYO tobacco products used in the United States. The amount of projected total waste due to use and disposal of the new products is a minute fraction of the forecasted tobacco product waste generated in the United States. It is also a negligible fraction of municipal solid waste

generated in the United States. Therefore, no significant impacts on waste management capacity in the U.S. are anticipated as a result of the proposed actions.

No significant environmental impacts are expected from marketing the new products because no changes in production affecting air emission, water discharge, or solid waste disposal are foreseen and no additional use of resources and energy is anticipated.

Approved by Digitally signed by Kimberly A. Benson -S
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