

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

Gambler Single Wide 24 Count
Gambler Single Wide 50 Count

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 two roll-your-own (RYO) tobacco rolling paper products into interstate commerce for commercial distribution in the U.S. and submitted to FDA substantial equivalence (SE) reports to obtain market authorizations pursuant to Section 910(a)(3)(A)(ii) and Section 910(b) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated March 13, 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 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 products. The EA also provides analysis on energy and resource use as a result of marketing the new products.

The new products are manufactured in France and used and disposed of in the U.S. The only differences between the new products and the predicate product used for both new products, is a change in product quantity and labeling. The manufacturer is in compliance with all local, state 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 tobacco 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 and predicate products, as well as from other RYO products. The substances released during use of the new products are no different from the predicate product.

The Agency believes that the disposal of the new products resembles the disposal conditions of RYO cigarette papers that are currently marketed. The waste generated from use of the products may be disposed of into the environment as litter, transferred to publically 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 papers, 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 additional use of resources and energy due to marketing the new products is anticipated.

Approved by _____
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