

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

High Card Regular 100 mm
High Card Gold King Size
High Card Menthol King Size
High Card Regular King Size
Top Gold 100 mm
Top Gold 100 mm
Top Regular 100 mm
Top Regular 100 mm
Top Silver 100 mm
Top Silver 100 mm

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 ten new roll-your-own (RYO) tobacco products into interstate commerce for commercial distribution in the U.S. and submitted to FDA substantial equivalence (SE) reports to obtain market authorizations under the provisions of section 910 and 905(j) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated August 15, 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 analysis on energy and resource use as a result of marketing the new products.

To evaluate the environmental introduction for the proposed action due to the manufacturing of the new product, the Agency used historical data from 2011 to 2016 from the U.S. International Trade Commission (USITC) to forecast the amount of RYO tobacco products imported to the U.S. from Canada. 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 product, the Agency utilized historical data of the use of RYO tobacco 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 RYO tobacco products consumed and found the projection for use of RYO tobacco products is declining. Also, the Agency does not foresee new substances or additional air emissions to be released into the environment as a result of use of the new product.

The Agency believes that the disposal of the new products resembles the disposal conditions of other RYO tobacco products 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 RYO tobacco products used in the U.S. The amount of projected tobacco waste and packaging materials waste due to use and disposal of the new products is a minute fraction of the forecasted tobacco product waste generated due to use of tobacco 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.

Approved by Digitally signed by Kimberly A. Benson -S
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