

FINDING OF NO SIGNIFICANT IMPACT

Product Marketing Order for TOP 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 this action and has concluded that the action 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 a roll-your-own (RYO) tobacco filtered cigarette tube product into interstate commerce for commercial distribution in the United States and submitted to FDA a substantial equivalence (SE) report to obtain a marketing order under the provisions of sections 905(j) and 910 of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the environmental assessment (EA), dated October 31, 2017, under the Council on Environmental Quality's regulations (40 CFR 1500-1508) and FDA (21 CFR Part 25) implementing the National Environmental Policy Act 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 assessment due to manufacturing, use, and disposal after use of the new product. The new product is manufactured in Canada, and used and disposed of in the United States. The only difference between the new product and the predicate product is a change in the weight of the tipping paper in the products. The manufacturer claims to be 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 product.

During use, the new product, like other RYO products, is 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 product will be discontinued after the new product is authorized.

The Agency believes that the disposal of the new product resembles the disposal conditions of RYO cigarette tubes that are currently marketed. The waste generated as a result of use of the product 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 product 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 United States are anticipated as a result of the proposed action.

No significant environmental impacts are expected from marketing the new product 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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