

# FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

OCB® Yellow Cigarette Paper with Tips and OCB® Slim Long Cigarette Papers with Tips

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 new roll-your-own (RYO) tobacco products into interstate commerce for commercial distribution in the United States (U.S.) and submitted to FDA substantial equivalence (SE) reports to obtain market authorizations under the provisions of section 910 and 950(j) of the Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated September 20, 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 that covers the manufacturing, use, and disposal after use of the new and corresponding predicate products. The PEA 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 United States.

To evaluate the potential environmental impacts of the proposed actions due to the manufacturing of the new products, the Agency used historical data from 2007 to 2016 from U.S. International Trade Commission to forecast the amount of RYO tobacco products imported to the United States from France. No new types of emissions due to manufacturing are anticipated, and no new pollution control practices are anticipated.

To evaluate the potential environmental impacts of the proposed actions due to the use of the new products, the Agency utilized historical data of the use of RYO tobacco products from 2000 to 2015 from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau Statistical Release reports to forecast the number of RYO tobacco products consumed and found the projection of 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 products.

The Agency believes that the disposal of the new products will resemble the disposal conditions of the corresponding predicate products and other RYO tobacco products that are currently marketed. The waste generated from the products may be disposed of in municipal solid waste (MSW) or litter 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 solid waste landfills is not anticipated as a result of the proposed action. Furthermore, air emissions associated with MSW is miniscule.

Based on the information provided, the Agency does not anticipate the market volume for RYO tobacco products to be noticeably changed due to the authorization of the new products because the new products will compete with the same type of products on the market. Consequently, no additional use of resources and energy due to marketing the new products is anticipated.

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.

Approved by Digitally signed by Kimberly A. Benson -S  
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