

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for

OCB Xpert Blue, OCB Xpert Double, and OCB Xpert XXL

Manufactured by Republic Tobacco, LP

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts of these action and has concluded that this 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 three new roll-your-own (RYO) cigarette papers into interstate commerce for commercial distribution in the United States and submitted to FDA three substantial equivalence (SE) reports to obtain marketing orders under the provisions of sections 910 and 905(j) of the Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated February 2, 2018, 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 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, then used and disposed of in the United States.

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

To evaluate the potential environmental impacts for the proposed actions due to the use of the new products, the Agency utilized historical data of the use of RYO products from 2008 to 2016 from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports to forecast the number of RYO products consumed. The market projections of the new products are a minute fraction of the forecasted use of RYO products. 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 be the same as the disposal conditions of other RYO products that are currently marketed. The waste generated from use of the new products may be disposed of as municipal solid waste (MSW) and transferred to publicly owned treatment works (POTWs) or as litter, in the same manner as the waste generated from other RYO products that are used in the United States. The projected total waste due to the 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 and POTWs are not anticipated as a result of the proposed actions. Furthermore, air emissions associated with MSW for these actions are miniscule.

Based on the information provided, the Agency does not anticipate the total market volume for RYO cigarette papers to be noticeably changed due to the authorization of the new products because the new products will compete with the same type of tobacco products currently 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 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.

The applicant also provided evidence of their compliance with relevant federal, state, and local environmental laws and regulations.

Approved by

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