

## FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

OCB® NO. 1 SINGLE WIDE

OCB® SLIM

OCB® RED 1-1/4

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 three new roll-your-own (RYO), rolling papers into interstate commerce for commercial distribution in the U.S. and submitted to FDA substantial equivalence (SE) reports to obtain market authorization pursuant to Section 910(a)(2) of the FD&C Act.

The agency prepared the programmatic environmental assessment (PEA), dated August 23, 2016, 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 and use of the new products and disposal after the new products are used. The PEA also provides analysis on resources used as a result of marketing the new products. The new products are manufactured in France, but are used and disposed of in the U.S.

To evaluate the environmental introduction for the proposed action due to manufacturing of the new products, the agency used historical data from 2000 to 2015 from U.S. International Trade Commission (USITC), statistics to provide U.S. import of cigarette papers from France. The statistics show a decline of cigarette paper imports from France into the U.S. The new products projected market volumes would represent a negligible portion of cigarettes imported into the U.S. from France. In addition, the applicant stated that the manufacturing operation abides by all French regional and federal emissions, solid waste, and liquid waste regulations and requirements, which are applicable to their facility. The agency does not foresee any additional emissions to be released into the environment due to their manufacturing. Therefore, the introduction of released substances due to manufacturing the new products is negligible from the environmental viewpoint.

To evaluate the environmental introduction for the proposed action due to use of the new products, the agency utilized historical data of RYO cigarette equivalents in the US from 2008 to 2015 from TTB to forecast the number of RYO cigarettes consumed. The projected market

volumes of the new products represent a negligible portion of the forecasted use of RYO cigarettes in the U.S. The agency does not foresee new substances to be released into the environment as a result of use of the new products, in comparison to the substances released by the predicate products and by other RYO cigarettes currently marketed. Therefore, the introduction of released substances due to use of the new products is negligible from the environmental viewpoint.

The agency believes that the disposal of the new products resembles the disposal conditions of RYO cigarettes that are currently marketed. The waste generated as a result of use of the products will be released to the environment, transferred to publically owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from other combusted RYO tobacco products used in the U.S. The amount of projected packaging materials waste, which includes paper, due to use and disposal of the new products is a minute fraction of the forecasted total 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 2013*". Therefore, construction of new POTWs and landfills are not anticipated as a result of the proposed action.

The market volume projections for the new products are a negligible fraction of the total RYO cigarettes sold in the U.S. The agency does not anticipate the market volume for RYO cigarettes to be noticeably changed based on the provided information. Consequently, no additional use of resources due to marketing the new products is anticipated.

No significant environmental impacts are expected from marketing the new products because no new air emission, water discharge, or solid waste disposal is foreseen; no additional use of resources due to marketing the new products is anticipated.

The applicant also stated their compliance with relevant French regional and federal emissions, solid waste, and liquid waste regulations and requirements, which are applicable to their facility and environmental regulations.

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Approved by

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