

FINDING OF NO SIGNIFICANT IMPACT

for

Product Market Authorization Orders for

Abadie 1-1/2 Size, JOB 1.5 Gold, TOP Standard, Zip-Zag 1¼ Size French Orange, Rolling Standard, Zig-Zag King Size, Ventura Whites, Zig-Zag Kutcorners Slow Burning, JOB 1.0 Silver, TOP 1-1/2 Size, OCB Organic Hemp King Size Slim, OCB Ungummed, OCB Yellow Cigarette Papers with Tips, Zig-Zag White, JOB 1.0 Gold, JOB Tribal King Size, OCB Organic Hemp Single Wide, OCB Slim Long Cigarette Papers with Tips, JOB Single Wide (White), Abadie 1-1/4 Size, JOB Brown Double Wide, Abadie Single Width, OCB Organic Hemp 1-1/4 Size, JOB Brown 1-1/4, JOB Brown 1-1/2, JOB French White, JOB Double Wide Gold, JOB Cutcorners (White), JOB 1-1/4 (Orange), JOB 1-1/2 (White) 99¢, JOB 1.5 Slim Gold, JOB 1.5 Silver, JOB 1.25 Silver, JOB 1.25 Gold

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 multiple 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 pursuant to Section 910(a)(3)(A)(ii) and Section 910(b) of the FD&C Act.

The Agency prepared the programmatic environmental assessment, dated March 16, 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 analysis 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. The new products are manufactured in France, and used and disposed of in the U.S.

To evaluate the environmental introduction for 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 (USITC) to forecast the amount of RYO tobacco products imported to the U.S. from France. 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 actions due to the use of the new products, the Agency utilized historical data for the use of RYO tobacco products from 2000 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 greenhouse gas emissions to be released into the environment as a result of use of the new products. Therefore, the introduction of released substances due to use of the new products is negligible from the environmental perspective.

The Agency believes that the disposal of the new products resembles the disposal conditions of RYO tobacco products that are currently marketed. The waste generated as a result of use of the products will be released to the environment, transferred to publicly owned treatment works (POTWs), 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 total waste due to use and disposal of the new products is a minute fraction of the forecasted tobacco product 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 POTWs and landfills are not anticipated as a result of the proposed actions. Furthermore, no additional control of greenhouse gas emissions is anticipated in the existing landfills.

The Agency does not anticipate the market volume for RYO tobacco products to be noticeably changed based on the provided information because the new products will ultimately replace the corresponding predicate products and compete with the same types 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
Date: 2017.03.16 16:31:39 -04'00'
Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
Food and Drug Administration