

FINDING OF NO SIGNIFICANT IMPACT

for

Product Marketing Orders for

Roll-Your-Own rolling papers “Smoking Master Double Cigarette Paper, Smoking Red Double Cigarette Paper (120 Ct.), Smoking Orange Double Cigarette Paper (120 Ct.)”

Manufactured by Miquel Y Costas & Miquel, S.A.

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.

Miquel Y Costas & Miquel, S.A. (MCM) wishes to introduce three new roll-your-own (RYO) tobacco rolling paper products into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence (SE) reports to obtain marketing orders under the provisions of sections 905(j) and 910 of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated October 27, 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 new products are manufactured in Spain, and used and disposed of in the United States.

To assess the environmental introduction for the proposed actions due to the manufacturing of the new products, the Agency evaluated the differences between the new products and the predicate products and concluded that the package quantity change would not result in the release of any new substances or emissions into the environment. Because once marketing orders are issued, the new products would compete with the predicate products, and the [REDACTED] along with other products made in the same facility, the Agency would not anticipate an expansion of the manufacturing facility or any new substances or new type of emissions to be released into the

environment as a result of manufacturing the new products. No anticipated additional resources with new control measures for air emission, water discharge, or solid waste disposal would be required for manufacturing the new products. In addition, there would be no anticipated net increase in energy use.

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 and cigarettes in the United State from 2008 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) Statistical Release reports to forecast the number of products consumed and found the projection for use of RYO tobacco products to be declining. Also, the Agency does not foresee new substances 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 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 United States. The amount of projected total waste and disposal of the new products following use is a minute fraction of the forecasted tobacco product waste 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 POTWs and landfills are not anticipated as a result of the proposed actions.

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.

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Date: 2017.10.30 09:27:59 -04'00'

Approved by _____

Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
Food and Drug Administration