

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

Vera Cruz Nocturne King Size Slim

Vera Cruz Midnight King Size Slim

Vera Cruz Elegante King Size Slim

Manufactured by Silverfoiltubes International, Inc.

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.

Silverfoiltubes International, Inc. wishes to introduce three roll-your-own (RYO) filtered cigarette tube products 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 March 25, 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, 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 the Philippines and 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 utilized historic data from 2008 to 2014 to forecast the amount of RYO tobacco products imported to the U.S. from the Philippines. We found that the projected market volumes of the new products would represent a small portion of the U.S. import forecast of total RYO from the Philippines. 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 historic data of RYO use from 2005 to 2014 from U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau statistics to forecast the amount of use of RYO tobacco products. We found that the projected market volumes of the new products represent a fraction of the forecasted use of RYO tobacco products 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 that are already on the market and all other RYO cigarette tubes. 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 current RYO and other combusted 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 publically owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from other combusted tobacco products used in the U.S. The amounts of projected tobacco waste and packaging materials waste, including paper and plastics, due to use and disposal of the new products is a minute fraction of the forecasted tobacco product waste generated due to use of RYO tobacco products. Also, it is a negligible fraction of municipal solid 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 tobacco products sold in the U.S. The agency does not anticipate the market volume for RYO tobacco products to be changed noticeably based on the provided information. 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, and solid waste disposal are foreseen; no additional use of resources and energy due to marketing the new products is anticipated.

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Approved by

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