

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Order for

Silver Tip Extra 250

Marketed by GIZEH Raucherbedarf GmbH

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement is not required.

GIZEH Raucherbedarf GmbH wishes to introduce a new roll-your-own (RYO) filtered cigarette tube into interstate commerce for commercial distribution in the United States (U.S.) and submitted to FDA a substantial equivalence (SE) report to obtain a market authorization pursuant to Section 910(a)(B)(3) and Section 910(b) of the FD&C Act.

The agency prepared the environmental assessment (EA) , dated October 5, 2015, under the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act to support the finding of no significant impact (FONSI). The evidence supporting this finding is contained in the attached EA, which is available to the public upon request.

The EA provides an environmental effect assessment on manufacturing, use, and disposal after use of the product. The new product is manufactured in France and used and disposed of in the U.S.

To evaluate the environmental introduction of the proposed action due to manufacturing of the new product in France, the agency utilized historic data from the United States International Trade Commission for total tobacco products imported from France. Based on the historic data, the projected market volumes of the new product are a small portion of the import forecast of tobacco products in the U.S. in 2014. In addition, the new product is anticipated to compete with other cigarette papers marketed in the U.S. and the agency does not foresee any additional emissions to be released into the environment due to manufacturing. Therefore, the introduction of released substances due to manufacturing the new product is negligible from the environmental viewpoint.

To evaluate the environmental introduction of the proposed action due to use of the new product, the agency utilized historic RYO use data from 2008-2014 from U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau statistics to estimate future use in the U.S. The projected market volumes of the new product are a small fraction of the forecasted use of RYO products in the U.S. The agency does not foresee any additional materials released into the environment due to product use. Therefore, the introduction of released substances due to use of the new product is negligible from the environmental viewpoint.

The agency believes that the disposal of the new product resembles the disposal conditions of current filtered cigarette tube products and any other RYO tobacco products that are being marketed. The waste generated as a result of use of the product will be released to the environment and disposed of in landfills in the same manner as the waste generated from any other RYO tobacco products used in the

U.S. The amounts of projected filter waste and packaging material waste, including paper and plastics, due to use and disposal of the new product is a minute fraction of municipal solid waste generated in the U.S. based on information presented in the U.S. Environmental Protection Agency's "Advancing Sustainable Materials Management: Facts and Figures 2013" Report. Therefore, the introduction of released substances due to disposal after use of the new product is negligible from the environmental viewpoint.

The market volume projections for the new product are a fraction of the total RYO tobacco products sold in the U.S. Furthermore, the new product will compete with currently marketed products. The agency does not anticipate the market volume for all RYO tobacco products to be changed noticeably based on the provided information. Consequently, the additional use of resources and energy due to marketing the new product is also negligible.

Because the environmental introduction is miniscule and the additional use of resources and energy is negligible, no significant environmental impacts are expected from marketing the new product.

Approved by _____

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