

FINDING OF NO SIGNIFICANT IMPACT

for

Product Market Authorization Orders for

Real Menthol 3 oz Medium Bag, Real Silver 8 oz Large Bag, Top Turkish 0.6 oz Pouch, Top Turkish 6 oz Canister, Real Menthol 8 oz Large Bag, Real Full Flavor 8 oz Large Bag, Real Gold 3 oz Medium Bag, Real Full Flavor 3 oz Medium Bag, Real Gold 8 oz Large Bag, Real Silver 3 oz Medium Bag

Manufactured by Top Tobacco, L.P.

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 they will not have a significant impact on the quality of the human environment. Therefore, an environmental impact statement is not required.

Top Tobacco L.P. wishes to introduce 10 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 under the provisions of section 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated September 5, 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 and documents the conclusions in this finding of no significant impact. The attached PEA contains the analysis supporting this finding, and is available to the public upon request. The PEA assesses the environmental effects due to manufacturing, use, and disposal after use of the new products. The PEA also discusses impacts from resource and energy use from marketing the new products.

The new products will be assembled into finished components in the U.S. from tobacco processed in the U.S. The new products will be used and disposed of in the U.S.

To evaluate the environmental effects of the proposed actions due to manufacturing the new products, the Agency reviewed applicant data demonstrating that the new products would comprise, cumulatively, only a fraction of a percent of the total production at their U.S. RYO product manufacturing facility. Manufacturing the new products at this existing facility would not release any new compounds.

To evaluate the environmental effects from the proposed actions due to use of the new products, the Agency utilized historical data on the use of RYO tobacco products from 2000 to 2016 from the U.S. Alcohol and Tobacco Tax and Trade Bureau's *Tobacco Statistical Release Reports* to forecast future consumption of RYO tobacco products. The new products are expected to compete with other RYO products on the market, and represent a small fraction of the total RYO products market in the U.S.; therefore, the Agency anticipates minimal or no net increase in the use of all RYO products. The Agency does not anticipate use of the new RYO products would release more substances, including greenhouse

gases, into the environment, relative to the substances released by the predicate products and other RYO products already on the market.

The Agency believes that disposal of the new products resembles the disposal conditions of RYO tobacco products that are currently marketed. After using the new products, the users may recycle the packaging material or dispose of it as municipal solid waste (MSW). Used RYO tobacco products, consisting of cigarette butts, are usually disposed of as MSW or litter. 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. Therefore, no construction of new solid waste landfills or incinerators, and no additional litter compared to that already occurring, is anticipated as a result of the proposed actions. Furthermore, greenhouse gas emissions associated with MSW disposal would be minuscule.

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 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.

Based on the analysis in the PEA, as summarized above, no significant environmental impacts are expected from manufacturing, use, or disposal from marketing the new products. The applicant stated their compliance with relevant federal, state, and local environmental laws and regulations.

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