

## FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

Largo Sun Grown Natural 8 oz Bag  
Largo Full Flavor 0.35 oz Pouch  
Largo Sun Grown Natural 3 oz Bag  
4 Aces Turkish 3.5 oz Canister

Largo Sun Grown Natural 0.35 oz Pouch  
Largo Gold 0.35 oz Pouch  
Largo Menthol 0.35 oz Pouch  
4 Aces Turkish 0.35 oz Pouch

Manufactured by Top 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.

Top Tobacco, LP wishes to introduce eight new roll-your-own (RYO), tobacco and rolling papers 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 October 3, 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 and use of the new products and disposal after the new products are used. The PEA also provides analysis on resources used as a result of marketing the new products. The new RYO tobacco products are manufactured in the U.S., while the rolling papers are imported, with both used and disposed of in the U.S.

To evaluate the environmental introduction for the proposed action due to manufacturing of the rolling paper portion of the new RYO tobacco products, the Agency used historical data from 2000 to 2015 from the U.S. International Trade Commission (USITC) for U.S. import of cigarette papers from the country of origin. The USITC data show an overall decline of cigarette paper imports from the country of origin into the U.S. The new products' projected market volumes would represent a negligible portion of RYO rolling papers imported into the U.S. from the country of origin.

To evaluate the environmental introduction for the proposed action due to manufacturing of the tobacco portion of the new RYO tobacco products, the Agency used historical data from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) for U.S.

manufacturing of RYO tobacco. The TTB data show RYO tobacco manufacturing increased from 4,100 metric tons in 2000 to 9,100 metric tons in 2008. The data also show a decline in U.S. manufacturing of RYO tobacco from 9,100 metric tons in 2008 to 1,400 metric tons in 2015.

The applicant stated that the proposed action will not require an expansion of the existing manufacturing facilities. In addition, the applicant stated there will not be a net increase in energy use from the proposed action as the new products will compete with and replace existing market shares of products that are already being manufactured in the same manner. Also, the applicant stated that the paper used to manufacture the RYO rolling papers is produced from sustainable resources and does not impact critical habitats or endangered species in accordance with the Forest Stewardship Council (FSC) and the Programme for the Endorsement of Forest Certification Schemes (PEFC). These standards require that the applicant use raw materials that do not impact critical habitats or endangered species. Lastly, the applicant stated they comply with the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).

The new products are anticipated to compete with other RYO tobacco and cigarette papers and therefore, the Agency does not expect the introduction of the new products to notably affect the current manufacturing waste generated from the production of all RYO cigarette tobacco and papers. In addition, the applicant stated additional resources are not expected to be added and no new substances created for waste disposal. Furthermore, the applicant stated no new substances will be emitted and no new environmental controls will be needed for the proposed action. The applicant stated they comply with relevant federal, state, and local environmental regulations. Cumulative introduction is not expected to exceed what is allowed to be introduced to the environment under relevant environmental laws. If the manufacturer remains in compliance with the existing laws, the environmental effects are expected to be below the level that would cause environmental harm, therefore no substantial effects are anticipated.

To evaluate the environmental introduction for the proposed action due to use of the new products, the Agency utilized historical data of RYO cigarette equivalents in the U.S. from 2008 to 2015 from TTB to forecast the number of RYO cigarettes consumed. The projected market volumes of the new products represent a negligible portion of the forecasted use of RYO cigarettes 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 and by other RYO cigarettes currently marketed. 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 RYO cigarettes 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 RYO tobacco products used in the U.S. The amount of projected packaging material waste, which includes paper, metal and plastic, due to use and disposal of the new products is a minute fraction of the forecasted total 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 amount of materials anticipated to enter the environment due to use and disposal following use of the new products is negligible. Therefore, the environmental effects of the materials released due to the use and disposal following use of the new products are negligible. Consequently, no new environmental

effects are anticipated due to the new products. The market volume projections for the new products are a negligible fraction of the total RYO cigarettes sold in the U.S. The Agency does not anticipate the market volume for RYO cigarettes to noticeably change based on the provided information. Consequently, no additional use of resources due to marketing the new products is anticipated.

No significant environmental impacts are expected from marketing the new products because no new air emission, water discharge, or solid waste disposal is foreseen. No additional use of resources due to marketing the new products is anticipated.

Approved by Digitally signed by Kimberly A. Benson -S  
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