

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for

Top Gold 0.6 oz Pouch
Top Regular Plain-Vu 0.65 oz Pouch
Top Regular 0.6 oz Pouch
Top Menthol 0.6 oz Pouch
Top Menthol Plain-Vu 0.65 oz Pouch
Gambler Full Flavor 0.6 oz Pouch
Gambler Menthol 0.6 oz Pouch
Drum Halfzware Shag 5 oz Canister
Drum Halfzware Shag 1.14 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 nine new roll-your-own (RYO) tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA substantial equivalence (SE) reports to obtain market authorizations under the provisions of section 910 and 905(j) of the FD&C Act.

The Agency prepared the programmatic environmental assessment (PEA), dated September 29 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. 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.

To evaluate the potential environmental impacts of the proposed actions due to the manufacturing of the new products, the Agency used historical data from 1999-2016 from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Tobacco Statistics to analyze RYO tobacco manufacturing in the U.S. No new types of emissions due to manufacturing are anticipated, and no new pollution control practices are anticipated.

To evaluate the potential environmental impacts of the proposed actions due to the use of the new products, the Agency utilized historical data of the use of RYO tobacco products from 2008 to 2016 from the TTB Statistical Release reports to forecast the number of RYO tobacco products consumed and found the projection for use of RYO tobacco products is declining. Also, the Agency does not foresee new substances or additional air emissions 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 other RYO tobacco products that are currently marketed. The waste generated from the new products may be disposed of into the environment as litter or as municipal solid waste (MSW) in the same manner as the waste generated from other RYO tobacco products used in the United States. The projected total waste due to disposal of the new products is a miniscule fraction of the MSW generated in the United States based on information in the U.S. Environmental Protection Agency's Report "*Advancing Sustainable Materials Management: Facts and Figures 2014*". Therefore, construction of new MSW facilities is not anticipated as a result of the proposed actions. Furthermore, the Agency does not foresee additional air emissions to be released into the environment as a result of disposal of the new products.

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 release of new substances, no expansion of the manufacturing facility, no additional use of resources and energy, and no impact on endangered or threatened species or critical habitat due to marketing the new products is anticipated.

Approved by Digitally signed by Kimberly A. Benson -S
Date: 2017.09.29 11:19:50 -04'00'

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