

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Order for

Red Seal Fine Cut Natural

Manufactured by U.S. Smokeless Tobacco Company, LLC

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

U.S. Smokeless Tobacco Company, LLC wishes to introduce a new moist snuff into interstate commerce for commercial distribution in the United States and submitted to FDA a substantial equivalence (SE) report to obtain a marketing order under the provisions of sections 910 and 905(j) of the Food, Drug, and Cosmetic Act.

The Agency prepared the environmental assessment (EA), dated March 20, 2018, 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 EA, which is available to the public upon request.

The EA provides an environmental effect assessment that covers the manufacturing, use, and disposal of the new product. The EA also provides analysis on energy and resource use as a result of marketing the new product. The new product is manufactured, used, and disposed of in the United States.

To evaluate the potential environmental impacts for the proposed action due to the manufacturing of the new product, the Agency used historical data from 2001 to 2016 from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Tobacco Statistical Release reports to forecast the amount of smokeless tobacco manufactured in the United States. No new types of emissions due to manufacturing are anticipated, and no new pollution control practices are anticipated.

To evaluate the potential environmental impacts for the proposed action due to the use of the new product, the Agency utilized historical data of the use of smokeless tobacco from 2001 to 2016 from TTB Statistical Release reports to forecast the amount of smokeless tobacco consumed. The market projection of the new product is a minute fraction of the forecasted use of snuff. Also, the Agency does not foresee new substances or increased air emissions to be released into the environment as a result of use of the new product.

The Agency believes that the disposal of the new product will be the same as the disposal conditions of other smokeless tobacco products that are currently marketed. The waste generated from use of the product may be disposed of in municipal solid waste (MSW) or litter and transferred to publicly owned treatment works (POTWs) in the same manner as the waste generated from other smokeless tobacco products used in the United States. The projected total waste due to the disposal of the new product is a miniscule fraction of the MSW generated in the United States, based on information presented in the U.S. Environmental Protection Agency's Report *"Advancing Sustainable Materials Management: Facts*

and Figures 2014". Therefore, construction of new solid waste landfills and POTWs are not anticipated as a result of the proposed action. Furthermore, air emissions associated with MSW is miniscule.

Based on the information provided, the Agency does not anticipate the market volume for smokeless tobacco products to be noticeably changed due to the authorization of the new product because the new product will compete with the same type of products on the market. Consequently, no additional use of resources and energy due to marketing the new product is anticipated.

No significant environmental impacts are expected from marketing the new product 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 product is anticipated.

The applicant also provided evidence of their compliance with relevant federal, state, and local environmental laws and regulations.

Approved by Digitally signed by Kimberly A. Benson -S
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