

# FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Orders for

Copenhagen Bold Wintergreen Flavor Packs (1.55g)

Copenhagen Bold Wintergreen Flavor Packs (2.0g)

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 impacts of these actions and has concluded that these actions will not have significant effects on the quality of the human environment. Therefore, an environmental impact statement is not required.

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

The Agency prepared the programmatic environmental assessment (PEA), dated June 4, 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 PEA, which is available to the public upon request.

The PEA provides an environmental effect assessment that covers the manufacturing, use, and disposal of the new products. The PEA 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 actions due to the manufacturing of the new products, the Agency used historical data from 2001 to 2017 from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) Tobacco Statistical Release reports regarding the manufacturing of smokeless tobacco to forecast the amount of smokeless tobacco to be manufactured in the United States. No new types of emissions due to manufacturing the new products are anticipated, and no new pollution control practices are anticipated.

To evaluate the potential environmental impacts for the proposed actions due to the use of the new products, the Agency utilized historical data from 2001 to 2017 from the TTB Statistical Release reports regarding the use of smokeless tobacco to forecast the amount of smokeless tobacco to be consumed. The market projections of the new products are minute fractions 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 products.

The Agency believes that the disposal of the new products will be the same as the disposal conditions of similar smokeless tobacco products that are currently marketed. The waste generated from use of the products may be disposed of in municipal solid waste (MSW) or as 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 collective projected total waste due to the disposal of the new products 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 actions.

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

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.

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

Approved by \_\_\_\_\_  
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