FINDING OF NO SIGNIFICANT IMPACT

Modified Risk Orders for

Copenhagen Classic Snuff

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 loose moist snuff tobacco product with a modified risk claim into interstate commerce for commercial distribution in the United States and submitted to FDA a modified risk tobacco product application to obtain a modified risk order under the provisions of section 911(g)(1) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the environmental assessment (EA), dated October 24, 2022, in accordance with the Council on Environmental Quality's regulations (40 CFR 1500−1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40) to support the finding of no significant impact. The evidence supporting this finding is contained in the attached EA, which is available to the public upon request.

The EA evaluates potential environmental effects due to manufacturing, use, and disposal of the tobacco product with the modified risk claim. No increased or new types of environmental impacts due to manufacturing the tobacco product are anticipated. The Agency does not foresee that use of the tobacco product would result in new or different environmental impacts. The Agency believes that disposal of the tobacco product is the same as the disposal conditions of similar smokeless tobacco products that are currently marketed. Therefore, the Agency does not foresee significant adverse impacts to the environment due to the proposed action as a result of manufacturing, use, and disposal of the tobacco product.

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Approved by _____

Luis G. Valerio, Jr., PhD, ATS
Associate Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
U.S. Food and Drug Administration