

FINDING OF NO SIGNIFICANT IMPACT

Product Marketing Orders for

**Copenhagen Pouches
Copenhagen Snuff Fine Cut
Copenhagen Long Cut Black
Copenhagen Long Cut Straight
Copenhagen Long Cut**

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 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.

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

The Agency prepared the programmatic environmental assessment (PEA), dated September 5, 2018, 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). The PEA concluded that the marketing orders would have no significant impact and is available to the public upon request.

The PEA evaluates potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impacts due to manufacturing are anticipated. The Agency does not foresee use of the new products to result in new or different environmental impacts. The Agency believes that the disposal of the new products 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 actions as a result of manufacturing, use, and disposal of the new products.

Approved by Digitally signed by Kimberly A. Benson -S
Date: 2018.09.05 15:06:47 -04'00'

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