FINDING OF NO SIGNIFICANT IMPACT

Product Marketing Order for

Copenhagen Long Cut Special Wintergreen

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 moist smokeless tobacco product into interstate commerce for commercial distribution in the United States and submitted to FDA a substantial equivalence report to obtain a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the environmental assessment (EA), dated February 3, 2020, 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 EA concluded that the marketing order would have no significant impact and is available to the public upon request.

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

Approved
by

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