

FINDING OF NO SIGNIFICANT IMPACT

Modified Risk Orders for

General Loose, General Dry Mint Portion Original Mini, General Portion Original Large, General Classic Blend Portion White Large, General Mint Portion White Large, General Nordic Mint Portion White Large, General Portion White Large, General Wintergreen Portion White Large

Manufactured by Swedish Match USA, Inc.

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 a significant effect on the quality of the human environment. Therefore, environmental impact statements are not required.

Swedish Match USA, Inc. wishes to communicate modified risk information to consumers, by adding the following claim to the advertising of the eight General Snus products that are the subject of these applications: "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis." They submitted to FDA modified risk tobacco product applications to obtain modified risk orders under the provisions of section 911(g) of the Federal Food, Drug, and Cosmetic Act.

The Agency prepared the programmatic environmental assessment (PEA), dated October 3, 2019, 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 modified risk orders would have no significant impacts and is available to the public upon request.

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

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Approved by

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