

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 U.S.A. Inc.

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impacts of this action and has concluded that this action will not have significant effects on the quality of the human environment. Therefore, an environmental impact statement is 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 a programmatic environmental assessment (PEA), dated November 6, 2024, in accordance with the Council on Environmental Quality's regulations (40 CFR Part 1500) 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 these findings is contained in the attached PEA, which is available to the public upon request.

The PEA evaluates potential environmental effects due to manufacturing, use, and disposal of the modified risk tobacco product. No increased or new types of environmental impacts due to manufacturing are anticipated. The Agency does not foresee use of the modified risk tobacco product would result in new or different environmental impacts. The Agency believes that the disposal of the modified risk tobacco product is the same as the disposal conditions of other heat-not-burn tobacco products that are currently marketed in the United States. Therefore, the Agency does not foresee adverse impacts to the environment due to the proposed action as a result of manufacturing, use, and disposal of the modified risk tobacco product.

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Approved by

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