FINDING OF NO SIGNIFICANT IMPACT FOR

Product Marketing Order for

Red Man Gold Blend

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 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 introduce a new smokeless chewing 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 an environmental assessment (EA), dated June 12, 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) 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 new product. No increased or new types of environmental impacts due to manufacturing are anticipated. The Agency does not foresee that use of the new product would 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 other smokeless chewable 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 the manufacturing, use, and disposal of the new product.

Approved by

Digitally signed by Hans M. Rosenfeldt -S
Date: 2019.06.12 10:09:34 -04'00'

For Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
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