

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization 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 North America, Inc.

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.

Swedish Match North America, Inc. wishes to introduce eight new snus products into interstate commerce for commercial distribution in the United States (U.S.) and submitted to FDA the premarket tobacco product (PMT) applications to obtain market authorizations pursuant to Section 910(b) of the FD&C Act.

The agency prepared the programmatic environmental assessment (PEA) , dated October 8, 2015, under the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act to support the finding of no significant impact (FONSI). The evidence supporting this finding is contained in the attached PEA, which is available to the public upon request.

The PEA provides an environmental effect assessment due to manufacturing, use, and disposal after use of the new products. The PEA also provides analysis on energy and resource use as a result of marketing the new products. The new products are manufactured in Sweden and used and disposed of in the U.S.

To evaluate the environmental introduction of the proposed action due to manufacturing of the new products in Sweden, the agency utilized historic data from 2009-2014 to forecast the amount of smokeless tobacco products imported to the U.S. from Sweden. We found that the projected market volumes of the new products are a small portion of the U.S. import forecast of snuff tobacco from Sweden. In addition, the new products are expected to replace the currently marketed products with the same names. The agency does not foresee any additional emissions to be released into the environment due to their manufacturing. Therefore, the introduction of released substances due to manufacturing the new products is negligible from the environmental viewpoint.

To evaluate the environmental introduction of the proposed action due to use of the new products, the agency utilized historic data of use in 2005-2014 from U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau statistics to forecast the amount of use of smokeless tobacco products and snuff. We found that the projected market volumes of the new products are a fraction of the forecasted use of smokeless products or snuff tobacco in the U.S. As previously noted, the new products are expected to replace currently marketed products with

the same names. The agency does not foresee any additional materials to be released into the environment due to their use. Therefore, the introduction of released substances due to use of the new products is negligible from the environmental viewpoint.

The agency believes that the disposal of the new products resembles the disposal conditions of the current snus products and any other smokeless tobacco products that are being marketed. The waste generated as a result of use of the products will be released to the environment, transferred to publically owned treatment works, and disposed of in landfills in the same manner as the waste generated from any other smokeless tobacco products used in the U.S. The amounts of projected tobacco waste and packaging materials, including paper and plastics, due to use and disposal of the new products is a minute fraction of the forecasted tobacco product waste generated due to use of smokeless tobacco products. Also, it is a negligible fraction of municipal solid waste generated in the U.S. based on information presented in US Environmental Protection Agency's Report "*Advancing Sustainable Materials Management: Facts and Figures 2013*". Therefore, the introduction of released substances due to disposal after use of the new products is negligible from the environmental viewpoint.

The market volume projections for the new products are a negligible fraction of the total smokeless tobacco products sold in the U.S. Furthermore, the new products will replace the currently marketed products with the same names. The agency does not anticipate the market volume for all smokeless tobacco products to be changed noticeably based on the provided information. Consequently, the additional use of resources and energy due to marketing the new products is also negligible.

Because the environmental introduction is miniscule and the additional use of resources and energy is negligible, no significant environmental impacts are expected from marketing the new products.

Approved by Digitally signed by Kimberly A. Benson -S
Date: 2015.10.08 10:17:33 -04'00'
Kimberly Benson, Ph.D.
Director
Division of Nonclinical Science
Office of Science
Center for Tobacco Products
Food and Drug Administration