

FINDING OF NO SIGNIFICANT IMPACT FOR

Product Market Authorization Orders for

Timber Wolf Pouches Wintergreen

Timber Wolf Pouches Natural

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 two new snus products into interstate commerce for commercial distribution in the United States (U.S.) and submitted to FDA substantial equivalence (SE) reports to obtain market authorizations pursuant to Section 910(a)(B)(3) and Section 910(b) of the FD&C Act.

The agency prepared the programmatic environmental assessment (PEA), dated December 30, 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 on FDA's Tobacco Product Marketing Orders website.

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, used and disposed of in the U.S.

To evaluate the environmental introduction for the proposed action due to manufacturing of the new products, the agency utilized historic data from U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau statistics from 2009 to 2014 to forecast the amount of snuff tobacco products manufactured in the U.S. We found that the projected market volumes of the new products are a small fraction of the total snuff manufactured in the U.S. The agency does not foresee any additional emissions to be released into the environment due to the new products' manufacturing. Therefore, no new control practices of air emission, water discharge, or solid waste disposal are needed. .

To evaluate the environmental introduction for the proposed action due to use of the new products, the agency utilized historic data of use from 2005 to 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 and snuff tobacco in the U.S..

The agency believes that the disposal of the new products resembles the disposal conditions of current portioned moist snuff products and other smokeless tobacco products that are currently marketed. The waste generated as a result of use of the products will be released to the environment, transferred to publically owned treatment works (POTWs), and disposed of in landfills in the same manner as the waste generated from other smokeless tobacco products used in the U.S. The amounts of projected tobacco waste and packaging materials waste, 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 the U.S. Environmental Protection Agency's Report "*Advancing Sustainable Materials Management: Facts and Figures 2013*". Therefore, construction of new POTWs and landfills are not anticipated as a result of the proposed action.

The market volume projections for the new products are a negligible fraction of the total smokeless tobacco products sold in the U.S. The agency does not anticipate the market volume for all smokeless tobacco products to be changed noticeably based on the provided information. Consequently, no additional use of resources and energy due to marketing the new products is anticipated.

No significant environmental impacts are expected from marketing the new products because no new control practices of air emission, water discharge, and solid waste disposal are; and, no additional use of resources and energy due to marketing the new products is anticipated.

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