

# FINDING OF NO SIGNIFICANT IMPACT

for

Product Market Authorization Orders for

Longhorn Long Cut Mint

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 a new smokeless tobacco product 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)(3)(A)(ii) and Section 910(b) of the FD&C Act.

The agency prepared the environmental assessment, dated November 3, 2016, under the Council on Environmental Quality's regulations (40 CFR 1500-1508) implementing the National Environmental Policy Act and in accordance with 21 CFR 25.41 to support the finding of no significant impact (FONSI). The evidence supporting this finding is contained in the attached EA, which is available to the public upon request.

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

To evaluate the environmental introduction for the proposed action due to the manufacturing of the new product, the agency used historical data from 2006 to 2015 from the U.S. Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) statistics to forecast the amount of smokeless tobacco products manufactured in the U.S. Because the projected market volumes of the new products would represent a negligible portion of smokeless tobacco products manufactured in the U.S., no new types of emissions due to manufacturing are anticipated, and no new pollution control practice is anticipated.

To evaluate the environmental introduction for the proposed action due to the use of the new product, the agency utilized historical data of the use of smokeless tobacco products from 2006 to 2015 from TTB statistics to forecast the number of smokeless tobacco products consumed. Because the projected market volume of the new product represents a negligible portion of the forecasted use of smokeless tobacco products in the U.S., the agency does not foresee new substances or additional greenhouse gas emissions to be released into the environment as a result of use of the new product. Therefore, the introduction of released substances due to use of the new product is negligible from the environmental perspective.

The agency believes that the disposal of the new product resembles the disposal conditions of smokeless tobacco products that are currently marketed. The waste generated as a result of use of the product will be released to the environment, transferred to publicly 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 amount of projected tobacco waste and packaging materials waste, including paper and plastic, due to use and disposal of the new product is a minute fraction of the forecasted tobacco product 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. Furthermore, no additional control of greenhouse gas emissions is anticipated in the existing landfills.

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

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

The applicant also provided evidence of their compliance with relevant federal, state, and local environmental laws and regulations.

Digitally signed by Kimberly A. Benson -S  
Date: 2016.11.18 11:56:11 -05'00'  
Approved by \_\_\_\_\_  
Kimberly Benson, Ph.D.  
Director  
Division of Nonclinical Science  
Office of Science  
Center for Tobacco Products  
Food and Drug Administration