DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

December 14, 2016

DENIAL

Swedish Match North America, Inc.
Attention: Gerard Roerty, Vice President, General Counsel & Secretary
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Number (STN): MR0000022

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed review of your Modified Risk Tobacco Product Application (MRTPA) submitted under section 911(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) seeking a modified risk order under section 911(g)(1) of the FD&C Act, for the following tobacco product[1]:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Manufacturer:	Swedish Match North America, Inc.
Tobacco Product Name[2]:	General Portion Original Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Product Order under 911(g):	911(g)(1) Risk Modification Order
Proposed Modified Risk Claim(s):	• Remove the mouth cancer warning • Remove the gum disease and tooth loss warning • Revise the "not a safe alternative" warning to "WARNING: No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes"
Package Type:	Plastic Can
Package Quantity:	24.0 g
Characterizing Flavor:	None

We have completed the review of your MRTPA, as amended, and other available information including public comments and recommendations of the Tobacco Products Scientific Advisory

[1] Properties to uniquely identify the new tobacco product were provided by the applicant as of the date of this letter.
[2] Brand/sub-brand or other commercial name used in commercial distribution

Committee, and deny issuance of a section 911(g)(1) modified risk order with respect to your request to remove the gum disease and tooth loss warning, because the application does not contain sufficient evidence to demonstrate that the product, as actually used, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole. Therefore, you may not introduce or deliver for introduction into interstate commerce the proposed modified risk tobacco product that omits the gum disease and tooth loss warning from the rotation of required warnings.

Our review of your application revealed the following deficiency:

- You request to omit from the label and advertising of the eight General Snus products "WARNING: This product can cause gum disease and tooth loss." This warning is currently required for smokeless tobacco products generally. Omission of this warning from a subset of smokeless tobacco products indicates that unlike other smokeless tobacco products, the eight General Snus products cannot cause gum disease or tooth loss. Thus, the request is to market the products with an implied modified risk claim that the products, as compared to other smokeless tobacco products, cannot cause gum disease or tooth loss.

  After conducting a thorough assessment of the scientific substantiation of the claim that the eight General Snus products cannot cause gum disease or tooth loss, FDA determined that the claim is not substantiated. On the contrary, there is little biologically plausible reason to expect that outcomes related specifically to gum and teeth of users resulting from the use of the eight products would differ from those outcomes resulting from the use of other smokeless tobacco products. Indeed, given that these eight General snus products, like other smokeless tobacco products, cause delayed soft tissue wound healing, these products would not be expected to differ from other smokeless tobacco products with respect to these disease outcomes. Furthermore, the epidemiological evidence indicates that the use of these products, as actually used by consumers in Sweden and Norway, increases the risks of certain outcomes classified as gum disease or tooth loss, or precursors to gum disease and tooth loss. Because the totality of the scientific evidence supports the statement that smokeless tobacco products in general and these products in particular "can cause gum disease and tooth loss," the proposed modified risk claim is not substantiated. Additionally, you did not provide evidence regarding how the modified risk information (i.e., the removal of the gum disease and tooth loss warning) would impact consumer behavior or whether consumers would understand the modified risk information in the context of total health. As a result, you have not demonstrated that, as actually used by consumers, the product sold or distributed with the proposed modified risk information, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole. Accordingly, the request to omit the warning related to gum disease and tooth loss is denied.

If you wish to request supervisory review of this decision under 21 CFR 10.75, please submit the request via the CTP Portal[3] (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm) using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

[3]The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The CTP Portal and FDA Electronic Submission Gateway (ESG) are both available 24 hours a day, seven days a week; if the upload is successful, submissions are considered received by DCC on the day of upload. Submissions delivered to DCC by couriers or physical mail will be considered timely if received during delivery hours on or before the due date (see http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on the prior business day. We are unable to accept regulatory submissions by electronic mail.

We request that your package be sent as a single submission with a cover letter that includes the following text in your subject line: **REQUEST FOR SUPERVISORY REVIEW FOR MR0000022**. In addition, we request that your package identify each basis for the request and contain all information on which you wish your request to be based; it may not contain any new data or analysis that was not part of your MRTPA.

You may not legally introduce or deliver for introduction into interstate commerce the proposed modified risk tobacco product that omits the gum disease and tooth loss warning from the rotation of required warnings without an order in effect under section 911(g) of the FD&C Act. Under section 301(pp) of the FD&C Act, it is a prohibited act to introduce or deliver for introduction into interstate commerce a tobacco product in violation of section 911. In addition, under section 902(8) of the FD&C Act, a tobacco product is deemed adulterated if it is in violation of section 911 of the FD&C Act, and the introduction or delivery for introduction into interstate commerce of any adulterated tobacco product is a prohibited act under section 301(a) of the FD&C Act.
Failure to comply with the FD&C Act may result in FDA taking regulatory action without further notice. These actions may include, but are not limited to, civil money penalties, seizure, and/or injunction.

If you have any questions, contact Shireen Ahmad, M.S., Regulatory Health Project Manager, at (240) 402-0435.

Sincerely,

Digitally signed by David Ashley -S
Date: 2016.12.14 07:04:13 -05'00'

David L. Ashley, Ph.D.
RADM (Ret.), United States Public Health Service
Director
Office of Science
Center for Tobacco Products