DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850-3229

November 15, 2013

SUBSTANTIALLY EQUIVALENT

FDA Submission Tracking Number (STN): SE0004386

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

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed review of your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), for the following tobacco product:

Applicant:	Swedish Match North America, Inc.
Tobacco Product Name[1]:	Timber Wolf Long Cut Straight
Tobacco Product Category:	Smokeless
Tobacco Product Sub-Category:	Moist Snuff loose
Package Size:	34.02 g
Package Type:	Plastic can

Based on our review of your SE Report, we find the new tobacco product specified above substantially equivalent to a tobacco product commercially marketed in interstate commerce as of February 15, 2007.

Under the provisions of section 910 and 905(j) of the FD&C Act, you may introduce, or deliver for introduction into interstate commerce, the new tobacco product specified above.

[1] Brand/sub-brand or other commercial name used in commercial distribution

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Report. No later than December 14, 2013, we will make your summary available to the public.

In accordance with 40 CFR 1506.6, we will make your environmental assessment publicly available.

It is important to note our finding of substantial equivalence for your new tobacco product specified above to an appropriate predicate tobacco product permits marketing of your new tobacco product. Our finding does not mean FDA "approved" the new tobacco product specified above; therefore, you may not promote or in any way represent the new tobacco product specified above, or its labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act.

The finding that your product is substantially equivalent to the predicate product is based upon the information you provided in your SE Report and the standards contained in the FD&C Act, Section 910(a)(3). This marketing order is subject to reconsideration, with notice to the manufacturer, and rescission to the extent authorized by law.

We remind you that all regulated tobacco products, including the new tobacco product specified above, are subject to the requirements of Chapter IX of the FD&C Act and its regulations. These requirements currently include, but are not limited to, annual registration, listing of products, listing of ingredients, reporting of harmful and potentially harmful constituents, and payment of user fees. There are also labeling and advertising requirements with which you must comply. A review of labeling and advertising was not conducted as part of this substantial equivalence review. It is your responsibility to ensure the tobacco product specified above complies with all applicable statutory and regulatory requirements, including those which may be forthcoming. FDA will monitor your compliance with these applicable statutes and regulations.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

We remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

Center for Tobacco Products
Food and Drug Administration
Document Control Center, Rm 020J
9200 Corporate Boulevard
Rockville, MD 20850-3229

We are unable to accept regulatory submissions by electronic mail.

If you have any questions, please contact Stephanie Redus, M.S., Regulatory Health Project Manager, at (301) 796 -7380.

Sincerely,

Digitally signed by David Ashley -S
Date: 2013.11.15 07:55:39 -05'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science
Center for Tobacco Products