U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

November 05, 2018

SUBSTANTIALLY EQUIVALENT

Swedish Match USA, Inc.
ATTENTION: Gerard J. Roerty, Jr., Vice President, General Counsel & Secretary
Two James Center
1021 E Cary Street, Suite 1600
Richmond, VA 23219

FDA Submission Tracking Number (STN): SE0013001

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 (FD&C Act), for the following tobacco product:

New Tobacco Product

Date of Submission:	March 7, 2016
Date of Receipt:	March 7, 2016
Product Manufacturer:	Swedish Match USA, Inc.
Product Name:[1]	Timber Wolf Long Cut Wintergreen
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
Package Type:	Plastic can and lid
Package Quantity:	408.24 grams
Characterizing Flavor:	Wintergreen
Tobacco cut size:	(b)(4) CPI[2]

[1] Brand/sub-brand or other commercial name used in commercial distribution
[2] Cuts per inch (CPI)

Based on our review of your SE Report, we find the new tobacco product specified above is in compliance with the requirements of the FD&C Act and substantially equivalent to the following eligible predicate tobacco product:[3]

Predicate Tobacco Product

Product Manufacturer:	Swedish Match USA, Inc.
Product Name:[1]	Timber Wolf Long Cut Wintergreen
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Moist Snuff
Package Type:	Plastic can and lid
Package Quantity:	34.02 grams
Characterizing Flavor:	Wintergreen
Eligibility Type:	Previously found SE under SE0001762
Tobacco cut size:	 CPI[2]

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 product specified above.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Report. It is your responsibility under section 910(a)(4) to make your health information summary available upon request by any person.

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[3]. Our finding does not mean FDA "approved" the new 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. It is your responsibility to ensure that 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.

[3] In addition to comparing the new tobacco product to the predicate tobacco products named by the applicant, FDA also compared the new tobacco product in this SE Report to the grandfathered tobacco product in SE0001762. Although the new product has different characteristics than the grandfathered tobacco product in SE0001762, FDA found that those differences do not cause the new tobacco product to raise different questions of public health, and thus the new tobacco product is also substantially equivalent to the grandfathered product in SE0001762.

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 encourage you to submit all regulatory correspondence electronically via the CTP Portal (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm)[4] using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). Alternatively, submissions may be mailed to:

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

The CTP Portal and the FDA Electronic Submission Gateway (ESG) are generally 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 courier or physical mail will be considered timely if received during delivery hours on or before the due date (see http://www.fda.gov/tobaccoproducts/abouctp/contactus/default.htm); if the due date falls on a weekend or holiday the delivery must be received on or before the preceding business day. We are unable to accept regulatory submissions by e-mail.

If you have any questions, you may contact Shireen Fotelargias, Regulatory Health Project Manager, at (240) 402-0435 or Shireen.Fotelargias@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.11.05 10:04:59 -05'00'

Matthew R. Holman, Ph.D.
Director
Office of Science
Center for Tobacco Products

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