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

July 17, 2018

SUBSTANTIALLY EQUIVALENT

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

FDA Submission Tracking Number (STN): SE0000097

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:

New Tobacco Product

Date of Submission:	March 8, 2011
Date of Receipt:	March 10, 2011
Product Manufacturer:	Swedish Match USA, Inc.
Product Name:[1]	Timber Wolf Pouches Mint
Product Category:	Smokeless Tobacco
Product Sub-Category:	Portioned Moist Snuff
Package Type:	Plastic Can and Lid
Package Quantity:	23.25 g; 15 pouches
Characterizing Flavor:	Peppermint
Portion mass:	1.55 g
Portion length:	41 mm
Portion width:	17 mm
Portion thickness:	6 mm
Tobacco cut size:	[redacted] CPI
Additional properties:	[redacted]

Based on our review of your SE Report, we find the new tobacco product specified above is substantially equivalent to the following tobacco product, which was commercially marketed in the United States as of February 15, 2007:

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

- Providing portion mass plus two of the three portion dimensions (along with other specified properties) will allow for full identification of portioned moist snuff and snus products.

Predicate Tobacco Product

Product Manufacturer:	Swedish Match USA, Inc.
Product Name:[2]	Timber Wolf Packs Wintergreen
Product Category:	Smokeless Tobacco
Product Sub-Category:	Portioned Moist Snuff
Package Type:	Plastic Can and Lid
Package Quantity:	23.25 g; 15 pouches
Characterizing Flavor:	Wintergreen
Portion mass:	1.55 g
Portion length:	41 mm
Portion width:	17 mm
Portion thickness:	6 mm
Tobacco cut size:	(b) (4) CPI

Under the provisions of section 910 and 905(j) of the FD&C Act, you continue to legally market the new tobacco 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. No later than 30 days from date of letter, we will make your summary available to the public.

In accordance with 40 CFR 1506.6, we will make publicly available the finding that this marketing authorization is in a class of actions categorically excluded under 21 CFR 25.35(a). No extraordinary circumstances exist for this action.

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 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.

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

- Providing portion mass plus two of the three portion dimensions (along with other specified properties) will allow for full identification of portioned moist snuff and snus products.

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.

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)[3] 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/aboutctp/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, MS, Regulatory Health Project Manager, at (240) 402 - 0435 or Shireen.Fotelargias@fda.hhs.gov.

Sincerely,

Digitally signed by Matthew R. Holman -S
Date: 2018.07.17 11:12:32 -04'00'

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

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