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

December 16, 2019

SUBSTANTIALLY EQUIVALENT

Swedish Match USA, 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): SE0015504**,** see Appendix A

Dear Mr. Roerty:

We completed our review of your SE Report [1] and determined that the new tobacco product is substantially equivalent to the predicate tobacco product listed in Appendix A[2] and is in compliance with the requirements of the FD&C Act. 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 subject of this letter.

Our finding does not mean we "approved" the new product specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco product specified in Appendix A, or the labeling, as being "approved" by FDA (see Section 301(tt) of the FD&C Act).

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 (EA) publicly available.

All regulated tobacco products, including the tobacco product specified in Appendix A, are subject to the requirements of the FD&C Act and its implementing regulations. It is your responsibility to ensure the tobacco product specified in Appendix A complies with all applicable statutory and regulatory requirements. FDA will monitor your compliance with all applicable statutes and regulations.

[1] Substantially Equivalent (SE) Report submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
[2] In addition to comparing the new tobacco product to the predicate tobacco product named by the applicant, FDA also compared the new tobacco product in SE0015504 to the grandfathered tobacco product SE0012445. Although the new product has different characteristics than the grandfathered tobacco product in SE0012445, 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 are also substantially equivalent to the grandfathered product in SE0012445.

If you have any questions, please 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: 2019.12.16 14:35:39 -05'00'

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

Enclosures:

Appendix A – New and Predicate Tobacco Products Subject of This Letter

Appendix A

New and Predicate Tobacco Products Subject of This Letter

Common Attributes of SE Report		
Date of Submission:	September 19, 2019	
Date of Receipt:	September 19, 2019	
Product Manufacturer:	Swedish Match USA, Inc.	
Product Category:	Smokeless Tobacco Products	
Product Sub-Category:	Portioned Moist Snuff	
	New Tobacco Product	**Predicate Tobacco Product**
	SE0015504: Timber Wolf Pouches Peach[3,4]	**SE0012445: Timber Wolf Pouches Wintergreen**[3,4]
Package Type:	Plastic can and plastic lid	Plastic can and plastic lid
Package Quantity:	23.25 g	23.25 g
Characterizing Flavor:	Peach	Wintergreen
Eligibility Status:	N/A	Previously Found SE
Tobacco Cut Size:	(b) (4)	(b) (4)
Portion Count:	15 Pouches	15 Pouches
Portion Mass:	1.55 g	1.55 g
Portion Length:	41 mm	41 mm
Portion Width:	17 mm	17 mm
Portion Thickness:	6 mm	6 mm

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

[4] 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.