



April 05, 2018

SUBSTANTIALLY EQUIVALENT

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

FDA Submission Tracking Number (STN): SE0000103

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

Tobacco Product Manufacturer:	Swedish Match USA Inc.
Tobacco Product Name¹:	Longhorn Pouches Straight 23.25 g
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Moist Snus
Package Type:	Plastic Can and Lid
Package Quantity:	23.25 g (15 pouches)
Characterizing Flavor:	None
Portion Weight:	1.55 g
Length:	41 mm
Portion Width:	17 mm
Portion Thickness:	6 mm
Tobacco Cut Size:	(b) (4)

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

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:

Predicate Tobacco Product

Tobacco Product Manufacturer:	Swedish Match USA Inc.
Tobacco Product Name²:	Timber Wolf Packs Wintergreen 23.25 g
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Moist Snuff
Package Type:	Plastic Can and Lid
Package Quantity:	23.25 g (15 pouches)
Characterizing Flavor:	Wintergreen
Portion Weight:	1.55 g
Portion Length:	41 mm
Portion Width:	17 mm
Portion Thickness:	6 mm
Tobacco Cut Size:	(b) (4)

Under the provisions of section 910 and 905(j) of the FD&C Act, you may 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 product³. 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.

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

³ Please see footnote 2.

The finding that your product is substantially equivalent to the predicate product⁴ 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 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>)⁵ 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 FDA Electronic Submission Gateway (ESG) are both generally available 24 hours a day, seven days a week. 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 e-mail.

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

⁴ Please see footnote 2.

⁵ The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal.

Sincerely,

Digitally signed by Matthew R. Holman -S

Date: 2018.04.05 15:19:19 -04'00'

Matthew R. Holman, Ph.D.

Director, Office of Science

Center for Tobacco Products