DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993

January 13, 2017

SUBSTANTIALLY EQUIVALENT

Swedish Match North America, Inc.
Attention: Gerard J. Roerty, Jr., Vice President,
General Counsel & Secretary
Two James Center
1021 East Cary Street Suite 1600
Richmond, VA 23219
via Certified Mail or UPS

FDA Submission Tracking Number (STN): SE0010528

Dear Mr. Roerty:

This letter is in reference to your Report Preceding Introduction of Certain Substantially Equivalent Products into Interstate Commerce (SE Report), for General Classic Blend Portion White Large (SE0010528), submitted under section 905(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

On November 10, 2015, you received a determination that your new tobacco product was not substantially equivalent to a tobacco product which was commercially marketed in the United States as of February 15, 2007. On December 22, 2015, you submitted a request for supervisory review under 21 C.F.R. § 10.75.

On January 13, 2017, CTP's Office of the Center Director issued its decision on your request for supervisory review. The decision letter directed the Office of Science to rescind the November 10, 2015, NSE Order and to issue an SE Order in accordance with the outcome of the decision for the following tobacco product:

New Tobacco Product

Tobacco Product Manufacturer:	Swedish Match North America, Inc.
Tobacco Product Name[1]:	General Classic Blend Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can

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

Package Quantity:	10.8 g
Portion Count:	12 pouches
Characterizing Flavor:	None
Portion Mass:	900 mg
Portion Length:	34 mm
Portion Width:	14 mm
Portion Thickness:	5 mm
Tobacco Cut Size[2]	(b)(4)

Based on our re-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 tobacco product, which was commercially marketed in the United States as of February 15, 2007:

Predicate Tobacco Product

Tobacco Product Manufacturer:	Swedish Match North America, Inc.
Tobacco Product Name[3]**:**	General Portion White Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24 g
Portion Count:	24 pouches
Characterizing Flavor:	None
Portion Mass:	1000 mg
Portion Length:	34 mm
Portion Width:	18 mm
Portion Thickness:	5.5 mm
Tobacco Cut Size[4]**:**	(b)(4)

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.

[2] The applicant provided (b)(4) buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single size value and corresponding range limit.
[3] Brand/sub-brand or other commercial name used in commercial distribution
[4] The applicant provided (b)(4) buckets to characterize the tobacco cut size. Therefore, the tobacco cut size cannot be represented with a single size value and corresponding range limit.

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 the date of this letter, 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. 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:

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

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 Cecilia Robinson, Regulatory Health Project Manager, at (240) 402-5881.

Sincerely,

Digitally signed by David Ashley -S
Date: 2017.01.13 11:31:21 -05'00'

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