DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

November 10, 2015

SUBSTANTIALLY EQUIVALENT

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

FDA Submission Tracking Number (STN): SE0010526

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 North America, Inc.
Tobacco Product Name[1]:	General Portion Original Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24 g
Characterizing Flavor:	None
Portion Count:	24 pouches
Portion Mass:	1000 mg
Portion Length:	33 mm
Portion Width:	18 mm
Portion Thickness:	6 mm
Tobacco Cut Size[2]:	(b) (4)

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

Based on our review of your SE Report, we find the new tobacco product specified 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 Original Large
Tobacco Product Category:	Smokeless Tobacco
Tobacco Product Sub-Category:	Portioned Snus
Package Type:	Plastic Can
Package Quantity:	24 g
Characterizing Flavor:	None
Portion Count	24 pouches
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.

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 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.

[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.

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 remind you all regulatory correspondence can be submitted via the FDA Electronic Submission Gateway (http://www.fda.gov/esg) using eSubmitter or by mail to:

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

We are unable to accept regulatory submissions by electronic 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: 2015.11.10 06:14:53 -05'00'

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