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

August 24, 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): SE0005816

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]	J.D.'s Blend 9 oz
Product Category:	Smokeless Tobacco
Product Sub-Category:	Loose Chewing Tobacco
Package Type:	Pouch
Package Quantity:	255.15 g
Characterizing Flavor:	None
Tobacco cut size:	(b) (4) mm

Based on our 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:

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

Predicate Tobacco Product

Product Manufacturer:	Swedish Match USA, Inc.
Product Name:[2]	J.D.'s Blend 3 oz
Product Category:	Smokeless Tobacco
Product Sub-Category:	Loose Chewing Tobacco
Package Type:	Pouch
Package Quantity:	85.05 g
Characterizing Flavor:	None
Tobacco cut size:	(b) (4) mm

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 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 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[3]. 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[4] 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 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

[2] Brand/sub-brand or other commercial name used in commercial distribution
[3] Please see footnote 2
[4] Please see footnote 2

(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 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: 2018.08.24 12:25:27 -04'00'

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

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