U.S. FOOD & DRUG ADMINISTRATION

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

April 15, 2019

SUBSTANTIALLY EQUIVALENT

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

FDA Submission Tracking Number (STN): MULTIPLE STNs, SEE APPENDIX A

Dear Mr. Roerty:

The Food and Drug Administration (FDA) completed review of your Reports 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 (FD&C Act), for the tobacco products specified in Appendix A.

Based on our review of your SE Reports, we find the new tobacco products are in compliance with the requirements of the FD&C Act and substantially equivalent to the corresponding eligible predicate tobacco products[1], specified in Appendix A.

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 products specified in Appendix A.

To fulfill the provisions of section 910(a)(4) of the FD&C Act, you submitted a health information summary in your SE Reports. 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 publicly available.

It is important to note our finding of substantial equivalence for your new tobacco products to an appropriate predicate tobacco product permits marketing of your new tobacco products Our finding does not mean FDA "approved" the new products specified in Appendix A; therefore, you may not promote or in any way represent the new tobacco products specified in Appendix A, or the labeling, as being "approved" by FDA. See Section 301(tt) of the FD&C Act.

The finding that your products are substantially equivalent to the predicate products is based upon

[1] In addition to comparing the new tobacco products to the predicate tobacco products named by the applicant, FDA also compared the new tobacco products in this SE Report to the grandfathered tobacco products in SE0000083, SE0000088, and SE0000089. Although the new products have different characteristics than the grandfathered tobacco products in SE0000083, SE0000088, and SE0000089, 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 is also substantially equivalent to the grandfathered product in SE0000083, SE0000088, and SE0000089.

the information you provided in your SE Reports and the standards contained in the FD&C Act, Section 910(a)(3). These marketing orders are 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 products specified in Appendix A, 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 products specified in Appendix A comply 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)[2] 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.

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

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: 2019.04.15 14:51:55 -04'00'

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

Enclosure- Appendix A: List of New Tobacco Products Subject of This Letter

Appendix A

List of new tobacco products that FDA has determined are substantially equivalent when compared to its corresponding predicate tobacco product.

Common Attributes of SE Reports	
Date of Submission:	March 26, 2015
Date of Receipt:	March 26, 2015
Product Manufacturer:	Swedish Match USA, Inc.
Product Category:	Smokeless Tobacco Products
Product Sub-Category:	Loose Chewing Tobacco
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011047
Product Name:[3]	Granger Select 16 oz.
Package Type:	Foil Pouch
Package Quantity:	16 ounces
Characterizing Flavor:	Natural[4]
Tobacco cut size:	(b) (4)
Predicate Tobacco Product Specific Attributes	
Product Name:[3]	Granger Select 3 oz.
Package Type:	Foil Pouch
Package Quantity:	3 ounces
Characterizing Flavor:	Natural[4]
Eligibility Status:	SE0000083
Tobacco cut size:	(b) (4)
New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011048
Product Name:[3]	J.D.'s Blend 16 oz.
Package Type:	Foil Pouch
Package Quantity:	16 ounces
Characterizing Flavor:	Natural[4]
Tobacco cut size:	(b) (4)
Predicate Tobacco Product Specific Attributes	
Product Name:[3]	J.D.'s Blend 3 oz.
Package Type:	Foil Pouch
Package Quantity:	3 ounces
Characterizing Flavor:	Natural[4]
Eligibility Status:	SE0000088
Tobacco cut size:	(b) (4)

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

[4] As provided by the applicant's certification statement. For product quantity change SE Reports, FDA does not conduct substantive scientific review to evaluate the information contained in the applicant's certification statement.

New Tobacco Product Specific Attributes	
Submission Tracking Number	SE0011050
Product Name:[3]	Southern Pride 16 oz.
Package Type:	Foil Pouch
Package Quantity:	16 ounces
Characterizing Flavor:	Natural[4]
Tobacco cut size:	(b) (4)
Predicate Tobacco Product Specific Attributes	
Product Name:[3]	Southern Pride 3 oz.
Package Type:	Foil Pouch
Package Quantity:	3 ounces
Characterizing Flavor:	Natural[4]
Eligibility Status:	SE0000089
Tobacco cut size:	(b) (4)