

September 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):** SE0012725

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**

<b>Date of Submission:</b>	December 14, 2015
<b>Date of Receipt:</b>	December 14, 2015
<b>Product Manufacturer:</b>	Swedish Match USA, Inc.
<b>Product Name:<sup>1</sup></b>	J.D.'s Blend 2.5 oz
<b>Product Category:</b>	Smokeless Tobacco Products
<b>Product Sub-Category:</b>	Loose Chewing Tobacco
<b>Package Type:</b>	Foil Pouch
<b>Package Quantity:</b>	2.5 oz
<b>Characterizing Flavor:</b>	Natural <sup>2</sup>
<b>Tobacco cut size:</b>	(b) (4)

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 eligible predicate tobacco product:<sup>4</sup>

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

<sup>2</sup> 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.

<sup>3</sup> The applicant provided a tobacco cut size of (b) (4) which is equivalent to (b) (4)

<sup>4</sup> In addition to comparing the new tobacco product to the predicate tobacco products named by the applicant, FDA also compared the new tobacco product in this SE Report to the grandfathered tobacco product in SE0000088. Although the new product has different characteristics than the grandfathered tobacco product in SE0000088, 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 SE0000088.

**Predicate Tobacco Product**

<b>Product Manufacturer:</b>	Swedish Match USA, Inc.
<b>Product Name:<sup>1</sup></b>	J.D.'s Blend 3 oz
<b>Product Category:</b>	Smokeless Tobacco Products
<b>Product Sub-Category:</b>	Loose Chewing Tobacco
<b>Package Type:</b>	Foil Pouch
<b>Package Quantity:</b>	3 oz
<b>Characterizing Flavor:</b>	Natural <sup>2</sup>
<b>Eligibility Type:</b>	Previously found SE under SE0000088
<b>Tobacco cut size:</b>	(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 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 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 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 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](mailto:AskCTP@fda.hhs.gov), or [SmallBiz.Tobacco@fda.hhs.gov](mailto: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>)<sup>5</sup> 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, Regulatory Health Project Manager, at (240) 402 - 0435 or [Shireen.Fotelargias@fda.hhs.gov](mailto:Shireen.Fotelargias@fda.hhs.gov).

Sincerely,  
Digitally signed by Matthew R. Holman -  
S  
Date: 2018.09.24 14:25:20 -04'00'  
Matthew R. Holman, Ph.D.  
Director  
Office of Science  
Center for Tobacco Products

---

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