October 27, 2017

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
SWEDISH MATCH USA, INC.
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
Phone: 804-787-5100
e-mail: Gerry.Roerty@Swedishmatch.com

FOOD AND DRUG ADMINISTRATION
CENTER FOR TOBACCO PRODUCTS
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: PERIODIC REPORT for STN PM0000012

Dear Sir or Madam:

Swedish Match USA, Inc. ("Swedish Match" or "we") writes in regard to FDA's Marketing Order PM0000012 for General Portion Original Large ("PM0000012"), included below as **Attachment A.2017-PM0000012**.

Per requirements under section 910(f) of the FD&C Act, we are submitting a Postmarket Annual Report ("Report") for PM0000012 beginning October 2016 so that FDA may determine whether continued marketing of the tobacco product is appropriate for the protection of public health or whether there are or may be grounds for withdrawing or temporarily suspending the Marketing Order.

Periodic Report for the following tobacco product:

STN	PM0000012
Tobacco Product Name	General Portion Original Large
Applicant	Swedish Match
Date of Report	10/31/2017
Reporting Period	10/1/2016 – 9/30/2017
Marketing Order Status USA	In market date is 4/6/2016
Marketing Status Outside USA	Commercially distributed in Sweden. No sales in EU member states. All other sales as governing law permits.

We set forth below our response to each Agency request enumerated in the Marketing Order. As directed by FDA, we are providing this single submission in response to the Marketing Order.

Swedish Match submits this Report with the confidence that continued marketing of the tobacco product is appropriate for the protection of public health.

Swedish Match submits that this submission and the information we are supplying in connection with this Report, are trade secret, proprietary information that is protected under state and federal law from public disclosure. This information should therefore be handled in accordance with the security procedures adopted by FDA in connection with enforcement of the FD&C Act.

If further information is required, please contact us.

Sincerely yours,

(b) (6)

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary

Document attachments:

Attachment A.2017-PM0000012 – Marketing Order PM0000012
Attachment 2A1.2017-PM0000012.pptx – General Snus PMTA Post-Surveillance Market Research *(in Microsoft PowerPoint format)*
Attachment 2A2.2017-PM0000012 – SM Market Tracker (FY16-User Groups) *(in Microsoft Excel format)*
Attachment 2A3.2017-PM0000012 – SM Market Tracker (FY15 vs. FY16) *(in Microsoft Excel format)*
Attachment 2B.2017-PM0000012 – Full Text Articles of Relevant New Publications
Attachment 2C.2017-PM0000012 – Summary of Consumer Complaints (Adverse Experiences)
Attachment 2D.2017-PM0000012 – Summary of Sales and Distribution Data
Attachment 3A.2017-PM0000012 – Certification Statement
Attachment 4A.2017-PM0000012 – Summary of Manufacturing Deviations
Attachment 5A.2017-PM0000012 – Full Color Copies of Advertising