

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29

October 21, 2016

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

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

**SUBJECT: PERIODIC REPORT for STN PM0000012**

Dear Sir or Madam:

Swedish Match North America ("Swedish Match" or "we") writes in regard to FDA's Marketing Order PM0000012 for General Portion Original Large ("PM0000012"), included below as **Attachment A.2016-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 North America
Date of Report	10/31/2016
Reporting Period	4/6/2016 – 10/1/2016
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.

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

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

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

38 If further information is required, please contact us.

39 Sincerely yours,

40 (b) (6)

41 Gerard J. Roerty, Jr.

42 Vice President, General Counsel & Secretary

43  
44 Document attachments:

- 45 Attachment A.2016-PM0000012 – Marketing Order PM0000012  
46 Attachment 2A.2016-PM0000012 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016  
47 (Microsoft Word format)  
48 Attachment 2B.2016-PM0000012 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016  
49 (Microsoft Excel format)  
50 Attachment 2C.2016-PM0000012 – Full Text Articles of Relevant New Publications  
51 Attachment 2D.2016-PM0000012 – Summary of Consumer Complaints (Adverse Experiences)  
52 Attachment 2E.2016-PM0000012 – Summary of Sales and Distribution Data  
53 Attachment 4A.2016-PM0000012 – Summary of Manufacturing Deviations  
54 Attachment 5A.2016-PM0000012 – Full Color Copies of Advertising  
55 Attachment 6A.2016-PM0000012 – Final Printed Labeling  
56