

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

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

42 Gerard J. Roerty, Jr.

43 Vice President, General Counsel & Secretary

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