

October 21, 2016

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**SUBJECT: PERIODIC REPORT for STN PM0000014**

Dear Sir or Madam:

Swedish Match North America ("Swedish Match" or "we") writes in regard to FDA's Marketing Order PM0000014 for General Mint Portion White Large ("PM0000014"), included below as **Attachment A.2016-PM0000014.**

Per requirements under section 910(f) of the FD&C Act, we are submitting a Postmarket Annual Report ("Report") for PM0000014 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	PM0000014
Tobacco Product Name	General Mint Portion White 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.

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

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

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

39 If further information is required, please contact us.

40 Sincerely yours, (b) (6)

41 (b) (6)  
42 (b) (6)

43 Gerard J. Roerty, Jr.

44 Vice President, General Counsel & Secretary

45 Document attachments:

46 Attachment A.2016-PM0000014 – Marketing Order PM0000014

47 Attachment 2A.2016-PM0000014 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016  
48 (Microsoft Word format)

49 Attachment 2B.2016-PM0000014 – Ongoing Tobacco User Tracking Study Data Crosstabs March-June 2016  
50 (Microsoft Excel format)

51 Attachment 2C.2016-PM0000014 – Full Text Articles of Relevant New Publications

52 Attachment 2D.2016-PM0000014 – Summary of Consumer Complaints (Adverse Experiences)

53 Attachment 2E.2016-PM0000014 – Summary of Sales and Distribution Data

54 Attachment 4A.2016-PM0000014 – Summary of Manufacturing Deviations

55 Attachment 5A.2016-PM0000014 – Full Color Copies of Advertising

56 Attachment 6A.2016-PM0000014 – Final Printed Labeling  
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