

1 October 21, 2016

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19 **SUBJECT: PERIODIC REPORT for STN PM0000015**
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21 Dear Sir or Madam:

22 Swedish Match North America ("Swedish Match" or "we") writes in regard to FDA's Marketing Order
23 PM0000015 for General Nordic Mint Portion White Large ("PM0000015"), included below as **Attachment**
24 **A.2016-PM0000015.**

25 Section 910(f) of the FD&C Act requires a Postmarket Annual Report be submitted to FDA for any
26 tobacco product in US commerce by virtue of a Marketing Order issued under section 910(b) of the FD&C
27 Act. Swedish Match submits that, to date, the new product contemplated under PM0000015 has not been
28 introduced or delivered for introduction into interstate commerce in the US. Thus, no Postmarket Annual
29 Report is required for the 12-month period ending October 2016 for PM0000015.

30 Furthermore, Swedish Match submits that because the new product has never been introduced into
31 US commerce it has likewise never been discontinued and, as such, Swedish Match would not be obligated
32 to contact the Office of Science prior to introducing the new product into US commerce at some future date.
33

34 For recordkeeping purposes, Swedish Match provides the following information relative to
35 PM0000015 for the 12-month period ending 10/31/2016:

STN	PM0000015
Tobacco Product Name	General Nordic Mint Portion White Large
Applicant	Swedish Match North America
Date of Report	10/31/2016
Reporting Period	11/10/2015 – 10/1/2016
Marketing Order Status USA	To date, the new product under Marketing Order PM0000015 has not been introduced or delivered for introduction into interstate commerce in the US. Additionally, the provisional product (SE0000142) was discontinued 1/15/2016.
Marketing Status Outside USA	Commercially distributed in Sweden. No sales in EU member states. All other sales as governing law permits.

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

41 If further information is required, please contact us.

42 Sincerely yours,

43 (b) (6)
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45 Gerard J. Roerty, Jr.

46 Vice President, General Counsel & Secretary

47 Document attachments:

48 Attachment A.2016-PM0000015 – Marketing Order PM0000015

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