

1 October 27, 2017

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3 Gerard J. Roerty, Jr.  
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19 **SUBJECT: PERIODIC REPORT for STN PM0000013**

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21 Dear Sir or Madam:

22 Swedish Match USA, Inc. ("Swedish Match" or "we") writes in regard to FDA's Marketing Order  
23 PM0000013 for General Classic Blend Portion White Large ("PM0000013"), included below as **Attachment**  
24 **A.2017-PM0000013.**

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 PM0000013 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 from October 1, 2016 through September 30, 2017 for  
30 PM0000013.

31 Furthermore, Swedish Match submits that because the new product has never been introduced into  
32 US commerce it has likewise never been discontinued and, as such, Swedish Match would not be obligated  
33 to contact the Office of Science prior to introducing the new product into US commerce at some future date.  
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35 For recordkeeping purposes, Swedish Match provides the following information relative to  
36 PM0000013 for the 12-month period from October 1, 2016 through September 30, 2017:

STN	PM0000013
Tobacco Product Name	General Classic Blend Portion White Large
Applicant	Swedish Match
Date of Report	10/31/2017
Reporting Period	10/1/2016 – 9/30/2017
Marketing Order Status USA	To date, the new product under Marketing Order PM0000013 has not been introduced or delivered for introduction into interstate commerce in the US. Additionally, the provisional product (SE0000138) 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.

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

42 If further information is required, please contact us.

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48 Document attachments:

49 Attachment A.2017-PM0000013 – Marketing Order PM0000013

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