

1 July 8, 2015

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19 **SUBJECT: RESPONSE TO JUNE 29, 2015 TELECONFERENCE and SUBSEQUENT EMAIL REGARDING**
20 **PM000011-PM000017 and MR000021- MR000029**

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22 Dear Sir or Madam:

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24 Swedish Match North America, Inc. ("Swedish Match" or "we") provides this correspondence in
25 response to the June 29, 2015 telephone conference between Swedish Match and FDA and FDAs
26 subsequent email ("Request Letter") presenting specific questions, included below as **Attachment A-**
27 **20150629**, regarding seven (7) of our Premarket Tobacco Applications ("PMTAs") received by FDA March 11,
28 2015 and our corresponding nine (9) Modified Risk Tobacco Product Applications ("MRTPAs") received by
29 FDA June 10, 2014 (collectively, the "PM/MR Reports"):

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- 31 • PM000011 / MR000021, General Dry Mint Portion Original Mini
 - 32 • PM000012 / MR000022, General Portion Original Large
 - 33 • No Corresponding PMTA / MR000023, General Classic Blend Portion White Large – 15 ct
 - 34 • PM000013 / MR000024, General Classic Blend Portion White Large – 12 ct
 - 35 • PM000014 / MR000025, General Mint Portion White Large
 - 36 • No Corresponding PMTA / MR000026, General Nordic Mint Portion White Large – 15 ct
 - 37 • PM000015 / MR000027, General Nordic Mint Portion White Large – 12 ct
 - 38 • PM000016 / MR000028, General Portion White Large
 - 39 • PM000017 / MR000029, General Wintergreen Portion White Large

40 We set forth below our response to each Agency request enumerated in the Request Letter. Where
41 appropriate, we have included any previously submitted information as well as direct FDA to the sections(s),
42 page(s) and line number(s) of our prior PM/MR Reports and SE Reports, including amendments, where this

43 information can also be found. For FDA's aid following is a list of corresponding MR and SE numbers related
44 to PM numbers.

PM STN	New Product Name	SE STN	MR STN
PM0000010	General Loose 1.59 oz. (45g)	SE0010524	MR0000020
PM0000011	General Dry Mint Portion Original Mini 0.21 oz. (6g)	SE0010525	MR0000021
PM0000012	General Portion Original Large 0.9 oz. (24g)	SE0010526	MR0000022
PM0000013	General Classic Blend Portion White Large 0.38 oz. (10.8g)	SE0010528	MR0000024
PM0000014	General Mint Portion White Large 0.9 oz. (24g)	SE0010529	MR0000025
PM0000015	General Nordic Mint Portion White Large .38 oz. (10.8g)	SE0010531	MR0000027
PM0000016	General Portion White Large 0.9 oz. (24g)	SE0010532	MR0000028
PM0000017	General Wintergreen Portion White Large 0.9 oz. (24g)	SE0010533	MR0000029

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46 Swedish Match submits that this response and the information we are supplying in connection with
47 this response are trade secret, proprietary information that is protected under state and federal law from
48 public disclosure. This information should therefore be handled in accordance with the security procedures
49 adopted by FDA in connection with enforcement of the FDCA.

50 We appreciate your consideration of this Response and amendments to our PMTAs identified
51 above. If further information is required, please contact us.

52 Sincerely yours,
53 (b) (6)
54 [Redacted Signature]
55

56 Gerard J. Koerty, Jr.
57 Vice President, General Counsel & Secretary
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59 Tables & Attachments

- 60 Table 1-1. Air Permeability
- 61 Table 2-1. Heat Sealability

- 62 Attachment A-20150629 – Request Letter
- 63 Attachment B-20150629 – Air Permeability Updated DOA
- 64 Attachment C-20150629 – Heat Sealability Updated DOA
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