

1 February 13, 2024

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4 Vice President, General Counsel & Secretary
5 Swedish Match USA, Inc.
6 Two James Center
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9 Phone: (b) (6)
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12
13 Food and Drug Administration
14 Center for Tobacco Products
15 Document Control Center (DCC)
16 Building 71, Room G335
17 10903 New Hampshire Avenue
18 Silver Spring, MD 20993-0002

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21 **SUBJECT: CENTER FOR TOBACCO PRODUCTS CLARIFICATION OF DATA REQUEST RE: SWEDISH**
22 **MATCH RESPONSE TO FDA FEBRUARY 8, 2024 TELEPHONE CALL FOR MR0000256.PD1-**
23 **MR0000256.PD5, MR0000256.PD7-MR0000256.PD9**

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26 Dear Sir or Madam:

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28 On January 30, 2024, Swedish Match USA, Inc. ("Swedish Match", "we", "us" or "our")
29 submitted a response to the Center for Tobacco Products' (the "Agency") deficiency communication,
30 dated January 17, 2024 (the "Deficiency Letter"). We acknowledged the Deficiency Letter to be in
31 response to the Agency's review of the MRTPA Renewal, previously submitted by Swedish Match on July
32 17, 2023, as well as our referenced Amendment Response dated December 13, 2023.

33
34 Regarding our telephone call with Regulatory Health Project Manager ("RHPM"), Diana
35 Osemhen on February 8, 2024: we discussed the January 30th Deficiency Response Submission and,
36 specifically, the Agency's request for "a data dictionary that includes the names and the codes and
37 format of all variables used in the data set." Swedish Match respectfully submits the solicited data
38 clarification as Attachment A, etc. The mapping files in Attachment G – Data Maps Files (.xlsx files G.1
39 – G.4) in our previous January 30, 2024 submission were meant to serve that purpose (i.e., "data
40 dictionary that includes the names and the codes and format of all variables used in the data set"), but
41 we have attempted to provide additional clarifications in this submission.

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43 Where appropriate, we have included any previously submitted information, as well as direct
44 the Agency to the section(s), page(s), and line number(s) of our prior Reports, including amendments,
45 where this information can also be found.

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47 Swedish Match submits that this Response and the information we are supplying in connection
48 with this Response are trade secret, proprietary information that is protected under state and federal

49 law from public disclosure. This information should therefore be handled in accordance with the
50 security procedures adopted by FDA, in connection with enforcement of the FDCA.

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52 We appreciate your consideration and evaluation of this Response. If you should have any
53 questions, please let me know.

54
55 Sincerely yours,

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57  (b) (6)
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60 Gerard J. Roerty, Jr., ESQ.
61 Vice President, General Counsel & Secretary
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64 **Document Attachments (List)**

- 65 Attachment A-General Snus Patterns of Use Study Wave 1 and 2.xpt
- 66 Attachment B-General Snus Patterns of Use Study Wave 1 and 3.xpt
- 67 Attachment C- General Snus Patterns of Use Study Wave 1 and 4.xpt
- 68 Attachment D- General Snus Patterns of Use Study Wave 1.xpt
- 69 Attachment E-General Snus Patterns of Use Study Wave 2 Data Dictionary.xlsx
- 70 Attachment F- General Snus Patterns of Use Study Wave 3 Data Dictionary.xlsx
- 71 Attachment G- General Snus Patterns of Use Study Wave 4 Data Dictionary.xlsx
- 72 Attachment H- General Snus Patterns of Use Study Wave 1 Data Dictionary.xlsx
- 73 Attachment I-FDA Form 4057a dated 2/13/2024