

February 13, 2024

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Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
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SUBJECT: CENTER FOR TOBACCO PRODUCTS CLARIFICATION OF DATA REQUEST RE: SWEDISH MATCH RESPONSE TO FDA FEBRUARY 8, 2024 TELEPHONE CALL FOR MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9

Dear Sir or Madam:

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

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

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

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

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

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

Sincerely yours,

(b) (6)

Gerard J. Roerty, Jr., ESQ.
Vice President, General Counsel & Secretary

Document Attachments (List)

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