January 30, 2024

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SUBJECT: **RESPONSE TO DEFICIENCY LETTER – MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9)**

Dear Sir or Madam:

We received your correspondence dated January 17, 2024 ("Letter") (**see attachment, Attachment A)** regarding FDA's review of the MRTPA Renewal that Swedish Match USA, Inc. ("Swedish Match", "we", "us" or "our") had previously submitted on July 17, 2023, as well as the referenced Amendment Response dated December 13, 2023, for the following products:

- MR0000256.PD1: General Loose
- MR0000256.PD2: General Dry Mint Portion Original Mini
- MR0000256.PD3: General Portion Original Large
- MR0000256.PD4: General Classic Blend Portion White Large – 12ct
- MR0000256.PD5: General Mint Portion White Large
- MR0000256.PD7: General Nordic Mint Portion White Large – 12ct
- MR0000256.PD8: General Portion White Large
- MR0000256.PD9: General Wintergreen Portion White Large

As part of our reply to the Agency's request for additional information, we set forth below, our response ("Response") to each request enumerated in the Letter. This Response and its associated reference and attachments have been constructed as directed by FDA in the Letter. Where appropriate, we have included any previously submitted information, as well as direct FDA 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 concerning our MRTPAs identified above. If you should have any questions, please let me know.

Sincerely yours,

(b) (6)

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

Document Attachments (List)

Attachment A – CTP Correspondence re: MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9 dated January 17, 2024
Attachment B – IRB Review and Exemption Determination Letter
Attachment C – Summary of Previous Periodic Reporting (Excel File Format)
Attachment D – Response to CTP Correspondence dated December 14, 2023
Attachment E – Study Materials for General Snus Patterns of Use Study (see sections E.1 – E.5)
Attachment F – "Readme" Summary of General Snus Patterns of Use Study (Data and Analyses)
Attachment G – Data Maps Files (.xlss files G.1 – G.4)
Attachment H – Solicited Code (.txt file format H.1 - H.5)
Attachment I – Data Files (.xpt format I.1 - I.4)