

December 5, 2022

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Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

SUBJECT: [AMENDMENT - APPENDIX 1C (1.5)] PMTA and MRTP POSTMARKET ANNUAL REPORT for Submission Tracking Numbers – PM0000010 – PM0000017, and MR0000020 - MR0000022, MR0000024 - MR0000025, & MR0000027- MR0000029

Dear Sir or Madam:

On October 27, 2022, per the FDA Center for Tobacco Products PMTA and MRTP Annual Report requirements, Swedish Match USA, Inc. ("Swedish Match", "our" or "we") submitted all required combined documents to encompass one PMTA MRTP Postmarket Annual Report submission.

To fulfill the document requirements for Section 1 – Annual Post-Market Surveillance and Studies Report Summary (see document summary below), Swedish Match submitted the document **Appendix 1C (1.5) Technical Rpt General Snus Patterns of Use Study Wave 4 DRAFT**, as the finalized version was not available at that time.

In the meantime, that document has been finalized and we now submit **Appendix 1C (1.5) Technical Rpt General Snus Patterns of Use Study Wave 4 FINAL** to replace the draft version of the document.

Swedish Match submits that this amended document and the information we are supplying in connection with this amendment, are trade secret, proprietary information, that is protected under state and federal law from public disclosure.

If further information is required, please contact us.

Sincerely,
(b) (6)
(b) (6)
Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary

Section 1 – Annual Post-Market Surveillance and Studies Report Summary

Surveillance Consumer Perception Behavior & Health – [MRTP Report Specific]

See Attachment 1C - Annual PMSS Surveillance Consumer Perception Behavior & Health

See Attachment 1C.1 - Proposed PMSS CTP Approval to Proceed dated 4/16/20

- **Appendix 1C (1.1)** - Descriptive Tables 14, 14.1, 16-18, & 20-24: General Snus Patterns of Use Study – Wave 4 Study Report (**Excel Attachment**)
- **Appendix 1C (1.2)** - Study Questionnaire: General Snus Patterns of Use Study – Wave 4 Study Report
 - **Appendix 1C (1.2a)** - Consumer Facing General Snus Patterns of Use Study Baseline to Wave 4
- **Appendix 1C (1.3)** - Study Protocol - General Snus Patterns of Use Study - Version 4
- **Appendix 1C (1.4)** - Statistical Analysis Plan: General Snus Patterns of Use Study – Wave 4 Study Report
- **Appendix 1C (1.5) – Technical Report: General Snus Patterns of Use Study – Wave 4 Study Report FINAL (“FINAL” version replaces the “DRAFT” version)**