

January 17, 2024

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
SWEDISH MATCH USA INC.
Two James Center
1021 East Cary Street, Suite 1600
Richmond, VA 23219
Phone: (b) (6)
e-mail: (b) (6)

FOOD AND DRUG ADMINISTRATION
CENTER FOR TOBACCO PRODUCTS
Document Control Center
Building 71, Rm G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

**Subject: Solicited Updated Environmental Assessments for: General Snus FDA STNs:
MR0000256.PD1-MR0000256.PD5, MR0000256.PD7-MR0000256.PD9.**

Dear Secretary,

We received your correspondence dated November 30, 2023 (“the Filing Letter”), included as **Attachment A**, relating to the Agency’s preliminary review of certain MRTPAs that Swedish Match USA, Inc. (“Swedish Match”, “we”, “us” or “our”) had previously submitted on July 17, 2023, for the following products in Table 1 (collectively, the “MR reports”):

Table 1

- 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

Furthermore, we received correspondence dated November 30, 2023 (“the Courtesy Copy” mail), included as **Attachment B**, relating to Agency’s recommendation we submit updated Environmental Assessment (“EA”) information for the renewal applications MR0000256, and cross reference of additional post market information.

Swedish Match USA, Inc. (“Swedish Match” or “we”) submits this “Amendment” for the MRTPAs listed above. The Amendment submission is for a group of tobacco products previously submitted as a grouped MRTPA renewal submission, FDA STNs: MR0000256.

Swedish Match is amending the MRTPA renewal submission to provide updated EA information for the renewal applications. Swedish Match requests to change its MRTPA renewal submission(s) contents. Specifically, the inclusion of our 2023 PMTA MRTP Postmarket Annual Report(s) (collectively, “2023 Annual Report”) to be incorporated by cross-reference. This additional content further supports the MRTPA renewal request. The Amendment is relevant to all amended products in this submission.

FDA Form 4057a – Premarket Tobacco Product Application Amendment and General Correspondence Submission(s) is included.

The Amendment contains non-public, trade secret, proprietary and confidential information that is protected under state and federal law from public disclosure. Swedish Match reserves the right to redact information it considers to be confidential prior to any part of the Amendment being made public. This information should therefore be handled in accordance with the security procedures adopted by the FDA in connection with enforcement of the FD&C Act.

If further information is required, please contact me.

Sincerely yours,

(b) (6)

Gerard J. Roerty, Jr., Esq.
Vice President, General Counsel & Secretary
Swedish Match USA, Inc.