

October 12, 2023

Gerard J. Roerty, Jr.
Vice President, General Counsel & Secretary
SWEDISH MATCH USA INC.
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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: **LETTER OF AUTHORIZATION (LOA) FOR SWEDISH MATCH USA, INC.**

Date: 12 October 2023
FDA Submission Tracking Number: (b) (4)
Holder: Swedish Match USA INC.
Letter of Authorization for: Swedish Match TPMF - FDA STN: (b) (4)

Dear TPMF Staff:

Swedish Match USA, Inc. (hereinafter "Swedish Match" or "the company"), hereby authorizes Swedish Match USA, Inc. to incorporate by reference information and data contained in Swedish Match TPMF - FDA STN: (b) (4) into tobacco products filed by Swedish Match. These documents include confidential information related to Swedish Match (b) (4) for Swedish Match's Premarket Tobacco Product Applications (PMTAs).

We also authorize the Center for Tobacco products (CTP) to review the specific information in (b) (4) incorporated by Swedish Match when considering the products filed by Swedish Match. We understand that the TPMF process has been developed solely as a means of making proprietary data available to the CTP to assist in its review of submissions to the Agency. See U.S. Food and Drug Administration's (FDA's) Guidance for Industry: Tobacco Product Master Files (May 2016). Swedish Match's TPMF assigned [TPMF STN: (b) (4)] contains trade secret and confidential commercial information which is protected from disclosure under 21 C.F.R. § 20.61. The company asserts that the information included in the TPMF: (a) will remain confidential and subject to all applicable legal protections, (b) will not

*** Swedish Match.

be shared with any third party by CTP, (c) will not be otherwise released by CTP, and (d) will be used by CTP exclusively in the context of its review of PMTAs under the terms of any Letter of Authorization provided by the company.

Name of Item: Swedish Match TPMF - FDA STN: (b) (4)

Original Submission to FDA: August 27, 2021

Authorized Party	Contact information	Limitation to Authorization
Swedish Match USA, Inc.	Gerard Roerty, Jr., Esq. VP, General Counsel & Secretary Two James Center 1021 East Cary Street, Suite 1600 Richmond, VA 23219	None

Swedish Match is authorized to reference the entirety of Swedish Match TPMF (b) (4) without limitation. CTP may review those parts of the TPMF (b) (4) incorporated by reference in Swedish Match tobacco products applications.

Swedish Match states that the TPMF (b) (4) is current and Swedish Match will comply with the statements made within it. Swedish Match will notify CTP through an amendment to TPMG (b) (4) of any addition, change, or deletion of information in the TPMF. Swedish Match will also notify in writing Swedish Match that an addition, change, or deletion of information has been made to the TPMF (b) (4)

The information contained in (b) (4) contains trade secret and confidential information which is protected from disclosure under 21 CFR 20.61. No information in our TPMF will be provided to any unauthorized persons without written consent.

The information and data in (b) (4) are confidential and trade secret. The company hereby claims the protection afforded to such material under 18 U.S.C. § 1905, 21 U.S.C. §§ 331(j) and 387f(c), and 5 U.S.C. § 552. Please do not hesitate to contact me should you need additional information.

Sincerely yours,

(b) (6)

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



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