

August 4, 2025

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

ATTENTION:
Anab Kemal, Regulatory Health Project Manager

Submitted via CTP Portal

Subject: Withdrawal of July 11, 2025, Amendment for MR0000254.PD1, MR0000254.PD3,
MR0000254.PD5 – MR0000254.PD7

To Whom It May Concern,

PMI US Corporate Services, Inc.¹ (PMI US), on behalf of Philip Morris Products S.A. (PMP S.A.), withdraws the amendment submitted on July 11, 2025, pursuant to section 911 of the Federal Food, Drug, and Cosmetic Act. Accordingly, PMI requests FDA no longer consider the July 11, 2025, submission as part of its review of MR0000254.PD1, MR0000254.PD3, and MR0000254.PD5 – MR0000254.PD7.²

Sincerely,

(b) (6)

Sarah Amyot (Aug 4, 2025 15:16:26 CDT)

Sarah Amyot, M.P.H.
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PMI US Corporate Services, Inc.
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(b) (6)

This letter contains confidential commercial information that PMI US Corporate Services, Inc., PMI Global Services Inc., Triaga Inc., Philip Morris Products S.A., Swedish Match USA, Inc., and their affiliates (collectively the "PMI Entities") consider to be proprietary and highly sensitive, and which is protected from disclosure under FD&C Act §§ 301(j) and 906(c) (21 U.S.C. §§ 331(j) and 387(c)), the Trade Secrets Act (18 U.S.C. § 1905), the Freedom of Information Act (5 U.S.C. § 552), and FDA's implementing regulations (21 CFR Part 20). If FDA receives a request for these records and tentatively determines that any portion of the submission is disclosable, the PMI Entities request that FDA provide notice and an opportunity for the PMI Entities to object to any disclosure in accordance with 21 CFR §§ 20.47 and 20.61. The PMI Entities reserve all legal rights to protect against public disclosure of its trade secret and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.

¹ PMI US Corporate Services Inc. is a services company for the Philip Morris International (PMI) family of companies.

² PMI US is contemporaneously submitting a successor amendment to replace the submission being withdrawn.