PHILIP MORRIS
PRODUCTS S.A.

December 22, 2020

Lillian Ortega
Director, Division of Enforcement and Manufacturing
Office of Compliance and Enforcement
Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via CTP portal

**Subject: Response to Information Request Letter for PS0000042 and PS0000078**

Dear Ms. Ortega,

Philip Morris Products S.A. (PMP S.A.) hereby submits its response to the Information Request letter of December 11, 2020 in which the Agency provided review and comments on our November 4, 2020 and November 5, 2020 response to the FDA's October 5, 2020 request concerning the postmarket surveillance and studies (PMSS) protocols proposed for the *IQOS* System.

Study protocols have been updated to reflect the Agency's feedback and recommendations, including the advice provided on December 17, 2020 to proceed with responses to sections I, II, III and IV of the Information Request letter and to exclude the computational toxicology response as it is pending a subsequent teleconference with the Office of Science. As requested, the response document contains detailed information and explanation for each update that was introduced.

The updated protocol for the computational toxicology assessment will be provided separately, upon concluding the discussion on the protocol content.

As previously communicated, upon acceptance of the PMSS Program, the studies in progress will be reported on an annual basis, by April 30 of each year in a PMSS Report[1]. Once a study is completed, the PMSS Report will include the complete final study report.

This response addresses sections I, II, III and IV of the second Information Request letter issued by the FDA in the context of the PMSS protocols for the *IQOS* System.

We appreciate FDA's consideration of this PMSS Program for the *IQOS* System and remain available for any further information that may be required.

Sincerely,

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Daniel Verstappen
Vice President Regulatory, Quality & Standards
Philip Morris Products S.A.

(b) (6)

Jeffrey Walker, M.D.
U.S. Agent for PMP S.A.
CEO, Teton Regulatory Sciences

Please note that this submission contains confidential commercial information, and/or trade secret information, and the legal protections provided to such information are hereby claimed under the applicable provisions of Unites States law, including relevant provisions of the Federal Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 et seq. (specifically, 5 U.S.C. § 552(b)(4)), the Trade Secrets Act (18 U.S.C. § 1905), the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., (specifically FDCA §§ 301(j) and 906(c), 21 U.S.C. §§ 331(j) and 387f(c)) and FDA's implementing regulations, 21 C.F.R. Part 20 (specifically 21 C.F.R. §§ 20.47 and 20.61). PMP S.A. understands that FDA will hold this documentation confidential and will refrain from the public disclosure of the information contained in this submission in conformity with such provisions of the law. Accordingly, if FDA tentatively determines that any portion of this submission is disclosable to the public, FDA is required to provide PMP S.A. with notice and an opportunity to object in accordance with 21 C.F.R. §§ 20.47 and 20.61. PMP S.A. reserves all legal rights to protect against public disclosure of its trade secrets and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.

**Enclosures**: Annex A

[1] Similar to the annual report associated with the April 30, 2019 PMTA Order, the cut-off date for data and report generation will be the end of February. The PMSS Report will include the MRTP specific sections of the joint PMTA/MRTPA annual report that will be submitted by April 30 of each year.

**Annex A**:

Index of documents provided for the Response to Information Request letter for PS0000042 and PS0000078

| **Attachment [Filename]** |
|---|
| Response to December 11, 2020 Information Request Letter for PS0000042 and PS0000078 - responses for sections I, II, III and IV.<br>[2020-12-22-Resp-to-2nd-FDA-request-from-11Dec2020-PS0000042] |
| Appendix B1 – *IQOS* with Marlboro *HeatSticks* Cross-Sectional Postmarket Adult Consumer Study (PACS) Protocol<br>[B1-iqos-cross-sectional-PACS-protocol] |
| Appendix B2 – *IQOS* with Marlboro *HeatSticks* Cross-Sectional Postmarket Adult Consumer Study (PACS) Questionnaire<br>[B2-iqos-cross-sectional-PACS-questionnaire] |
| Appendix B3 – *IQOS* with Marlboro *HeatSticks* Cross-Sectional Postmarket Adult Consumer Study (PACS) Statistical Analysis Plan<br>[B3-iqos-cross-sectional-PACS-sap] |
| Appendix C1 – *IQOS* with Marlboro *HeatSticks* Longitudinal Cohort Postmarket Adult Consumer Study (PACS) Protocol<br>[C1-iqos-cohort-PACS-protocol] |
| Appendix C4 – *IQOS* with Marlboro *HeatSticks* Longitudinal Cohort Postmarket Adult Consumer Study (PACS) Statistical Analysis Plan<br>[C4-iqos-cohort-PACS-sap] |
| Appendix D – Estimation of Prevalence of *IQOS* Use Research Analysis Plan<br>[D-research-ana-plan-iqos-prevalence-of-use] |
| Appendix F – Research Analysis Plan: Estimation of Awareness and Use of *IQOS* Among Underage Individuals 13-20 Years of Age.<br>[F-research-ana-plan-awareness-use-underage] |