PHILIP MORRIS
PRODUCTS S.A.

November 04, 2020

Lillian Ortega
Director, Division of Enforcement and Manufacturing
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

Dear Ms. Ortega,

PMP S.A. hereby submits its response to the Information Request Letter of October 5, 2020 in which FDA provided the review and comments on the Postmarket Surveillance and Studies (PMSS) Plan for *IQOS* System. Study protocols have been updated to reflect the Agency's feedback and recommendations. As requested, the response document contains detailed information and explanation for each update.

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 the additional information and clarifications requested by the Agency.

[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.

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,

(b) (6)

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

Annex A:

Index of documents provided for the RESPONSE TO INFORMATION REQUEST LETTER FOR PS0000042

Attachment [Filename]
Response to FDA Information request Letter dated October 5, 2020 for PS0000042 [2020-11-04-Resp-to-FDA-request-PS0000042.pdf]
Appendix B1 - *IQOS* Cross-Sectional PACS Protocol (Version 2.0) [B1-iqos-cross-sectional-PACS-protocol.pdf]
Appendix B2 - *IQOS* Cross-Sectional PACS Questionnaire (Version 2.0) [B2-iqos-cross-sectional-PACS-questionnaire.pdf]
Appendix B3 - *IQOS* Cross-Sectional PACS SAP (Version 2.0) [B3-iqos-cross-sectional-PACS-sap.pdf]
Appendix C1 - *IQOS* Cohort PACS Protocol (Version 2.0) [C1-iqos-cohort-PACS-protocol.pdf]
Appendix C2 - *IQOS* Cohort PACS Baseline Questionnaire (Version 2.0) [C2-iqos-cohort-PACS-baseline-questionnaire.pdf]
Appendix C3 - *IQOS* Cohort PACS Follow-up Questionnaire (Version 2.0) [C3-iqos-cohort-PACS-follow-up-questionnaire.pdf]
Appendix C4 - *IQOS* Cohort PACS SAP (Version 2.0) [C4-iqos-cohort-PACS-sap.pdf]
Appendix D - Research Analysis Plan: Estimation of Prevalence of *IQOS* Use (Version 2.0) [D-research-ana-plan-iqos-prevalence-of-use.pdf]
Appendix E - Reporting Plan: U.S. *IQOS* Owners Panel (Version 2.0) [E-reporting-plan-US-iqos-owners-panel.pdf]
Appendix F - Research Analysis Plan: Estimation of Awareness and Use of *IQOS* among Underage Individuals 13-20 Years of Age (Version 2.0) [F-research-ana-plan-awareness-use-underage.pdf]
Appendix G - Reporting Plan: U.S. *IQOS* Sales & Distribution Data (Version 2.0) [G-reporting-plan-US-iqos-sales-distribution.pdf]
Appendix J – Development of the Population Health Impact Model (PHIM) v.8 (Version 2.0) [J-population-health-impact-model.pdf]

Attachment [Filename]
Cancer Risk and Exposure to Chemicals Increased in THS2.2 Aerosol Compared to 3R4F Smoke: Hazard identification Protocol for PMSS (Version 2.0) [computational-toxicology-methodology.pdf]

Note: In addition to the above listed documents we also provide copies of additional scientific publications referenced in PMSS documents