PHILIP MORRIS
PRODUCTS S.A.

June 13, 2018

Benjamin Apelberg, Ph.D.
Director
Division of Population Health Science
Office of Science
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via ESG

Re: RESPONSE TO ADVICE/INFORMATION REQUEST JUNE 6, 2018 for MR0000059-MR0000061

Dear Dr. Apelberg,

We are hereby submitting the response to the FDA Information Request received via e-mail on June 1, 2018, which was further clarified in a teleconference organized upon the Agency's request on June 6, 2018. This response pertains to our Modified Risk Tobacco Product (MRTP) Applications submitted under section 911(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

STN	Tobacco Product Name
MR0000059	IQOS system with Marlboro *HeatSticks*
MR0000060	IQOS system with Marlboro Smooth Menthol *HeatSticks*
MR0000061	IQOS system with Marlboro Fresh Menthol *HeatSticks*

This response addresses the additional information and clarifications requested by the Agency. As part of response we hereby provide:

- MedWatch form and additional information related to the individual adverse event specifically discussed during the conference call on June 6, 2018,
- Safety Report Excel Workbook for IQOS completed with relevant information for the events in the latest SUR and 2018 events that have not yet been reported to FDA,

- Document with further clarifications concerning the Agency's Excel Workbook for IQOS.

This response/amendment contains confidential commercial and/or trade secret information. Protection of this information from public disclosure is hereby claimed under the applicable provisions of United States law. We request the agency to provide pre-disclosure notification and follow the procedures in 21 C.F.R. §20.61(e) before publicly disclosing any information contained in this amendment.

We remain available for any further information that is required.

Sincerely,

Malgorzata Wronowska, PhD
Director Regulatory and Scientific Affairs
Philip Morris Products S.A.

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

Enclosures : Appendix A

Appendix A:

Attachments [Filename]
MedWatch Form Philip Morris Products S.A. PMI001159 [PMI001159_MedWatch_report_final]
Safety Report Excel Workbook for IQOS [Safety Report Excel workbook for IQOS]
Additional Information Relating to the FDA Excel Workbook for IQOS Safety Update Report (SUR) [Additional-comments-on-responses-to-SUR]