PHILIP MORRIS
PRODUCTS S.A.

March 16, 2017

Dr. 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 MARCH 2, 2017 INFORMATION REQUEST for MR0000059-MR0000061 and AMENDMENT to MR0000059-MR0000061

Dear Dr. Apelberg,

PMP S.A. has received the FDA Advice/Information Request letter, dated March 2, 2017, relevant to our Modified Risk Tobacco Product Applications (MRTPAs) currently under filing review:

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

Please find herewith our response to your above-mentioned letter addressing the additional information and clarifications requested. Although most of the requested documents are provided with the response, as indicated in response to Questions 4 and 5, additional documentation has been sent today, March 16, to the Agency on an external, virus-checked drive. The DHL tracking number for the drive is 56 8862 3813. The delivery to FDA is expected beginning next week.

The requested IQOS system samples have also been shipped today, March 16, to the FDA Southeast Regional Laboratory in Atlanta. The DHL tracking numbers for the 2 boxes, sent according to your instructions, are 56 8861 3151 and 56 8861 4746. The delivery to SRL is also expected beginning next week.

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. To facilitate FDA's publication of the disclosable portions of this response/amendment, as required by Section 911(e) of the FD&C Act, PMP S.A. will submit proposed redactions under separate cover.

We remain available for any further information that is required.

Sincerely,

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

cc: Jeffrey Walker, US Agent for PMP S.A.

Enclosure: 02_Response to FDA March 2 2017 AI Request MR0000059-61