PHILIP MORRIS
PRODUCTS S.A.

March 16, 2017

Dr. Benjamin Apelberg, Ph.D.
Director, Division of Population Health Science
Office of Science
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: RESPONSE TO MARCH 2, 2017 INFORMATION REQUEST for MR0000059-MR0000061 and AMENDMENT to MR0000059-MR0000061 ADDITIONAL DOCUMENTATION

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

As per our response dated March 16, 2017, we are providing herewith additional documentation that could not be transmitted via the Electronic Submissions Gateway in response to Questions 4 and 5.

The enclosed, non-encrypted, external hard drive contains:

- Raw data for the Human Organotypic Gingival Epithelial Cultures study
- Documents and raw data pertaining to THS 2.1 studies (ZRHX-EX-01 and ZRHX-PK-02): Study reports, SDTM data submission packages (datasets, define.xml and Reviewer Guide) and ADaM data packages (datasets and ADaM Specifications)
- Safety Summary Report originally submitted as part of the ZRHM-PK-06-US protocol submission.
  (Submission Tracking Number: IU0000015)

This submission was scanned and certified as virus free using the System Center Endpoint Protection from Windows 7, Virus/Spyware definition 1.237.1302.0 (Definition last updated date: 16 March 2017).

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.