



PHILIP MORRIS
PRODUCTS S.A.

January 24, 2018

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: AMENDMENT TO PMP S.A. RESPONSE TO AUGUST 4, 2017 INFORMATION
REQUEST FOR MR0000059-MR0000061**

Dear Dr. Apelberg,

We are writing in reference to our submissions of September 8, 2017 that were submitted in response to the FDA Advice/Information Request, dated August 4, 2017, relevant to our Modified Risk Tobacco Product Applications (MRTPAs) currently under substantive review:

<u>STN</u>	<u>Tobacco Product Name</u>
MR0000059	IQOS system with Marlboro <i>HeatSticks</i>
MR0000060	IQOS system with Marlboro Smooth Menthol <i>HeatSticks</i>
MR0000061	IQOS system with Marlboro Fresh Menthol <i>HeatSticks</i>

It has been brought to our attention that Appendix “SR1_Q04-A2_Factory-Heater-Calibration”, submitted in response to Question 4, contains two corrupted figures (Figure 1 on page 3 and Figure 4 on page 6). It is our understanding that these figures were corrupted during the formatting of the document.

With this letter, we hereby provide the re-formatted PDF version of Appendix “[SR1_Q04-A2_Factory-Heater-Calibration](#)” with the corrected Figures 1 and 4.



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This letter 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 may be required.

Sincerely,

Malgorzata Wronowska
Director Regulatory & Scientific Affairs
Philip Morris Products S.A.

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