



**PHILIP MORRIS**  
**PRODUCTS S.A.**

---

August 31, 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: Request for extension for RESPONSE TO AUGUST 4, 2017 INFORMATION REQUEST for  
MR0000059-MR0000061**

Dear Dr. Apelberg,

We have received the FDA Advice/Information Request letter, dated August 4, 2017, relevant to our Modified Risk Tobacco Product Applications (MRTPAs) currently under review:

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

The letter requested a complete response within 30 days of the date of the A/I letter or that we inform the Agency of how much additional time is needed. We are working diligently on the response and intend to send the complete response to the Agency by September 15, 2017.

We will transmit the response and individual appendices via the FDA Electronic Submission Gateway (ESG). Additional documents and data that are contained in a folder structure will be sent by courier on physical media.

Please note that the battery samples requested under Question 27 have already been sent to the Winchester Engineering Analytical Center on August 30, 2017 and are expected to arrive there within one week.

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 correspondence.

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, M.D., US Agent for PMP S.A.