



June 13, 2018

Priscilla Callahan-Lyon, M.D.  
Deputy Director, Division of Individual 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 PM0000424-  
PM0000426**

Dear Dr. Callahan-Lyon,

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. As confirmed by the Agency during the teleconference, we understand this response also pertains to our Premarket Tobacco (PMT) Applications submitted under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

**STN**

**Tobacco Product Name**

PM0000424	IQOS system with Marlboro <i>HeatSticks</i>
PM0000425	IQOS system with Marlboro Smooth Menthol <i>HeatSticks</i>
PM0000426	IQOS system with Marlboro Fresh Menthol <i>HeatSticks</i>

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,



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

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- 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 [ <a href="#">PMI001159_MedWatch_report_final</a> ]
Safety Report Excel Workbook for IQOS [ <a href="#">Safety Report Excel workbook for IQOS</a> ]
Additional Information Relating to the FDA Excel Workbook for IQOS Safety Update Report (SUR) [ <a href="#">Additional-comments-on-responses-to-SUR</a> ]