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May 23, 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 APRIL 23, 2018 for MR0000059-MR0000061

Dear Dr. Callahan-Lyon,

We are hereby submitting the response to the FDA Information Request letter, dated April 23, 2018. This response pertains to our Modified Risk Tobacco Product (MRTP) Applications submitted under section 911(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act):

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*

Based on subsequent clarification provided by FDA during a conference call on May 2, 2018, the PMI response to Question 1 has been modified to reflect FDA's request for a smaller set of information pertaining to the NTDS study.

We are providing a complete response addressing the Advice/Information Request dated April 23, 2018 in light of the additional information and clarifications provided by the Agency on the May 2, 2018 teleconference.

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]
Response to the April 23, 2018 Advice/Information Request for MR0000059-MR0000061 and PM0000424-PM0000426 [Response-to-FDA_Apr-23-2018_AI-Request]