



PHILIP MORRIS
PRODUCTS S.A.

August 09, 2017

Ms. Ann Simoneau
Director, Office of Compliance and Enforcement
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via ESG

Confirmation of inspection details for
MR0000059 IQOS system with Marlboro HeatSticks;
MR0000060 IQOS system with Marlboro Smooth Menthol HeatSticks; and
MR0000061 IQOS system with Marlboro Fresh Menthol HeatSticks

Dear Ms. Simoneau,

Further to the telephone discussion between Dr. Jeffrey Walker and Mr. David Keith on July 28, 2017 and a follow up communication on August 03, 2017, we hereby confirm the locations and inspection dates as follows:

Firm Name and Location:	Inspection Dates:
(b) (4)	October 2 nd to October 6 th , 2017
Philip Morris International Research Laboratories (Singapore, Singapore)	
Philip Morris Products S.A. (Neuchatel, Switzerland)	October 9 th to October 13 th , 2017
(b) (4)	
Philip Morris Manufacturing and Technology (Bologna, Italy)	October 16 th to October 20 th , 2017

We also confirm that the inspection team will be able to observe the manufacturing and testing processes of the MRTPA products during the time periods mentioned above, and that any and all available records of the past four (4) years for manufacturing, quality control, ex-batch release, and stability testing can be reviewed during the scheduled inspections.

Finally, we confirm that records that are not written in English will be translated for the inspectors, and that an interpreter will be present during the inspections should the inspection team desire to speak with non-English speaking employees.



PHILIP MORRIS
PRODUCTS S.A.

Please note, this response 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 the response.

We remain available for any further information that is required.

Sincerely,

Shelley Moores
Manager, QMS Governance
Philip Morris Products S.A.

Jeffrey Walker, M.D.
United States Agent for PMP S.A.
CEO, Teton Regulatory Sciences

cc: Matthew R. Holman, Ph.D.
Director, Office of Science, CTP