PHILIP MORRIS
PRODUCTS S.A.

June 21, 2017

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via ESG

Re: Amendment to MR0000059 IQOS system with Marlboro HeatSticks;
MR0000060 IQOS system with Marlboro Smooth Menthol HeatSticks; and
MR0000061 IQOS system with Marlboro Fresh Menthol HeatSticks

Dear Sir or Madam,

We are hereby providing, in amendment to the above-mentioned applications, a letter from Labstat International ULC authorizing PMP S.A. to incorporate by reference the information regarding their detailed analytical methods contained in (b) (4) in support of our submissions.

These analytical methods are referenced within Module 7.1 of the applications in Labstat analytical test reports "Characterization of Tobacco and Tobacco Smoke" (FDA abbreviated list of HPHCs measured in aerosol and filler) and "Characterization of Mainstream Tobacco Smoke" (58 analytes measured in product aerosol vs. reference product) for each of the 3 HeatStick variants.

In addition, we would like to inform you that two Module 4 appendices (A4.2.25 iQOS DevicePackage and A4.2.26 iQOS DevicePackage) submitted in the MRTPAs contain some text that is not visible on the device package panels. We are hereby resubmitting, in replacement, those appendices containing correct display of the text. We kindly request that the documents submitted herewith be made available to the public in lieu of those where some of the package text was not properly displayed.

This 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

June 21, 2017 Amendment to MR0000059-61

Appendix A:

Attachments [Filename]	Replaces
1.6 Letter of Authorization(b) (4) [1.6 LoA(b) (4)]	(N/A - New)
A4.2.25 *iQOS* Device Package – slate kit [A4.2.25 iQOS DevicePackage]	MRTPA\4 LABELS ADV\ A4.2.25 iQOS DevicePackage (original submission)
A4.2.26 *iQOS* Device Package – white kit [A4.2.26 iQOS DevicePackage]	MRTPA\4 LABELS ADV\ A4.2.26 iQOS DevicePackage (original submission)