PHILIP MORRIS
PRODUCTS S.A.

March 30, 2020

Dr. Matthew Holman
Director, Office of Science
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via electronic media

Subject: Premarket Tobacco Product Application (PMTA) for modified version of the authorized *IQOS* System Holder and Charger (PM0000479)

Dear Dr. Holman,

Philip Morris Products S.A. (PMP S.A.) is submitting this PMTA in accordance with requirements of Section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and requesting a marketing order under Section 910(c)(1)(A)(i) of the FD&C Act for the *IQOS* 3 System, which is a modified version of the *IQOS* System Holder and Charger, as authorized by Marketing Order of April 30, 2019, (PM0000479) (the "Authorized *IQOS* System").

This application is submitted as supplemental PMTA (sPMTA) in accordance with the advice received from FDA in the December 18, 2019, written response to the PMP S.A.'s pre-submission meeting request related to the planned submission of a PMTA under section 910(b) of the FD&C Act for *IQOS* 3 System. The Agency concluded that a sPMTA submission would be appropriate as the *IQOS* 3 System requires only limited information or revisions to the *IQOS* PMTA which was the subject of the Marketing Order[1].

The *IQOS* 3 System, which is the subject of this application, is to be used with any of the authorized Tobacco Stick variants, Marlboro *HeatSticks* (PM0000424), Marlboro Smooth Menthol *HeatSticks* (PM0000425) and Marlboro Fresh Menthol *HeatSticks* (PM0000426), the same as the Authorized *IQOS* System (PM0000479).

[1] FDA's written response of December 18, 2019 (STN: TC0005319) to the PMP S.A.'s October 11, 2019 meeting request related to the planned submission of a PMTA under section 910(b) of the FD&C Act for *IQOS* 3.

Upon issuance of an marketing order for the *IQOS* 3 System, Altria Client Services LLC (ALCS)[2] and an ALCS affiliate will be licensed to distribute and sell the product in the United States, the same as with the Authorized *IQOS* System (PM0000479). The ALCS affiliate that will distribute and sell the product in the United States is Philip Morris USA Inc. (PM USA)[3].

Detailed information regarding this application is provided in Module 1, Section 1.2 *General Information*.

This application is being submitted on electronic media, along with confirmation that it is virus-free.

PMP S.A. appreciates FDA's consideration of this application and looks forward to working with the Agency to secure a marketing authorization order under Section 910(c)(1)(A)(i) for the upgraded modified version of the *IQOS* System Holder and Charger discussed herein.

Sincerely,

(b) (6)

Daniel Verstappen
Vice President Regulatory, Quality & Standards
Philip Morris Products S.A.

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

Please note that this submission contains confidential commercially sensitive, and/or trade secret information, and the legal protections provided to such information are hereby claimed under the applicable provisions of Unites States law. PMPSA understands that FDA will hold this documentation confidential and will refrain from the public disclosure of the information contained in this submission in conformity with such provisions of the law.

[2] PMP S.A.'s parent company, Philip Morris International Management S.A., has entered into a distribution agreement with Altria Client Services LLC

[3] PM USA is not part of Philip Morris International group of companies.

Enclosures
Appendix A – Enclosures:

(1) USB stick containing PMP S.A.'s supplemental PMTA for for *IQOS* 3 System, an upgraded modified version of the *IQOS* System Holder and Charger

(2) Virus-scan confirmation

(3) Printed Labeling Specimens