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PHILIP MORRIS
PRODUCTS S.A.

March 18, 2021

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 CTP Portal

Subject: Modified Risk Tobacco Product Application (MRTPA) for the *IQOS* 3 System Holder and Charger (PM0000634)

Dear Dr. Holman,

In accordance with the feedback from FDA provided in a letter dated February 11, 2021[1], Philip Morris Products S.A. (PMP S.A.[2]) hereby submits this supplemental MRTPA (sMRTPA) under section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requesting a marketing authorization order under section 911(g)(2) (exposure modification order) for the *IQOS* 3 System Holder and Charger, which was previously granted a Marketing Granted Order (MO) under Section 910 of the FD&C Act on December 7, 2020 (PM0000634). The requirements of an sMRTPA, as conveyed by FDA, are further explained in section 1.2 General Information.

The *IQOS* 3 System retains all functional elements of the *IQOS* 2.4 System which was authorized by the MO of April 30, 2019 (PM0000479), and which subsequently obtained the Modified Risk Granted Order (MRGO) – Exposure Modification on July 7, 2020. The *IQOS* 3 System is comparable to the *IQOS* 2.4 System as it preserves critical principles of the System performance, safety and consumer behaviour[3].

Given the comparability of the *IQOS* 3 System to the *IQOS* 2.4 System which received the MRGO, the authorized exposure claims apply equally to the *IQOS* 3 System.

[1] *See* February 11, 2021 letter from Stephanie Durkin to Adam Susser Re: (STN: TC00006573).

[2] PMP S.A. is a subsidiary of Philip Morris International Inc.

[3] As confirmed in the Marketing Granted Order of December 7, 2020 (STN: PM0000634) and associated Technical Project Lead (TPL) Review of PMTA.

With this sMRTPA PMP S.A. is seeking for the *IQOS* 3 System an MRGO of the type that FDA issued on July 7, 2020 for the *IQOS* 2.4 System (*i.e.*, MRTPA order under section 911(g)(2) of the FD&C Act). As a consequence, there is no change to the modified risk statements or changes outside the scope of the authorized claims under the original MRTPA, namely:

AVAILABLE EVIDENCE TO DATE:

- *The IQOS system heats tobacco but does not burn it.*
- *This significantly reduces the production of harmful and potentially harmful chemicals.*
- *Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.*

PMP S.A. is not submitting new data for review in this sMRTPA for the *IQOS* 3 System. Studies that supported the original MRGO are the same and do not require reanalysis. To facilitate review of this application, PMP S.A. utilized cross-referencing to the original MRTPA and where relevant to the supplemental PMTA for the *IQOS* 3 System. This application has been structured in the same manner as the MRTPA for the *IQOS* 2.4 System.

Upon issuance of an MRGO – Exposure Modification, the *IQOS* 3 System will be incorporated into the Postmarket Surveillance and Studies (PMSS) Plan implemented for the *IQOS* 2.4 System, as confirmed by the FDA's letter of February 24, 2021 (STN: PS0000042).

As with the *IQOS* 2.4 System (MR0000133), Altria Client Services LLC (ALCS)[4] and an ALCS affiliate will distribute and sell the *IQOS* 3 System in the United States. The ALCS affiliate that distributes and sells the product in the United States is Philip Morris USA Inc. (PM USA).

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 911(g)(2) of the FD&C Act for the *IQOS* 3 System Holder and Charger discussed herein.

Sincerely,

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Daniel Verstappen
Vice President Scientific Regulatory Affairs
& Standards Management
Philip Morris Products S.A.

(b) (6)

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[4] PMP S.A. has entered into a licensing and distribution agreement with Altria Client Services LLC

Please note that this submission contains confidential commercial information, and/or trade secret information, and the legal protections provided to such information are hereby claimed under the applicable provisions of Unites States law, including relevant provisions of the Federal Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 et seq. (specifically, 5 U.S.C. § 552(b)(4)), the Trade Secrets Act (18 U.S.C. § 1905), the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., (specifically FDCA §§ 301(j) and 906(c), 21 U.S.C. §§ 331(j) and 387f(c)) and FDA's implementing regulations, 21 C.F.R. Part 20 (specifically 21 C.F.R. §§ 20.47 and 20.61). PMP S.A. 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. Accordingly, if FDA tentatively determines that any portion of this submission is disclosable to the public, FDA is required to provide PMP S.A. with notice and an opportunity to object in accordance with 21 C.F.R. §§ 20.47 and 20.61. PMP S.A. reserves all legal rights to protect against public disclosure of its trade secrets and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.