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PHILIP MORRIS
PRODUCTS S.A.

August 27, 2020

Priscilla Callahan-Lyon
Director, Division of Individual Health Science
Office of Science
Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via CTP Portal

Subject: RESPONSE TO DEFICIENCY LETTER for PM0000634

Dear Dr. Callahan-Lyon,

We hereby submit our response to the FDA's Deficiency Letter, dated August 13, 2020, pertaining to the PMTA for *IQOS* 3 System Holder and Charger (PM0000634), which was submitted on March 30, 2020, pursuant to section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and received by the Center for Tobacco Products on April 1, 2020.

As instructed in the Deficiency Letter, we hereby confirm that this is a complete response to each numerated deficiency outlined in the Agency's letter.

We appreciate FDA's consideration of this response and remain available for any further information that is required.

Sincerely,

(b) (6)

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

(b) (6)

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

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.

Enclosures: Annex A

Annex A:

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