PHILIP MORRIS
PRODUCTS S.A.

November 05, 2020

Lillian Ortega
Director, Division of Enforcement and Manufacturing
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: Amendment to the Response to Information Request Letter for PS0000042

Dear Ms. Ortega,

PMP S.A. hereby submits an amendment to the response to the Information Request Letter regarding the Postmarket Surveillance and Studies (PMSS) Plan for *IQOS* System.

Figure 3 in the document "*Cancer Risk and Exposure to Chemicals Increased in THS2.2 Aerosol Compared to 3R4F Smoke: Hazard identification Protocol for PMSS*" contains a typographical error. The protocol for hazard identification, under section "*Weight of Evidence (WoE)*" for the Clastogenicity/Aneugenicity assessment refers twice to the *in vitro* testing. The second reference should be replaced by *in vivo* testing.

The pdf version of Figure 3 has been corrected and a replacement page (page 11) is provided within this amendment.

We remain available for any further information that is required.

Sincerely,

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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:

Replacement page (11) of the document "*Cancer Risk and Exposure to Chemicals Increased in THS2.2 Aerosol Compared to 3R4F Smoke: Hazard identification Protocol for PMSS*".