PHILIP MORRIS
PRODUCTS S.A.

April 29, 2022

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 CTP Portal

SUBJECT: ANNUAL REPORT for PM0000424 - PM0000426, PM0000479 and PM0000634 and MR0000059 - MR0000061 and MR0000133 and PMSS REPORT for MR0000059 - MR0000061 and MR0000133

Dear Sir or Madam,

Philip Morris Products S.A. (PMP S.A.) is hereby submitting the Annual Report for the following products:

- PM0000424 - MR0000059 *Marlboro* Amber *HeatSticks*
- PM0000425 - MR0000060 *Marlboro* Green Menthol *HeatSticks*
- PM0000426 - MR0000061 *Marlboro* Blue Menthol *HeatSticks*
- PM0000479 - MR0000133 *IQOS* System Holder and Charger
- PM0000634 - *IQOS* 3 System Holder and Charger

This report covers the reporting period from March 1, 2021, to February 28, 2022, as specified in corresponding Marketing Orders and in accordance with requirements under section 910(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

In addition, this submission also contains PMSS Report for the following products:

- MR0000059 *Marlboro* Amber *HeatSticks*
- MR0000060 *Marlboro* Green Menthol *HeatSticks*
- MR0000061 *Marlboro* Blue Menthol *HeatSticks*
- MR0000133 *IQOS* System Holder and Charger[1]

This report covers the reporting period from March 1, 2021 to February 28, 2022, as specified in corresponding Marketing Orders and in accordance with requirements under section 911(g)(2)(C)(iii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

We remain available for any further information that is required.

Sincerely,

(b) (4), (b) (6)

Mark Bowden
VP Scientific Reg. Affairs & Standards Mgmt
Philip Morris Products S.A.

(b) (4), (b) (6)

Jeffrey Walker
Head of U.S. Regulatory Affairs
PMI Global Services

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 ("FDCA"), 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.

[1] On March 11, 2022, FDA has issued Modified Risk Granted Order for Exposure Modification order (MR0000192) for *IQOS 3* System Holder and Charger; no data are reported on this product as the MRGO was issued outside of the reporting period for the 2022 PMSS Report.

Enclosures:

- 2022 Annual Report
- 2022 Annual Report Index
- 2022 PMSS Report
- 2022 PMSS Report Index