PHILIP MORRIS
PRODUCTS S.A.

January 14, 2022

LCDR Michael Gu
Deputy 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: Adjustment to the Postmarket Surveillance and Studies (PMSS) Plan forMR0000059 - MR000061 and MR0000133

Dear Lieutenant Commander Gu,

In the Modified Risk Granted Orders (MRGO) for the *IQOS*® System and *HeatSticks*®[1] FDA stated that "you must initiate and conduct your PMSS per the timeframes established in your protocols and approved by FDA." Philip Morris Products S.A. (PMP S.A.), the holder of the MRGO, hereby provides updates to the studies "*IQOS*® with *Marlboro HeatSticks*® Cross-Sectional Postmarket Adult Consumer Study (PACS)," "*IQOS*® with *Marlboro HeatSticks*® Cohort Postmarket Adult Consumer Study (PACS)", "Reporting from the US *IQOS*® Owners Panel," and the planned "Secondary Analysis: Estimation of Awareness and Use of *IQOS*® among Underage Individuals," which are part of the PMSS Plan for MR0000059 - MR000061 and MR0000133.

[1] Modified Risk Granted Orders – Exposure Modification, July 7, 2020. The MRGO applies to *Marlboro* Amber *HeatSticks*® (MR0000059), *Marlboro* Green Menthol *HeatSticks*® (MR0000060), *Marlboro* Blue Menthol *HeatSticks*® (MR0000061) and IQOS® System Holder and Charger (MR0000133)

On February 24, 2021, FDA issued its letter of approval for the planned PMSS Plan. Since that time, Altria Client Services LLC (ALCS)[2] successfully added the *IQOS*® module to the ongoing Underage Tobacco Use Survey (UTUS) and initiated the first execution of the *IQOS*® cross-sectional study (ALCS-CMI-17-36-HT) in the 2nd and 3rd quarters of 2021, respectively. We had not planned to launch the first *IQOS*® cohort study (ALCS-CMI-17-36-HT) until 2022.

As documented in a letter to the FDA Office of Compliance and Enforcement on November 9th, 2021[3], the International Trade Commission (ITC) recently issued a decision that halted the importation of *IQOS*® and *Marlboro HeatSticks*® ("*IQOS*® products") into the United States (U.S.) and prohibits the sale and marketing of imported *IQOS*® products in the U.S. As of November 29, 2021, Philip Morris USA (PM USA) is no longer marketing or selling *IQOS*® products in the U.S. for an indeterminate amount of time. The unavailability of *IQOS*® products in the U.S. market hinders our ability to surveil *IQOS*® use. As such, we have adjusted our timing and plans for PMSS moving into 2022.

The altered timeline and study plans reflect current *IQOS*® market unavailability. Table 1 details the status of the PMSS Plan for *IQOS*® products.

Table 1: Status of the PMSS Plan for *IQOS*® products

Study Name	Status	2022 Adjustments
IQOS® with *Marlboro HeatSticks*® Cross-Sectional Postmarket Adult Consumer Study (PACS) ALCS-CMI-17-36-HT	The first execution of the *IQOS*® Cross-Sectional PACS fielded from September to November of 2021, prior to removal of *IQOS*® from the market. We expect to receive data tables and a final report for that study by the end of first quarter, 2022. We will report the results of the first execution of the *IQOS*® Cross-Sectional PACS in the 2022 annual report.	We had originally planned to launch the second execution of the *IQOS*® Cross-Sectional PACS in September of 2022. We do not expect a sufficient *IQOS*® consumer pool to recruit from in 2022 considering the unavailability of *IQOS*® and *HeatSticks*® in the market. We currently plan to skip the *IQOS*® Cross-Sectional PACS planned to be conducted in 2022, with hopes to launch the second execution of the study in 2nd or 3rd quarter of 2023 if *IQOS*® has been available for a sufficient time in the US market. We will communicate with FDA the

[2] Altria Client Services LLC (ALCS) is a wholly owned subsidiary of Altria Group, Inc. ALCS provides certain services to the Altria family of companies.

[3] Letter to Ann L. Simoneau, Director, Office of Compliance and Enforcement, Center for Tobacco Products, on November 9th, 2021 from Altria Client Services LLC, on behalf of Philip Morris USA

		detailed study timeline and provide an amended protocol when we have a firmer understanding of when *IQOS*® may be back on the market.
IQOS® with *Marlboro HeatSticks*® Cohort Postmarket Adult Consumer Study (PACS) ALCS-CMI-17-37-HT	As communicated in the approved PMSS plans for *IQOS*® products we have not yet launched the Cohort PACS.	We had originally planned to launch the Cohort PACS in the 3rd quarter of 2022. We do not expect a sufficient IQOS® consumer pool to recruit from in 2022 considering the unavailability of *IQOS*® and *HeatSticks*® in the market. We now hope to launch the Cohort PACS in the 2nd or 3rd quarter of 2023 if *IQOS*® has been available for a sufficient time in the US market. We will communicate with FDA the detailed study timeline and provide an amended protocol when we have a firmer understanding of when *IQOS*® may be back on the market.
Secondary Analysis: Estimation of Prevalence of *IQOS*® Use	Data collection relevant to *IQOS*® is ongoing. We provided a summary of Adult Tobacco Consumer Tracker (ATCT) data collected between July of 2020 and February of 2021 in our 2021 annual report. We will provide a summary of ATCT data collected between March 1st, 2021 and February 28th, 2022 in our 2022 annual report. We will continue *IQOS*® relevant data collection after that time.	We expect no adjustments to the 2022 ATCT survey data collection relevant to *IQOS*®.
Reporting from the U.S. *IQOS*® Owners Panel	We reported data from ALCS' dynamic longitudinal *IQOS*® Owners Panel. We provided a summary of *IQOS*® Owners Panel data collected between April of 2020 and February of 2021 in our 2021 annual report.	*IQOS*® Owners Panel data collection ceased as of November 29th, 2021 as a result of the ITC decision and *IQOS*® becoming unavailable in the US market. We will report *IQOS*® Owners Panel data collected between March 1st, 2021 and November 29th, 2021 in our 2022 annual report. We will notify FDA if and when the *IQOS*® Owners Panel may resume.

Secondary Analysis: Estimation of Awareness and Use of *IQOS*® among Underage Individuals	Underage Tobacco Use Survey (UTUS) data collection is ongoing. The *IQOS*®-specific module was implemented in the second quarter of 2021. Implementation of the *IQOS*® module included an oversample in three regions where *IQOS*® was marketed and sold including Atlanta, GA, Charlotte, NC and Richmond, VA.	Data collection relevant to *IQOS*® is ongoing. We will provide a summary of UTUS data collected between March 1st, 2021 and February 28th, 2022 in our 2022 annual report. We will continue *IQOS*®-relevant data collection after that time. However, we plan to halt the oversample in Atlanta, GA, Charlotte, NC and Richmond, VA starting in the second quarter of 2022. We decided to halt the oversample in these regions because 1) *IQOS*® will no longer be marketed or available in those regions, 2) we do not wish to exhaust available households within those regions, and 3) we may recoup costs associated with the oversampling that may then be used for future adjustments once *IQOS*® is back on the market. We will re-evaluate the need for an oversample and the potential regions to oversample when we have a firmer understanding of when *IQOS*® may be back on the market and in what regions *IQOS*® may be available. We will communicate updated plans to FDA as we learn more.

We will continue to identify any other developments in *IQOS*® products availability and will contact FDA with any future amendments to PMSS study documents that bring alignment between our surveillance activity and the current/future market conditions.

The PMSS Plan for the *IQOS*® System and *HeatSticks*® has been jointly developed by PMP S.A. and ALCS. The PMSS Plan will be jointly conducted with ALCS and an ALCS affiliate licensed to distribute and sell the product in the United States, on behalf of PMP S.A. The ALCS affiliate that distributes and sells the product in the U.S. is Philip Morris USA Inc. (PM USA)[4].

[4] PMP S.A.'s parent, Philip Morris International Management S.A. (PMI), has entered into a distribution agreement with ALCS by which ALCS and its affiliates, including PM USA, are licensed to sell and distribute IQOS® in the U.S. after FDA authorization.

We appreciate FDA's time and attention to this matter. Please feel free to contact us with any questions about these adjustments to our PMSS planned studies.

Sincerely,

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Mark Bowden
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U.S. Agent for PMP S.A.

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 FD&C Act §§ 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.