PHILIP MORRIS PRODUCTS SA

June 06, 2024

CDR Collins Mason
Director, Division of Enforcement and Manufacturing
Office of Compliance and Enforcement

Elizabeth Do
Regulatory Health Project Management, *Division of Regulatory Project Management, Branch IV*
Office of Science

Center for Tobacco Products
U.S. Food and Drug Administration
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via CTP Portal

Subject: Update of the Postmarket Surveillance and Studies (PMSS) Plan for *IQOS* Products (MR0000059 - MR0000061, MR0000133 and MR0000192)

Dear Mr. Collins and Ms. Do,

We, Philip Morris Products S.A. (PMP S.A.), the holder of MRGOs authorizing the marketing of *IQOS* products as modified risk tobacco products[1] are submitting a report from the computational toxicology assessment pursuant to the terms of that marketing orders.[2]

In May of this year, when we submitted an update of the PMSS Plan for *IQOS* products[3], the results from computational toxicology assessment (Phase 3) were still being analyzed. The analysis has now been finalized and we are providing the final study report. As requested, we are reporting identified hazards for each group of compounds (parents and metabolites) and segmented according to the quality and the reliability of data. The collected data have been evaluated on the potential genotoxicity/carcinogenicity risk of the parent and metabolite compounds.

[1] MR0000192, MR0000133 and MR0000059-MR0000061.

[2] February 24, 2021, PMSS Approval Letter for PS0000042 with subsequent amendment to include MR0000192 accepted by FDA on January 10, 2023.

[3] May 30, 2024, Update of the PMSS Plan for *IQOS* products.

The report is in the folder labeled "*MRTPA Renewal*" within the TPMF[4] and is cross-referenced for the purpose of this update.

The Letter of Authorization provided on October 18, 2023, authorizing the U.S. FDA to review the content submitted under the (b) (4) , when considering any type of applications filed by PMP S.A., including PMTAs and MRTPAs, for *IQOS ILUMA* devices and *TEREA* sticks, without limitations remains valid in the context of this renewal submission.

PMP S.A. believes that this submission fulfils the requirement of the PMSS Plan related to computational toxicology, and no further assessment will be executed.

We appreciate FDA's consideration of the computational toxicology assessment and look forward to working with the Agency further.

Sincerely,

(b) (6)

Mark Bowden
VP Scientific Regulatory Affairs
& Standards Management
Philip Morris Products S.A.

(b) (6)

Laura Leigh Oyler
Global Head of U.S. Regulatory Affairs
U.S. Agent
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 United States law, including relevant provisions of the Federal Freedom of Information Act, 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 CFR Part 20 (specifically 21 CFR 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 CFR 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.

[4] Study report is available in: (b) (4)