PHILIP MORRIS
PRODUCTS S.A.

February 17, 2021

Lillian Ortega
Director, Division of Enforcement and Manufacturing
Office of Compliance and Enforcement
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 for PS0000042

Dear Ms. Ortega,

Philip Morris Products S.A. (PMP S.A.) hereby submits its response to request for information issued via e-mail on February 16, 2021[1] in which the Agency requested submission of the following information, as an amendment:

1. Final computational toxicology protocol as an official amendment;
2. Curriculum Vitae (CV) and qualifications of the Principal Investigator; and
3. The names of *in silico* software PMP S.A. plans to use for the computational toxicology study.

The updated protocol for the computational toxicology assessment and CV with qualifications of the Principal Investigator for the computational toxicology study, (b) (4) are enclosed to this letter.

Regarding the third request, we hereby confirm that PMP S.A. is planning to use the following *in silico* software for the computational toxicology:

[1] E-mail from Mrs. Rose Bianchi, Lead Consumer Safety Officer, received on February 16, 2021.

- Derek Nexus from Lhasa Ltd,
- (b) (4)
- OECD QSAR Toolbox

This response fully addresses the request issued by the FDA in the context of computational toxicology assessment which is part of the PMSS for the *IQOS* System.

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

Sincerely,

(b) (6)

Daniel Verstappen
Vice President Scientific Regulatory Affairs
& Standards Management
Philip Morris Products S.A.

(b) (6)

Adam Susser
U.S. Agent for PMP S.A.
Philip Morris Products 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 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:

Index of documents provided as the Amendment for PS0000042

Attachment [Filename]
Cancer Risk and Exposure to Chemicals Increased in THS2.2 Aerosol Compared to 3R4F Smoke: Hazard identification Protocol for PMSS (Version 3.0) [computational-toxicology-protocol]
CV with qualifications of the Principal Investigator for the computational toxicology study - (b) (6) [CV_(b) (6)_02-2021]