PHILIP MORRIS
PRODUCTS S.A.

July 5, 2023

Dr. Matthew Farrelly
Director, Office of Science
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via CTP Portal

Subject: Renewal of the Modified Risk Granted Order (MRGO) for MR0000133, MR0000192, MR0000059, MR0000061 and MR00000060.

Dear Dr. Farrelly,

Philip Morris Products S.A. (PMP S.A.) is submitting this application under section 911(g)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act requesting a renewal of the Modified Risk Granted Order (MRGO) - Exposure Modification authorizing the marketing, as modified risk tobacco products, of *IQOS* 2.4 System Holder and Charger (MR0000133), *IQOS* 3.0 System Holder and Charger (MR0000192) and *Marlboro* Amber, Blue Menthol and Green Menthol *HeatSticks* (respectively MR0000059, MR0000061 and MR00000060).

The available new data collected in the United States is limited, due to the decision of the U.S. International Trade Commission (ITC), which resulted in the mandatory withdrawal of *IQOS* and *HeatSticks* (*IQOS* products) from the U.S. market as of November 28, 2021[1]. The ITC issued its Final Determination (FD), Limited Exclusion Order (LEO), and Cease and Desist Orders (CDO) after concluding that two patents of an affiliate of R.J. Reynolds Tobacco Company (RJR) are violated by PMI and not invalid. The CDO prohibits Altria Client Services (ALCS)[2] and PM USA[3] from, among other things, importing, selling, marketing, advertising, distributing, or transferring imported *IQOS* products (included their components).

[1] Investigation No. 337-TA-1199, *In the Matter of Certain Tobacco Heating Articles and Components Thereof.*

[2] PMP S.A., formerly Philip Morris International Management S.A., has entered into a distribution agreement with Altria Client Services LLC (ALCS) by which ALCS and an ALCS affiliate will be licensed to distribute and sell the candidate product in the United States, upon issuance of the requested marketing order. ALCS is a wholly-owned subsidiary of Altria Group, Inc. ALCS provides certain services to the Altria family of companies.

[3] PM USA is not part of Philip Morris International group of companies.

This application contains data from the U.S. market that was generated prior to the withdrawal of *IQOS* products and already transmitted to the Agency as part of Annual Reports. The evidence is supplemented with additional international data from Germany, Japan, South Korea, and Italy, where *IQOS* products have continued to prove successful in converting millions of adult smokers to this modified-risk tobacco product.

The combined evidence from U.S. pre-market studies and post-market studies, together with evidence from international post-market studies, indicate that *IQOS* products continue to satisfy the requirements of section 911(g)(2) of the FD&C Act, including the requirement that marketing the product is appropriate to promote the public health and is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

With this application, PMP S.A. is requesting a renewal of the MRGO – Exposure Modification for the *IQOS* products issued under section 911(g)(2) of the FD&C Act.

There is no change to the modified risk statements. Namely, PMP S.A. seeks to reaffirm the previously authorized claims language:

AVAILABLE EVIDENCE TO DATE:

- *The IQOS system heats tobacco but does not burn it.*
- *This significantly reduces the production of harmful and potentially harmful chemicals.*
- *Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.*

This application has been structured in the same manner as the initial MRTPAs for *IQOS* products.

It is important that FDA take action on this renewal request by the date that the original MRGO expires because PMP S.A. plans to re-introduce *IQOS* to the U.S. market by that date. PMP S.A. appreciates FDA's consideration of this application and looks forward to working with the Agency to secure the renewal of the MRGOs under Section 911(g)(2) of the FD&C Act before the current MRGO lapses.

Sincerely,

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Mark Bowden, Ph.D.
VP Scientific Reg. Affairs & Standards Management
Philip Morris Products S.A.

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Laura Leigh Oyler, J.D.
Global Head of US Regulatory Affairs
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 United 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.