Module 1: General Information

1.2 General Information

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1. CONTACT INFORMATION

1.1. Applicant

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Company Name	Philip Morris Products S.A.
Address	Quai Jeanrenaud 5 2000 Neuchatel Switzerland
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1.2. U.S. Agent

Contact Name	Laura Leigh Oyler
Position Title	Global Head of US Regulatory Affairs
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Company Name	Philip Morris Products S.A.
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2. PRODUCT IDENTIFICATION

Manufacturer	Philip Morris Products S.A. (PMP S.A.)
Product names, including the brand and subbrand if applicable	*IQOS* 2.4 System Holder and Charger *IQOS* 3.0 System Holder and Charger *Marlboro* Amber *HeatSticks* *Marlboro* Green Menthol *HeatSticks* *Marlboro* Blue Menthol *HeatSticks*
Product category	Device: Heated Tobacco Product (HTP)[1] Consumable: HTP[1]
Product subcategory	Device: Open HTP[2] Consumable: HTP Consumable[2]
Nicotine Source	Tobacco
Product properties (Device)	Package Type: Box Product Quantity: 1 Holder, 1 Charger Length: 92.25 mm (Holder) Diameter: 14.40 mm (Holder) (smallest) 14.90 mm (Holder) (with protruding button) Length: 114.80 mm (Charger) Width: 46.35 mm (Charger) Thickness: 23.00 mm (Charger) Source of Energy: Electric (rechargeable battery)

[1] In accordance with the Final Rule "Premarket Tobacco Product Applications and Record keeping Requirements", effective as of November 4, 2021, the product category 'Cigarette', referred to in the Modified Risk Granted Orders, has been replaced by 'Heated Tobacco Product (HTP)'.

[2] In accordance with the Final Rule "Premarket Tobacco Product Applications and Record keeping Requirements", effective as of November 4, 2021, the product sub-category 'Non-combusted', referred to in the Modified Risk Granted Orders, has been replaced by 'HTP Consumable' for consumables and 'Closed HTP' for devices.

	Additional properties: Battery Capacity: > 110 mAh (Holder) Battery Capacity: > 2600 mAh (Charger)
Product properties (*HeatSticks*)	Package Type: Box Product Quantity: 20 *HeatSticks* Length: 45 mm Diameter: 7.42 mm (max. diameter) Ventilation: Not Applicable[3] Source of Energy: Electric (rechargeable battery) Characterizing Flavor: - *Marlboro* Amber *HeatSticks*: None - *Marlboro* Green Menthol *HeatSticks*: Menthol - *Marlboro* Blue Menthol *HeatSticks*: Menthol

3. APPLICATION

Type of Application	MRTPA renewal
STNs / FDA identifying numbers	Modified Risk Granted Order (MRGO) - Exposure Modification of December 12, 2019, authorizing the marketing of the *IQOS* 2.4 System Holder and Charger (STN: MR0000133). MRGO - Exposure Modification of December 12, 2019, authorizing the marketing of *Marlboro* Amber, Blue Menthol and Green Menthol *HeatSticks* (STN respectively: MR0000059, MR0000061 and MR00000060). MRGO - Exposure Modification of March 11, 2022, authorizing the marketing of the *IQOS* 3.0 System Holder and Charger (STN: MR0000192).

[3] Filter efficiency or ventilation are not used to control aerosol deliveries.

Prior meetings with FDA	September 12, 2002, PMP S.A.'s Meeting Request regarding an extension of time for the MRGO renewal for the authorized *IQOS* products. November 17, 2022, FDA's written response to the Meeting Request regarding an extension of time for the MRGO renewal for the authorized *IQOS* products.
Facility Establishment Identifier (FEI) and address of manufacturer (Device)	(b) (4)

(b) (4)

Facility Establishment Identifier (FEI) and address of manufacturer (*HeatSticks*)	**Philip Morris Products S.A. (PMP S.A.)**[5] (part of the Philip Morris International group of companies) Address: Quai Jeanrenaud 3 2000 Neuchatel Switzerland Facility Establishment Identifier (FEI) number: 3008268329 **Philip Morris Manufacturing and Technology Bologna S.p.A. (PMMTB)** (part of the Philip Morris International group of companies) Address: Via Giacomo Venturi 1 40053 Località Crespellano, Valsamoggia, Bologna, Italy

PMP S.A. is submitting this application under section 911(g)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act requesting the renewal of a modified risk authorization order under section 911(g)(2) (exposure modification order) for the *IQOS* 2.4 System Holder and Charger (MR0000133), the *IQOS* 3.0 System Holder and Charger (MR0000192) and the corresponding three variants of *HeatSticks* (MR0000059, MR0000061 and MR00000060) (also referred to as *IQOS* products).

[5] PMP S.A. is in the process of qualifying a new U.S. (domestic) facility located in Wilson, North Carolina for both primary and secondary *HeatSticks* manufacturing. Upon completing qualification process, the establishment registration for the new manufacturing facility as well as the product listing for the products manufactured in this new facility will be submitted to FDA.

3.1. About the Applicant

PMP S.A., the applicant, is pursuing a business strategy that envisions a future where we stop selling combustible cigarettes. To that end, our organization has dedicated itself to developing, scientifically assessing, and commercializing a range of noncombustible alternatives to which adult smokers will switch completely. We have developed several products designed to create a nicotine-containing aerosol, without combustion and therefore, without tobacco smoke.

IQOS and *HeatSticks* will be marketed in the United States by Triaga Inc., a U.S. affiliate of PMP S.A.

3.2. Application Background

PMP S.A. is submitting this application under section 911(g)(2) of the FD&C Act requesting the renewal of the MRGO - Exposure Modification authorizing the marketing, as modified risk products\, of the *IQOS* 2.4 System Holder and Charger (MR0000133, dated December 12, 2019), *IQOS* 3.0 System Holder and Charger (MR0000192, dated March 11, 2021) and *Marlboro* Amber, Blue Menthol and Green Menthol *HeatSticks* (MR0000059, MR0000061 and MR00000060, respectively, dated December 12, 2019).

The available new data gathered in the U.S. is limited, due to the decision of the U.S. International Trade Commission (ITC) which resulted in the mandatory withdrawal of *IQOS* and *HeatSticks* from the U.S. market as of November 28, 2021[6]. 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)[7] and PM USA[8] from, among other things, importing, selling, marketing, advertising, distributing, or transferring imported *IQOS* Products (including their components).

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 the Annual Reports. The evidence is supplemented with additional international data from Germany, Japan, South

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

[7] 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.

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

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 the U.S. pre-market 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.

3.3. Structure of the Dossier

To facilitate the review of this renewal application, PMP S.A. cross-reference to the original MRTPA for the *IQOS* 2.4 System and *HeatSticks*, as well as to the supplemental MRTPA for the *IQOS* 3.0 System. This renewal application has been structured in the same manner as the initial MRTPAs for the *IQOS* products.

Table 1 below provides an overview of the PMP S.A.'s approach to providing the data and information.

Table 1: Structure of the renewal application

Module 1 General Information	Cross-referenced to MR0000133, MR0000192, MR0000059-MR0000061. Module content: - Cover Letter - General information - Letters of Authorization
Module 2 Table of Contents	Cross-referenced to PM0000479, PM0000424-PM0000426, PM0000634, MR0000133, MR0000192, MR0000059-MR0000061. Module content: - Table of Contents - Index - Glossary - Executive Summary
Module 3 Product Description	Cross-referenced to PM0000479, PM0000424-PM0000426, PM0000634. Module content: - Summary of the Product Formulation - Summary of Manufacturing

Module 4 Labeling and Advertising	Cross-referenced to PM0000479, PM0000424-PM0000426, PM0000634, MR0000133, MR0000192 MR0000059-MR0000061. Module content: - Labeling - Marketing Plans
Module 5 Environmental Impact Assessment	Cross-referenced to PM0000479, PM0000424-PM0000426, PM0000634, MR0000133, MR0000192, MR0000059-MR0000061.
Module 6 Research	Cross-referenced to MR0000133, MR0000192, MR0000059-MR0000061. Module content: - Summary of Health Risk Investigations - Effect on Tobacco Use Behavior Among Current Tobacco Users - Effect on Tobacco Use Initiation Among Non-Users - Consumer Understanding and Perceptions - Population Modelling and Analysis With subsequent update.
Module 7 Scientific Studies and Analyses	Cross-referenced to PM0000479, PM0000424-PM0000426, PM0000634, MR0000133, MR0000192, MR0000059-MR0000061. With subsequent update.
Module 8 Postmarket Information	Cross-referenced to MR0000133, MR0000192, MR0000059-MR0000061. Module content: - Postmarket Surveillance and Studies (PMSS) - Adverse Experience Reports With subsequent update
Module 9 References	With subsequent update.

4. COMPLIANCE WITH REQUIREMENTS OF SECTION 911(G)(2) OF THE FD&C ACT

Scientific evidence and data referenced in this application satisfies all criteria for the renewal of an order under section 911(g)(2) of the FD&C Act, specifically:

- It has been demonstrated that the magnitude of overall reductions in exposure to the HPHCs in the aerosol of *IQOS* products is maintained compared to cigarette smoke,
- *IQOS* products, when used as intended, expose consumers to significantly reduced levels of HPHCs compared to combustible cigarettes,
- It has been demonstrated that the consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products, and
- The renewal of the exposure modification order 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.