Module 1: General Information

1.2 General Information

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1. CONTACT INFORMATION

1.1. Applicant

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Email Address	(b) (6)
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1.2. U.S. Agent

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Position Title	CEO, U.S. Agent for PMP S.A.
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2. PRODUCT IDENTIFICATION

Manufacturer	Philip Morris Products S.A.
Product name, including the brand and subbrand if applicable	*IQOS* 3 System Holder and Charger
Product category	Cigarettes
Product subcategory	Non-Combusted
Product properties	Package Type: Box Product Quatity: 1 Holder, 1 Charger Length: 92.25 mm (Holder) Diameter: 14.40 mm (Holder) (smallest) 14.90 mm (Holder) (with pertruding button) Length: 114.80 mm (Charger) Width: 46.35 mm (Charger) Source of Energy: Electric (rechargeable battery) Additional properties: Thickness: 23.00 mm (Charger) Battery Capacity: > 110 mAh (Holder) Battery Capacity: > 2600 mAh (Charger)

3. APPLICATION

Type of PMTA	supplemental PMTA
Identifying information regarding prior submissions	PMTA Marketing Order of April 30, 2019 for *IQOS* System Holder and Charger (**STN: PM0000479**)
Prior communication and meetings with FDA	○ May 28, 2019, face-to-face meeting with FDA during which potential modifications and upgrades to the Authorized *IQOS* System Holder and Charger were discussed (**STN: TC0004997**) ○ October 11, 2019, Meeting Request to discuss the format, content and review process of a

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	streamlined PMTA for upgraded modified version of the *IQOS* System Holder and Charger o November 1, 2019, Amended Meeting Request to discuss the format, content and review process of a streamlined PMTA for upgraded modified version of the *IQOS* System Holder and Charger o December 18, 2019, FDA's written response to the Meeting Request for upgraded modified version of the *IQOS* System Holder and Charger (**STN: TC0005319**)
Request to refer the PMTA to TPSAC	PMP S.A. is not requesting that FDA refers the PMTA to the Tobacco Products Scientific Advisory Committee (TPSAC)
Address and Facility Establishment Identifier (FEI) of the establishment(s) involved in the manufacture of the new tobacco product	(b) (4) (part of the (b) (4) group of companies) Address: (b) (4) FEI number: (b) (4) (b) (4) (part of the (b) (4) group of companies) Address: (b) (4) FEI number: **not available**

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Philip Morris International (PMI[1]) is submitting this application under section 910(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requesting marketing authorization order under section 910(c)(1)(A)(i) for the *IQOS* 3 System Holder and Charger, which is a modified version of the *IQOS* System Holder and Charger, the marketing of which was authorized by a Marketing Order dated April 30, 2019 (PM0000479) (the "Authorized *IQOS* System"). As with the Authorized *IQOS* System, the modified version of the *IQOS* System Holder and Charger, also referred to as the *IQOS* 3 System, is intended for use with the currently authorized variants of Tobacco Sticks, *i.e.*, Marlboro *HeatSticks* (PM0000424), Marlboro Smooth Menthol *HeatSticks* (PM0000425), and Marlboro Fresh Menthol *HeatSticks* (PM0000426).

About Philip Morris International

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

Our most advanced product is the Tobacco Heating System (THS) commercialized under the brand name *IQOS* and used with tobacco *HeatSticks*. On April 30, 2019, the FDA issued a marketing order authorizing *IQOS* and *HeatSticks* for sale in the United States, after concluding that a marketing order was appropriate for the protection of the public health. PMI is marketing *IQOS* and *HeatSticks* in the U.S. in cooperation with Altria Group, Inc., and its subsidiary Philip Morris USA (PM USA).

Application Background

Since PMP S.A.'s original PMTAs were submitted in 2017, the *IQOS* System Holder and Charger commercialized outside the U.S. has continued to evolve. This evolution was informed by the learnings from actual adult *IQOS* users' feedback, consumer research among adult smokers and advances in electronic technology. These learnings and technological developments have been incorporated in the modified device, the *IQOS* 3 System, for which PMP S.A. is seeking a marketing authorization.

[1] We refer to Philip Morris International ("PMI") throughout this application. For clarity and ease of review, all of the following entities are included within the term "PMI": (1) Philip Morris International Inc., the general entity; (2) Philip Morris Products S.A., the PMTA applicant, manufacturer and the legal entity responsible for clinical trials and post marketing studies and surveillance, (3) Philip Morris International Management S.A. (PMPSA), the legal entity responsible for market research and management services, (4) Philip Morris International Research Laboratories Pte. Ltd. responsible for pre-clinical *in vivo* studies, and (5) Philip Morris Manufacturing & Technology Bologna S.p.A. responsible for the manufacture of Tobacco Sticks.

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The *IQOS* 3 System includes ergonomic and convenience features which bring improvements to the adult user experience for ease and convenience of use, while maintaining the same operating principles and performance ranges as the Authorized *IQOS* System. PMP S.A. has maintained the same process controls and quality assurance procedures as the ones applicable to the Authorized *IQOS* System.

The *IQOS* 3 System delivers reduced number and levels of HPHCs compared to combusted cigarettes and comparable to the ones delivered by the Authorized *IQOS* System. Furthermore, the overall patterns of use (e.g. daily *HeatSticks* use, total tobacco consumption) closely resemble those of the Authorized *IQOS* System as evidenced by data from countries where the *IQOS* 3 System is currently commercialized. Finally, the design of the *IQOS* 3 System does not contain any features that are expected to impact the low level of interest in trial and use among nonsmokers, former smokers and youth that was found with the Authorized *IQOS* System.

These modifications to the Authorized *IQOS* System have not changed the overall appropriateness of the product for the protection of the public health (APPH).

Supplemental PMTA (sPMTA) Pathway

On December 18, 2019, the FDA in its written response to PMP S.A.'s pre-submission meeting request related to the planned submission of a PMTA under section 910(b) of the FD&C Act for the *IQOS* 3 System[2], concluded that a sPMTA pathway would be appropriate for the *IQOS* 3 System submission.

With this application, PMP S.A. is seeking authorization to market a modified version of the Authorized *IQOS* System, the *IQOS* 3 System.

This application includes the necessary information to address the modificationsof the *IQOS* 3 System and the related modifications of the PMTA that was the source of the existing Marketing Order. Therefore, this application should be deemed as appropriate for review as a supplemental PMTA.

[2] FDA's written response of December 18, 2019 (STN: TC0005319) to the PMP S.A.'s October 11, 2019, meeting request related to the planned submission of a PMTA under section 910(b) of the FD&C Act for the *IQOS* 3 System.

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Structure of the Application

This supplemental application includes new information and data about the *IQOS* 3 System and cross-references to information and data from the original PMTA, for the Authorized *IQOS* System.

An overview of information and data supporting this supplemental PMTA is provided in Table 1 below. Previously provided information and data, which remains valid and applicable, is outlined in Module 2, Section 2.1 Table of Contents.

Table 1: Structure of the Supplemental PMTA for the *IQOS* 3 System

Module 1 General Information	Updated from PM0000479 Module content: - Cover Letter
Module 2 Table of Contents	Updated from PM0000479 Module content: - Table of Contents - Glossary - Executive Summary
Module 3 Product Description	Updated from PM0000479
3.1 Product Description	Updated from PM0000479 Module content: - Description of the Tobacco Product - Compliance to Product Standard - Product Naming - Similar Marketed Products or Prototypes - Restrictions on Sale, Distribution, Advertising or Promotion
3.2 Product Formulation	Updated from PM0000479
3.2.1 Components or parts, materials, ingredients, additives, and constituents	Updated from PM0000479 Module content: - Components or Parts - Materials - Constituents - Container Closure System

(table continues)

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3.2.2 Other Properties	Updated from PM0000479 Module content: - Product Dimensions and Construction - Design Parameters and Test Data - Function - Storage and Stability Information - Product and Packaging Design Risks and Misuse Hazards
3.2.3 Principles of Operation	Updated from PM0000479
3.2.4 Product Testing and Analysis Information	Updated from PM0000479
3.3 Manufacturing	Updated from PM0000479 Module content: - Manufacturers - Manufacturing Process - Standard Operating Procedures (SOPs)
Module 4 Labeling	Updated with package label for the *IQOS* 3 System
Module 5 Environmental Impact	Updated with Addendum to Environmental Impact Assessment (EIA) As part of the EIA submitted in the original PMTA, an addendum was prepared assessing whether the introduction of the *IQOS* 3 System would have an impact in the environment. The findings confirm that proposed upgrades and modification will result in a minimal change in environmental impact from the *IQOS* 3 System and that the assessment still provides a basis for a Finding of No Significant Impact (FONSI) due to *de minimis* exposure.
Module 6 Summary of all Research Findings	Provides a summary of emissions data specific to the *IQOS 3* System (with the Authorized *HeatSticks* and the reference *HeatSticks*), and demonstrates that the physico-chemical properties of the aerosol, in particular reductions in HPHCs levels compared to combustible cigarettes, are comparable to those reported for the Authorized *IQOS* System.Summary of data on the *IQOS* 3 System and *IQOS* 2.4/2.4+* Systems use from the *IQOS* Owner Panels conducted in Germany, Japan, Italy, South Korea and Switzerland. Otherwise cross-referenced to the original PMTA

(table continues)

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Module 7 Scientific Studies and Analyses	Updated with complete performance comparability testing reports for the Authorized *IQOS* System and the *IQOS* 3 System (including aerosol testing of PMI's list of 58 aerosol constituents). Data about the *IQOS* 3 System and *IQOS* 2.4/2.4+ Systems use from the *IQOS* Owner Panels conducted in Germany, Japan, Italy, South Korea and Switzerland. Otherwise cross-referenced to the original PMTA
Module 8 Post-Market Assessment	Cross-referenced to the original PMTA
Module 9 References	Updated with copies of publications referenced in the dossier and not previously submitted. Otherwise cross-referenced to the original PMTA
Module 10 Certification	Confirmation that the information and accompanying submission are true and correct, that no material fact has been omitted, that the signer is authorized to submit the information on the applicant's behalf, and that the signer understands that anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the Government of the U.S. is subject to criminal penalties under 18 U.S.C. 1001.

4. COMPLIANCE WITH REQUIREMENTS OF SECTION 910(B)(1) OF THE FD&C ACT

This supplemental PMTA satisfies the content requirements of section 910(b)(1) of the FD&C Act and provides the following information and documents:

(A) Reports concerning investigations which have been made to show the health risks of the *IQOS* 3 System and that it presents less risk than other tobacco products:

Module 3, Section 3.2.1.5 Constituents

Section 3.2.4 Product Testing and Analysis Information

Module 7, Section 7.1 Aerosol Characterization

Section 7.3 Human Studies

Module 8, Section 8.1 Periodic Reports

Section 8.2 Adverse Experience Reports

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(B) Statement of the components, parts and properties, and of the principles of operation, of the *IQOS* 3 System:

Module 3, Section 3.2.1.1 Components or Parts

Section 3.2.1.2 Materials

Section 3.2.3 Principles of Operation

(C) Description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing of the *IQOS* 3 System:

Module 3, Section 3.3.2 Manufacturing Process

Section 3.3.3 Standard Operating Procedures (SOPs)

(D) Identification of the manufacturing standard and relevant product standards applicable to the *IQOS* 3 System, and appropriate information to demonstrate compliance with those standards:

Module 3, Section 3.1.2 Compliance to Product Standards

(E) Samples of the tobacco product and of components thereof as the Secretary may require

Module 1, Section 1.4 Samples of New Tobaco Product

(F) Specimens of the labeling proposed to be used for the *IQOS* 3 System:

Specimens and labeling for the *IQOS* 3 System are provided as part of the submission.

(G) Other information relevant to the subject matter of the application:

Module 3, Section 3.1.4 Similar Marketed Products or Prototypes

5. DESCRIPTION OF HOW MARKETING OF THE *IQOS* 3 SYSTEM WOULD BE APPROPRIATE FOR THE PROTECTION OF THE PUBLIC HEALTH (APPH)

As an upgraded modified version of the Authorized *IQOS* System, the *IQOS* 3 System, operates with unchanged principles of aerosol generation and subsequently, when used with *HeatSticks*, generates an aerosol which is comparable with the aerosol generated by the Authorized *IQOS* System that was considered APPH.

The *IQOS* 3 System, when compared with the Authorized *IQOS* System is also APPH based on the:

1) similar effect that is expected on the health of the population as a whole, such as effects on tobacco use initiation, switching and cessation, and reductions in premature mortality, or increases in life-years lived,

2) comparable potential effects on health, including, but not limited to adverse experiences, tobacco use behavior, and tobacco use initiation,

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3) potential effect that the *IQOS* 3 System's marketing has or may have on overall tobacco-related morbidity and mortality, and

4) information regarding adverse experiences associated with use of or exposure to the product.

6. ENCLOSURES, LABELS AND LABELING

Complete list of all documents and appendices being submitted in this application is provided in Module 2.2 Index.

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