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Module 1: General Information

1.2 General Information

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1. CONTACT INFORMATION

1.1. Applicant

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1.2. U.S. Agent

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2. PRODUCT IDENTIFICATION

Manufacturer	Philip Morris Products S.A. (PMP S.A.)
Product name(s), 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 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) 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 Application	supplemental MRTPA
STNs / FDA identifying numbers	PMTA Marketing Order of December 7, 2020 for the *IQOS* 3 System Holder and Charger **(STN: PM0000634)**
Prior meetings with FDA	○ December 14, 2020, PMP S.A.'s Meeting Request concerning the approach to a modified risk tobacco

	product application (MRTPA) for the *IQOS* 3 System Holder and Charger ○ February 11, 2021, FDA's written response to the Meeting Request concerning the PMP S.A.'s proposed approach to the MRTPA for the *IQOS* 3 System Holder and Charger (**STN: TC0006573**)
Facility Establishment Identifier (FEI) and address of manufacturer	**(b) (4)**

PMP S.A. is submitting this application under section 911(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requesting a marketing authorization order under section 911(g)(2) (exposure modification order) for its *IQOS* 3 System Holder and Charger (further referred to as the *IQOS* 3 System), which on December 7, 2020 received marketing authorization order (PM0000634) under section 910(c) of the FD&C Act.

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 *Marlboro HeatSticks* are marketed in the United States under a license to Altria Client Services LLC (ALCS)[1] and an ALCS affiliate. The ALCS affiliate that distributes and sells the product in the U.S. is Philip Morris USA Inc. (PM USA)[2].

3.2. Application Background

The *IQOS* System commercialized outside the U.S. continues to evolve. This evolution is based on the learnings from consumer research among adult smokers and advances in electronic technology over the years. These learnings and technological developments have been incorporated in a modified device, the *IQOS* 3 System, for which PMP S.A. received the December 7, 2020 marketing order authorizing the sale and marketing of the product in the United States.

The *IQOS* 3 System, like the *IQOS* 2.4 System, delivers substantial reductions in the number and levels of Harmful and Potentially Harmful Constituents (HPHCs) compared to combustible cigarettes. As evidenced by data from countries where the *IQOS* 3 System is sold, the overall patterns of use (*e.g.*, daily *Marlboro HeatSticks* use, total tobacco consumption) of the *IQOS* 2.4 System and the *IQOS* 3 System are comparable. Finally, the design of the *IQOS* 3 System does not contain any features that are anticipated to alter the low level of interest in trial and use among nonsmokers, former smokers and young adults that was found with the *IQOS* 2.4 System.

The *IQOS* 3 System, similar to the *IQOS* 2.4 System, satisfies the requirements of section 911(g)(2), including the requirement that marketing of 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.

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[1] Altria Client Services LLC (ALCS) is a wholly owned subsidiary of Altria Group, Inc. ALCS provides certain services to the Altria family of companies.

[2] PMP S.A. has entered into an agreement with ALCS by which ALCS and its affiliates, including PM USA, are licensed to sell FDA authorized versions of *IQOS* in the United States.

This conclusion is based on the demonstrated comparability of the *IQOS* 3 System to the *IQOS* 2.4 System in performance, patterns of use, minimal use among non-users of tobacco products (including young adults) and successful switching of adult smokers to this modified-risk tobacco product[3]. As a result, the authorized exposure claims for the *IQOS* 2.4 System should equally apply to the *IQOS* 3 System.

3.3. Supplemental MRTPA (sMRTPA) Pathway

In FDA's February 11, 2021 written response to PMP S.A.'s pre-submission meeting request related to the planned submission of an MRTPA for the *IQOS* 3 System, the FDA stated that the sMRTPA pathway may be appropriate in certain circumstances that FDA described[4].

Applying those circumstances to the *IQOS* 3 System, the submission of sMRTPA is appropriate considering that:

- The *IQOS* 3 System already received a marketing order (PM0000634), under the PMTA pathway, authorizing marketing of the product in the U.S.;
- The *IQOS* 3 System represents a modified version of the tobacco product, the *IQOS* 2.4 System, that can be legally marketed and has a Modified Risk Granted Order (MRGO) – Exposure Modification;
- The implemented modifications do not render the original claims unsubstantiated for the *IQOS* 3 System;
- PMP S.A. does not submit significant new data for review in the sMRTPA for the *IQOS* 3 System (*i.e.*, studies that supported the original MRGO are the same and do not require reanalysis);
- There is no change to the modified risk statements or changes outside the scope of the authorized claims under the original MRTPA; and
- PMP S.A. is seeking an MRGO that reflects the order type that FDA issued under the original MRTPA (*i.e.*, MRTPA is seeking an order under § 911(g)(2)).

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[3] As confirmed in the Marketing Order Granted letter of December 7, 2020 (STN: PM0000634) and associated Technical Project Lead (TPL) Review of the PMTA.

[4] *See* February 11, 2021 letter from Stephanie Durkin to Adam Susser Re: (STN: TC00006573).

3.4. Structure of the Dossier

To facilitate review of the sMRTPA, PMP S.A. utilized cross-referencing to the original MRTPA and, where relevant, to the sPMTA for the *IQOS* 3 System. This application has been structured in the same manner as the MRTPA for the *IQOS* 2.4 System. Table 1 below provides an overview of PMP S.A.'s approach to providing the data and information.

Table 1: Structure of the sMRTPA for the *IQOS* 3 System

Module 1 General Information	Updated from MR0000479 and PM0000634 Module content: - Cover Letter - General information on the tobacco product - Letters of Authorization
Module 2 Table of Contents	Updated from MR0000479 and PM0000634 Module content: - Table of Contents - Index of Files - Glossary - Executive Summary
Module 3 3.1 Product Description 3.2 Product Formulation 3.3 Manufacturing	Cross-referenced to PM0000634
Module 4 Labeling and Advertising	Cross-referenced to PM0000634
Module 5 Environmental Impact	Cross-referenced to PM0000634
Module 6 Summary of all Research Findings	Cross-referenced to MR0000479 and PM0000634
Module 7 Scientific Studies and Analyses	Cross-referenced to MR0000479 and PM0000634

Module 8 Post-Market Assessment	Cross-referenced to MR0000479 and PM0000634
Module 9 References	Cross-referenced to MR0000479 and PM0000634

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

Scientific evidence and data referenced in this supplemental MRTPA for the *IQOS* 3 System, as for the *IQOS* 2.4 System, satisfies all of the criteria for issuance of an order under section 911(g)(2) of the FD&C Act, specifically:

- It has been demonstrated, as with the *IQOS* 2.4 System, that the magnitude of overall reductions in exposure to the HPHCs in the aerosol of the *IQOS* 3 System is substantial compared to cigarette smoke,
- The *IQOS* 3 System, like the *IQOS* 2.4 System, when used as intended, exposes consumers to significantly reduced levels of HPHCs compared to combustible cigarettes,
- The *IQOS* 3 System, like the *IQOS* 2.4 System, when used as intended by consumers, will not expose them to higher levels of other harmful substances compared to combustible cigarettes,
- As shown by cross-reference to the MRTPA for the *IQOS* 2.4 System, 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;
- Like for the *IQOS* 2.4 System, the issuance 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.

Given the comparability of the *IQOS* 3 System[5] to the *IQOS* 2.4 System which received the MRGO, the authorized exposure claims apply equally to the *IQOS* 3 System.

[5] As confirmed in the Marketing Order Granted letter of December 7, 2020 (STN: PM0000634) and associated Technical Project Lead (TPL) Review of PMTA.