PHILIP MORRIS
PRODUCTS S.A.

November 18, 2016

Center for Tobacco Products
Food and Drug Administration
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Modified Risk Tobacco Product Application for Tobacco Heating System (THS) - *IQOS* with *Marlboro Smooth Menthol HeatSticks*

Dear Sir or Madam,

Philip Morris Products S.A. (PMP S.A.) is submitting this application under Section 911(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requesting market orders under both § 911(g)(1) (risk modification order) and § 911(g)(2) (exposure modification order) for its Tobacco Heating System (THS). PMP S.A. is a subsidiary of Philip Morris International Inc.[1]

THS is composed of a Tobacco Heating Device (THD) and a Tobacco Stick that meets the definition of a "cigarette" under the FD&C Act. THS with a Tobacco Stick variant branded as ***Marlboro Smooth Menthol HeatSticks*** is the subject of this Application and referred to in the submission as "THS Menthol 1".

PMP S.A. is submitting this Application. Its parent company, Philip Morris International Management, S.A., has entered into a distribution agreement with Altria Client Services LLC (ALCS)[2] by which ALCS and an ALCS affiliate will be licensed to distribute and sell the product in the United States, upon issuance of a market order. The ALCS affiliate that will distribute and sell the product in the United States is Philip Morris USA Inc. (PM USA).

[1] For clarity and ease of review, we refer to Philip Morris International (PMI) throughout the attached application, a term within which all of the following entities are included: (1) Philip Morris International Inc., the general entity; (2) Philip Morris Products S.A., the MRTP applicant, the manufacturer and the legal entity responsible for clinical trials and post marketing studies and surveillance, (3) Philip Morris International Management S.A., 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.

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

The following information is provided in support of this Application:

Applicant:

Philip Morris Products S.A.
Quai Jeanrenaud 3
2000 Neuchâtel, Switzerland

D-U-N-S Number: 482163102

Authorized Contacts:

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Name of Manufacturer:

Philip Morris Products S.A.
Quai Jeanrenaud 3
2000 Neuchâtel, Switzerland

Product-identifying information:

Product name, including brand name	Tobacco Heating System (THS) *Marlboro Smooth Menthol HeatSticks* * *IQOS* **
Product category and subcategory	Cigarette, Non-combusted
Package type	Box
Package quantity	20 *HeatSticks* per box
Characterizing flavor	Menthol

* Referred to in the Application as: Tobacco Stick Menthol 1
** Referred to in the Application as: *iQOS* and Tobacco Heating Device (THD)

List of Previous Submissions on THS to FDA:

FDA Submission Tracking (STN)	Investigational Study	Date of Submission of Investigational Use Exemption	Date of Ingredient Listing Submission
IU0000015	ZRHM-PK-06-US	May 29, 2013	June 7, 2013
IU0000015	ZRHM-REXA-08-US	July 12, 2013	July 15, 2013
IU0000015	THS-PBA-07-US	May 8, 2015	April 30, 2015
IU0000145	ZRHR-ERS-09-US	May 26, 2014	August 28, 2014
IU0000145	ZRHR-ERS-09-EXT-US	May 5, 2015	-
IU0000145/ IU0000198	THS-PBA-07-US	May 8, 2015	April 30, 2015

Dates of Prior Meetings with FDA:

PMI and staff from FDA's Center for Tobacco Products met to discuss the assessment program and PMP S.A.'s plan to submit this Application on the following dates:

- May 16, 2012 TC0000299
- March 17, 2013 TC0000533
- September 5, 2013 TC0000737
- February 19, 2014 TC0000915
- November 18, 2015 TC0001414
- January 18, 2016 TC0001480
- July 19, 2016 TC0001574

Type of Order Sought:

PMP S.A. seeks a risk modification order under Section 911(g)(1) and an exposure modification order under Section 911(g)(2).

Trade Secrets or Confidential Commercial Information:

The submitted Application contains non-public, trade secret, and confidential, commercial information, which is protected by law from public disclosure. To facilitate FDA's publication of the disclosable portions of the Application, as required by Section 911(e) of the FD&C Act, PMP S.A. is submitting (1) a detailed, confidential appendix to this cover letter [1.4 Confidentiality Designation] designating the categories of information throughout all modules of the Application that we consider confidential and should be redacted from the publicly disclosed version of the Application; and (2) selected portions of the Application with transparent highlights of information that exemplifies what PMP S.A. considers confidential and/or that is particularly commercially sensitive for PMI.

We welcome the opportunity to discuss with FDA any questions about the categories of information designated as confidential in the document 1.4 Confidentiality Designation or any concerns about the proposed redactions. In the event that any information that has been identified or designated as confidential by PMI is considered non-confidential by FDA, we respectfully request that FDA provide predisclosure notice to PMP S.A. pursuant to the procedures set forth in 21 C.F.R. §201.61(d) and (e).

As detailed ingredient information is considered confidential, reference is made to Tobacco Product Master File (b) (4), submitted separately, containing information in support of this Application. The authorization letter granting FDA the right to access and rely on the Master File when reviewing this Application is provided in annex [1.5 TPMF Authorization Letter].

The Application is being submitted on electronic media, along with confirmation that the Application is virus-free.

PMP S.A. appreciates FDA's consideration of this Application and looks forward to working with the Agency to secure orders under Section 911(g) for the proposed modified risk tobacco product discussed herein.

Sincerely,

Bruce D. Clark, PhD
Vice President Regulatory and Scientific Affairs, Research & Development
Philip Morris International