



PHILIP MORRIS
PRODUCTS S.A.

September 8, 2017

Dr. Benjamin Apelberg, Ph.D.
Director, Division of Population Health Science
Office of Science
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via ESG

**Re: RESPONSE TO AUGUST 4, 2017 INFORMATION REQUEST for
MR0000059-MR0000061 and AMENDMENT to MR0000059-MR0000061**

Dear Dr. Apelberg,

In reference to our letter of August 31, 2017, we hereby submit the response to the FDA Advice/Information Request letter, dated August 4, 2017, relevant to our Modified Risk Tobacco Product Applications (MRTPAs) currently under substantive review:

<u>STN</u>	<u>Tobacco Product Name</u>
MR0000059	IQOS system with Marlboro Heatsticks
MR0000060	IQOS system with Marlboro Smooth Menthol Heatsticks
MR0000061	IQOS system with Marlboro Fresh Menthol Heatsticks

This complete response addresses the additional information and clarifications requested by the Agency. In addition to the documents and data provided herewith, as indicated in response to Question 13, documentation / data for studies and analyses completed post-submission have been sent to the Agency on physical electronic media today (DHL tracking number 9875942226). The delivery to FDA is expected to be beginning of next week.

In this response, we have also included amendments to the application reflecting post-submission changes pertaining to the products subject of the applications. The changes are described in [Appendix A](#) herewith.



PHILIP MORRIS
PRODUCTS S.A.

This response/amendment contains confidential commercial and/or trade secret information. Protection of this information from public disclosure is hereby claimed under the applicable provisions of United States law. We request the agency to provide pre-disclosure notification and follow the procedures in 21 C.F.R. §20.61(e) before publicly disclosing any information contained in this amendment.

We remain available for any further information that is required.

Sincerely,

Malgorzata Wronowska, PhD
Director Regulatory and Scientific Affairs
Philip Morris Products S.A.

Jeffrey Walker, M.D.
US Agent for PMP S.A.
CEO, Teton Regulatory Sciences

Enclosure: 02_Response-to-FDA_August-04-2017_AI-Request_MR0000059-61



PHILIP MORRIS
PRODUCTS S.A.

Appendix A

Since the submission of our MRTPAs end-2016, minor changes to THS2.2 have been made as part of continuous improvement, to address specific feedback received through our consumer complaints process, and to modify the supply chain according to the availability of materials. All changes have been made under the authorisation of our change control process.

These changes are summarized below, and have been documented in the following Module 3 appendices submitted in this response/amendment:

- [A3.2.1-21 \(v2\) Changes](#)
- [A3.2.2-2 \(v2\) Regular Tobacco Stick BOM](#)
- [A3.2.2-3 \(v2\) Menthol Tobacco Stick BOMs](#)
- [A3.2.3-2 \(v2\) Device BOMs](#)

The table below provides a grouped summary breakdown of the changes made:

Product	(b) (4)
Regular Tobacco Stick (CONS.02873.RD)	
Menthol 1 Tobacco Stick (CONS.02807.RD)	
Menthol 2 Tobacco Stick (CONS.02806.RD)	

ACP



PHILIP MORRIS
PRODUCTS S.A.

Product	Change Description	Rationale	Justification
Menthol 1 Tobacco Stick (CONS.02807.RD) Menthol 2 Tobacco Stick (CONS.02806.RD)	(b) (4)		
Dark Slate Holder (DV.000174)			
Matte White Holder (DV.000180)	Small i to big I, lightpipe design, middle part length	New logo printed on Front Housing (big I – marketing requirement) (b) (4) (b) (4) (b) (4) Middle part change of tolerance for total length of the part to minimize the gap between ring and front housing (aesthetic – design correction).	As the elements in this change are all aesthetic changes to improve design, (b) (4) (b) (4) (b) (4)

TOP



PHILIP MORRIS
PRODUCTS S.A.

Product	Change Description	Rationale	Justification
Dark Slate Holder (DV.000174) Matte White Holder (DV.000180)	(b) (4)		
	Supply Chain expansion	Additional vendors approved for electronic components (e.g. resistors and capacitors) to ensure a continuous and reliable supply for manufacturing.	No impact on product performance as all suppliers are provided specifications by PMI to which components must adhere. This ensures despite the supplier components are of the equivalent specification

TCP



PHILIP MORRIS
PRODUCTS S.A.

Product	Change Description	Rationale	Justification
Dark Slate Charger (DAC.000027) Matte White Charger (DAC.000028)	Technical drawing updates: e.g Lid engagement rib radius	Tolerance added to technical drawing, no change to the tolerance, just the addition of the number to the drawing.	Administrative changes to technical drawing, no impact on product performance
	New Design Latch small i to big I, (as for Holder) Certification markings added	(b) (4) (b) (4) (b) (4) (b) (4) New logo printed on Front Housing (big I – marketing requirement, as for Holder above)	(b) (4) Aesthetic changes to improve design and compliance for certification, no impact on performance
	Administrative changes	Harmonization and alignment of MPNs (Manufacturing Part Numbers) and codes to vendors to ensure full traceability.	These are administrative changes within the system for traceability purposes, therefore no impact on the product.
	Supply Chain Expansion	Additional vendors approved for electronic components (e.g. resistors and capacitors) to ensure a continuous and reliable supply for manufacturing.	No impact on product performance as all suppliers are provided specifications by PMP S.A. to which components must adhere. This ensures despite the supplier components are of the equivalent specification

We hereby certify that the above-mentioned changes did not result in any modification of product performance of the THS2.2 product.

Tony Pellaton
Director Product and Process QA & Compliance
September 4, 2017