



PHILIP MORRIS
PRODUCTS S.A.

January 25, 2017

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: Amendment to Modified Risk Tobacco Product Application for Tobacco Heating System (THS) - IQOS with *Marlboro HeatSticks* (MR0000059, MR0000060, MR0000061, MR0000062)

Dear Sir or Madam,

Philip Morris Products S.A. (PMP S.A.) is submitting this amendment to the Modified Risk Tobacco Product Applications (MRTPAs) for its Tobacco Heating System (THS), as per FDA's telephone request on 19th January 2017. The purpose of this amendment is to: (1) confirm that the Applicant is PMP S.A., (2) provide FDA with a complete list of the product configurations intended to be commercialized in the United States, (3) specify the precise modified risk claims that are being sought under § 911(g)(1) and § 911(g)(2) of the FSPTCA, and (4) provide clarification regarding the PMI "Important Warnings".

Product configurations

FDA has requested a list of configurations in which THS will be offered for sale in the U.S. PMP S.A. provides a list of such configurations in Attachment A. This list includes the items submitted for review in the MRTPAs, as well as other items that are planned to be available to consumers in the U.S.

This is a comprehensive list of all currently foreseen items that will be available for purchase by adult consumers in the U.S. In the event that some of these items will not be commercialized, PMP S.A. will notify FDA.

Modified Risk Claims

PMP S.A. would like to clarify that we are seeking authorization for two claims under §911(g)(1) risk modification order (Claims #1 and #2) and one claim under §911(g)(2) exposure modification order (Claim #3).

Claim #1:

- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system can reduce the risks of tobacco-related diseases.

Claim #2:

- Switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes.

Claim #3:

- Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.

For Claims #1 and #3, the following statements precede the claims to ensure that consumers are provided with scientifically accurate information that provides additional context for each claim.

- The IQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.

These claims and additional statements were subject of the perception and behavior assessment program included in PMP S.A.'s MRTPA.

Warnings

PMP S.A. would like to provide clarification regarding the PMI "Important Warnings" that accompany each modified risk claim. PMP S.A. understands that the statutorily mandated cigarette warnings ("Surgeon General Warnings") are applicable to the THS HeatStick products, given their classification as a cigarette. However, PMI developed a set of alternative warning statements which are scientifically accurate and designed to accompany the modified risk claim to enhance consumer understanding. Claims-based research was conducted which utilized both the Surgeon General Warnings and the PMI Important Warnings. Based on results provided in the Perception and Behavioral Research section of the application, we believe that the PMI "Important Warnings" are most appropriate and relevant for the THS product in conjunction with the modified risk claim. However, labeling materials with the Surgeon General Warnings have also been provided in the event that these statutorily-mandated warnings must be maintained.

PMP S.A. appreciates FDA's consideration of this MRTPA Amendment and is happy to entertain any questions or comments from the Agency following its receipt of this submission.

Sincerely,



Malgorzata Wronowska, PhD

Director Regulatory and Scientific Affairs, Research & Development
Philip Morris Products S.A.

APPENDIX A

Configurations	Notes
Kits	
<u>Kit A</u>	
Charger	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Holder (1)	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
A/C power adapter	
USB cable	
Cleaning brush	
Cleaning sticks	
<u>Kit B</u>	
Charger	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Holder (2)	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
A/C power adapter	
USB cable	
Cleaning brush	
Cleaning sticks	
<u>Kit C</u>	
Charger	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Holder (1)	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
<u>Kit D</u>	
Charger	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Holder (1)	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Marlboro Heatsticks	Pack of 20
<u>Kit E</u>	
Charger	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Holder (1)	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Marlboro Smooth Menthol Heatsticks	Pack of 20
<u>Kit F</u>	
Charger	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Holder (1)	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Marlboro Fresh Menthol Heatsticks	Pack of 20
Individual Items	
Charger	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Holder (1)	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Holder (2)	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
A/C power adapter	
USB cable	
Cleaning brush	

Cleaning sticks	
Marlboro Heatsticks	Pack of 20
Marlboro Heatsticks	Carton of 10 packs (200)
Marlboro Smooth Menthol Heatsticks	Pack of 20
Marlboro Smooth Menthol Heatsticks	Carton of 10 packs (200)
Marlboro Fresh Menthol Heatsticks	Pack of 20
Marlboro Fresh Menthol Heatsticks	Carton of 10 packs (200)
Desktop Disposal Unit	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Car Disposal Unit	Available in White, Slate, Red, Blue, Green, Gold, Silver, Gray
Clip-on Disposal Unit	Available in White and Slate
Pouch for charger	Available in White, Slate, Red, Blue, Orange, Pink, Green, Gold, Silver, Gray
Leather pouch for charger & Heatsticks pack	Available in White, Slate, Red, Blue, Orange, Pink, Green, Gold, Silver, Gray
Hard case for charger & Heatsticks pack	Available in White, Slate, Red, Blue, Orange, Pink, Green, Gold, Silver, Gray
Sleeve for charger	Available in White, Slate, Red, Blue, Orange, Pink, Green, Gold, Silver, Gray
Charging dock for 1 charger	
Charging dock for 2 chargers	
Charging dock for 4 chargers	
Holder replacement caps	Available in White, Slate, Black, Red, Ruby, Blue, Orange, Pink, Teal, Cyan, Green, Gold, Silver, Gray