



PMTA Coversheet: Environmental Science

SUBMISSION INFORMATION		
Applicant	Philip Morris Products S.A.	
Product Manufacturer	Philip Morris Products S.A.	
Submission Date	05-15-2017	FDA Receipt Date 05-15-2017
Primary STN(s)	PM0000424	Marlboro Heatsticks ¹
	PM0000425	Marlboro Smooth Menthol Heatsticks ¹
	PM0000426	Marlboro Fresh Menthol Heatsticks ¹
	PM0000479	IQOS System Holder and Charger ¹
Cross-referenced Submission(s)	Cross-referenced STN	Primary STN(s)
	MR0000059	APPLIES TO PM0000424-PM0000426, PM0000479
	MR0000060	
	MR0000061	
	MR0000133	
	MF0000013	
	MF0000243	
	MF0000264	

¹ May be sold individually or as co-packaged product.

Amendments			
Amendment STN	Primary STN	Description	FDA Receipt Date
PM0000440	PM0000424-426, PM0000479	Resubmitted label images	06-21-2017
PM0000443	PM0000424-426, PM0000479	Request for A/I Request letter response extension; confirmed battery samples	08-31-2017
PM0000457	PM0000424-426, PM0000479	Response to 11/22/17 A/I Request letter	12-26-2017
PM0000458	PM0000424-426, PM0000479	Response to 11/22/17 A/I Request letter	12-22-2017
PM0000461	PM0000424-426, PM0000479	Ongoing study data	12-08-2017
PM0000464	PM0000424-426, PM0000479	Response to 3/2/18 EA A/I Request letter	03-29-2018
PM0000466	PM0000424-426, PM0000479	P1 Characterization study update	04-26-2018
PM0000467	PM0000424-426, PM0000479	Response to 4/23/18 A/I Request letter	05-23-2018
PM0000468	PM0000424-426, PM0000479	Response to 6/6/18 teleconference questions	06-13-2018
PM0000475	PM0000424-426, PM0000479	Response to 7/18/18 teleconference questions	08-03-2018
PM0000476	PM0000424-426, PM0000479	Response to 8/20/18 A/I Request	09-05-2018
PM0000478	PM0000424-426, PM0000479	Corrected versions of two study reports	09-25-2018

NEW TOBACCO PRODUCT	
STN	PM0000424
Product Name	Marlboro Heatsticks ¹
Product Category	Cigarettes
Product Sub-Category	Non-Combusted
Package Type	Box
Package Quantity	20 Heatsticks
Characterizing Flavor	None
Length	45 mm
Diameter	7.42 mm
Ventilation	Not Applicable ²
Source of Energy	Electric (rechargeable battery) ³
STN	PM0000425
Product Name	Marlboro Smooth Menthol Heatsticks ¹
Product Category	Cigarettes
Product Sub-Category	Non-Combusted
Package Type	Box
Package Quantity	20 Heatsticks
Characterizing Flavor	Menthol
Length	45 mm
Diameter	7.42 mm
Ventilation	Not Applicable ²
Source of Energy	Electric (rechargeable battery) ³
STN	PM0000426
Product Name	Marlboro Fresh Menthol Heatsticks ¹
Product Category	Cigarettes
Product Sub-Category	Non-Combusted
Package Type	Box
Package Quantity	20 Heatsticks
Characterizing Flavor	Menthol
Length	45 mm
Diameter	7.42 mm
Ventilation	Not Applicable ²
Source of Energy	Electric (rechargeable battery) ³
STN	PM0000479
Product Name	IQOS System Holder and Charger ¹
Product Category	Cigarettes
Product Sub-Category	Non-Combusted
Package Type	Box
Package Quantity	1 Holder, 1 Charger

² For this product neither filter efficiency or ventilation are used to control aerosol deliveries.

³ The components and assemblies control the delivery of energy. The critical items include the Heater Printed Circuit Board Assembly (PCBA) including the heating blade and the battery.

Characterizing Flavor	None
Length	93.60 mm (Holder)
Diameter	15.04 mm (Holder)
Length	112.50 mm (Charger)
Width	51.20 mm (Charger)
Ventilation	Not Applicable ²
Source of Energy	Electric (rechargeable battery) ³
Additional Properties	Depth: 21.86 mm (Charger)
	Battery Capacity: (b) (4) (Holder)
	Wattage: (b) (4) (Charger) ⁴
	Battery Capacity: (b) (4) (Charger)

⁴ Wattage provided for the charger battery

FINDING OF NO SIGNIFICANT IMPACT

Product Marketing Orders for Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks, Marlboro Fresh Menthol Heatsticks, and IQOS System Holder and Charger

Manufactured by Philip Morris Products S.A.

The Center for Tobacco Products of the Food and Drug Administration (FDA) has carefully considered the potential environmental impact of these actions and has concluded that these actions will not have a significant effect on the quality of the human environment. Therefore, environmental impact statements are not required.

Philip Morris Products S.A. wishes to introduce four heated tobacco products into interstate commerce for commercial distribution in the United States and submitted to FDA premarket tobacco product applications to obtain marketing orders under the provisions of sections 910 of the Federal Food, Drug, and Cosmetic Act.

FDA prepared the programmatic environmental assessment (PEA), dated March 15, 2019, in accordance with the Council on Environmental Quality's regulations (40 CFR 1500 - 1508) implementing the National Environmental Policy Act (NEPA) and FDA's NEPA regulations (21 CFR 25.40). The PEA concluded that the marketing orders would have no significant impact and is available to the public upon request.

The PEA evaluates potential environmental effects due to manufacturing, use, and disposal of the new products. No increased or new types of environmental impacts due to manufacturing are anticipated. FDA does not foresee use of the new products to result in new or different environmental impacts. FDA believes that the disposal of the new products is the same as the disposal conditions of similar packaging waste, small consumer electronics, and currently marketed cigarette products. Therefore, FDA does not foresee significant adverse impacts to the environment due to the proposed actions from manufacturing, use, and disposal of the new products.

Digitally signed by Kimberly A. Benson -S
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Approved by

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