

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
Tobacco Products Scientific Advisory Committee (TPSAC)
FDA White Oak Conference Center
Building 31, Room 1503, 10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 24-25, 2018

On January 24-25, 2018, the Committee will discuss modified risk tobacco product applications (MRTPAs), submitted by Philip Morris Products S.A. for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks.

January 24, 2018

8:30 a.m.	Call to Order	Philip P. Huang, MD, MPH Chair, TPSAC
8:35 a.m.	Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
8:40 a.m.	Introduction of Committee Members	Philip P. Huang, MD, MPH Chair, TPSAC
8:45 a.m.	Opening Remarks	Mitchell Zeller, JD Director FDA/CTP
9:00 a.m.	Introduction to the Meeting Topics: PMP S.A. Modified Risk Tobacco Product Applications	Benjamin Apelberg, PhD Director, Population Health Science Office of Science, FDA/CTP
9:15 a.m.	Break	
9:30 a.m.	<u><i>Philip Morris Products S.A., Presentations:</i></u>	
	IQOS System and Heating Technology	Moira Gilchrist, PhD VP Scientific & Public Communications Philip Morris International
	Reduced Risk and Harm - Scientific Assessment of IQOS	Manuel Peitsch, PhD Chief Scientific Officer Philip Morris International
	Population Health Benefit - Perception and Behavior	Antonio Ramazzotti VP Human Insights and Behavioral Research Philip Morris International
	U.S. Commercialization and Controls	Sarah Knakmuhs VP Heated Tobacco Products Philip Morris USA
	Population Modeling and Conclusion	Moira Gilchrist, PhD VP Scientific & Public Communications Philip Morris International

11:30 a.m. **Lunch**

12:30 p.m. FDA Presentations:

Evidence Related to the Health Risk of *IQOS*
Use: Evaluation of Product Chemistry

Karina Zuck, PhD
Chemist
Office of Science, FDA/CTP

Evidence Related to the Health Risk of *IQOS*
Use: Evaluation of Nonclinical Studies

Mayo J. Wright, PhD
Toxicologist
Office of Science, FDA/CTP

Evidence Related to the Health Risks of *IQOS*
Use: Evaluation of Human Studies

Karen Konkel, MD
Medical Officer
Office of Science, FDA/CTP

Evidence Related to the Impact on Tobacco
Users: Evaluation of Clinical and Behavioral
Pharmacological Studies

Olga Rass, PhD & Elena Mishina, PhD
Pharmacologists
Office of Science, FDA/CTP

Evidence Related to the Impact on Tobacco
Users: Evaluation of Epidemiological Studies

Gabriella Anic, PhD
Epidemiologist
Office of Science, FDA/CTP

Evidence Related to the Impact on Tobacco
Users and Non-Users: Evaluation of Studies
Related to Proposed Labels, Labeling, and
Advertising (LLA)

Alexander Persoskie, PhD
Social Scientist
Office of Science, FDA/CTP

2:30 p.m. **Break**

2:45 p.m. Committee Discussion

5:00 p.m. Adjourn

January 25, 2018

8:00 a.m. Call to Order

Philip P. Huang, MD, MPH
Chair, TPSAC

8:05 a.m. Conflict of Interest Statement

Caryn Cohen, MS
Designated Federal Official
Office of Science, FDA/CTP

8:10 a.m. Introduction of Committee Members

Philip P. Huang, MD, MPH
Chair, TPSAC

8:15 a.m. Open Public Hearing Session

9:45 a.m. **Break**

10:00 a.m. Committee Discussion

12:00 p.m. **Lunch**

1:00 p.m. Committee Discussion (*continued*)

3:00 p.m. Adjourn