FOOD AND DRUG ADMINISTRATION (FDA)
Center for Tobacco Products (CTP)
Tobacco Products Scientific Advisory Committee (TPSAC)
Tommy Douglas Conference Center
10000 New Hampshire Avenue
Silver Spring, Maryland 20903

April 6, 2017

Under section 910(b)(2) (21 U.S.C. 387j(b)(2)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA may refer applications for premarket review of new tobacco products (PMTA) to the Tobacco Products Scientific Advisory Committee (Committee). The FD&C Act also provides for mandatory referral of modified risk tobacco product applications (MRTPA) to the Committee under section 911(f)(1). 21 U.S.C. 387k (f)(1). On April 6, 2017, FDA will present information to the Committee on the processes used in review of tobacco product applications, including premarket tobacco, substantial equivalence, and modified risk tobacco product applications. Topics will include the statutory standards applicable to the different types of applications, the scientific basis for review decisions, with a focus on PMTA and MRTPA, and the role of the Committee in the review process.

April 6, 2017

8:30	Call to Order	Philip P. Huang, MD, MPH Chair, TPSAC
	Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
	Introduction of Committee Members	Philip P. Huang, MD, MPH Chair, TPSAC
	Welcome and Introduction	David Ashley, PhD RADM (Ret.), U.S. Public Health Service Senior Advisor Office of the Director, FDA/CTP
9:00	Overview of Product Review Pathways	Matthew R. Holman, PhD Director Office of Science, FDA/CTP
9:30	The Substantial Equivalence Pathway: An Overview	Atasi Poddar, PhD Senior Regulatory Health Project Manager Office of Science, FDA/CTP
10:00	Break	
10:15	PMTA and MRPTA Review Process	Stephanie L. Redus, MS Senior Regulatory Health Project Manager Office of Science, FDA/CTP
11:00	Open Public Hearing	

12:00	Lunch	
1:00	Scientific Basis for Swedish Match NA Premarket Tobacco Product Authorization	Ii-Lun Chen, MD Director, Division of Individual Health Science Office of Science, FDA/CTP
1:45	Modified Risk Tobacco Product Marketing Decisions	Benjamin Apelberg, PhD Director, Division of Population Health Science Office of Science, FDA/CTP
2:30	Break	
2:45	Questions to the Committee	
3:00	Committee Discussion	
4:30	Adjourn	