Modified risk tobacco products (MRTPs) are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Before an MRTP can be introduced or delivered for introduction into interstate commerce, an order from FDA under section 911(g) (21 U.S.C. 387k(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) must be in effect with respect to the tobacco product. 21 U.S.C. 387k(a).

In reviewing modified risk tobacco product applications, among other things, FDA must evaluate the effects of a proposed product on the health of individual tobacco users and the population as a whole, taking into account (1) the relative health risks to individuals of the MRTP; (2) the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the MRTP; (3) the increased or decreased likelihood that persons who do not use tobacco products will start using the MRTP; (4) the risks and benefits to persons from the use of the MRTP compared to the use of smoking cessation drug or device products approved by FDA to treat nicotine dependence; and (5) comments, data and information submitted to FDA by interested persons. 21 U.S.C. 387k(g)(4).

On August 16, 2013, the Committee will discuss possible approaches for evaluating information on the risks and potential benefits of a proposed modified risk tobacco product to the population as a whole.

8:30 Call to Order Jonathan Samet, M.D., M.S.
Chair, TPSAC

8:35 Conflict of Interest Statement Caryn Cohen, M.S.
Designated Federal Official, FDA/CTP

8:40 Introduction of Committee Members

8:45 Welcome and Introduction Conrad Choiniere, Ph.D.
Director, Division of Population Health Sciences
Office of Science, FDA/CTP

9:00 Presentations:

Human Health Risk Assessment at EPA Rita Schoeny, Ph.D.
Senior Science Advisor
Environmental Protection Agency

Recommendations for Optimizing Studies for Risk Assessment and Regulatory Use David G. Hattan, Ph.D.
Senior Toxicologist
Center for Food Safety and Applied Nutrition

10:00 Break
10:00  **Presentations (continued):**

Review of New Drug Applications  
Christina Chang, M.D., M.P.H.  
Clinical Team Leader  
Division of Bone, Reproductive and Urologic Products  
Center for Drug Evaluation and Research

MRTPs: From Research to Claims  
Peter G. Shields, M.D.  
Deputy Director, Comprehensive Cancer Center  
Professor, College of Medicine  
The Ohio State University Medical Center

11:00  Open Public Hearing

12:00  Lunch

1:00  Evaluation of Modified Risk Tobacco Products: Questions for the Committee  
Carolyn Dresler, M.D., M.P.A.  
Associate Director for Medical and Health Sciences  
Office of Science, FDA/CTP

Committee Discussion

3:00  Adjourn