FOOD AND DRUG ADMINISTRATION
Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC)

Gaithersburg Marriott Washingtonian Center
9751 Washingtonian Boulevard, Rockville, MD 20878

July 15-16, 2010

AGENDA

July 15, 2010

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

8:35 Conflict of Interest Statement
Cristi Stark, M.S.
Acting Designated Federal Official
FDA

8:40 Introduction of Committee Members

8:50 FDA Update on Upcoming Items and
Other Committee Requests for Information
on Menthol Cigarettes
Corinne Husten, M.D., M.P.H.
CTP

9:00 Clarifying Questions

9:15 Industry Presentations – Characterization of Menthol

James E. Dillard III
Senior Vice President- Regulatory Affairs
Altria Client Services (on behalf of Philip Morris USA)

Jane Y. Lewis, Ph.D.
Senior Vice President- Health and Analytical Sciences
Altria Client Services (on behalf of Philip Morris USA)

Michael W. Ogden, Ph.D.
Senior Director- Regulatory Oversight
R.J. Reynolds Tobacco Company

William R. True, Ph.D.
Senior Vice President- Research & Development
Lorillard Tobacco Company

10:15 Break

10:30 Clarifying Questions

11:00 Industry Presentations – Clinical Effects of Menthol
Jane Y. Lewis, Ph.D.  
Senior Vice President- Health and Analytical Sciences  
Altria Client Services (on behalf of Philip Morris USA)

Michael W. Ogden, Ph.D.  
Senior Director- Regulatory Oversight  
R.J. Reynolds Tobacco Company

William R. True, Ph.D.  
Senior Vice President- Research & Development  
Lorillard Tobacco Company

12:00 Lunch

1:00 Clarifying Questions

1:30 Industry Presentations – **Biomarkers of Disease Risk**

Michael W. Ogden, Ph.D.  
Senior Director- Regulatory Oversight  
R.J. Reynolds Tobacco Company

Mohamadi A. Sarkar, Ph.D.  
Senior Principal Scientist- Health Sciences  
Altria Client Services (on behalf of Philip Morris USA)

William R. True, Ph.D.  
Senior Vice President- Research & Development  
Lorillard Tobacco Company

2:30 Break

2:45 Clarifying Questions

3:15 Industry Presentations – **Marketing Data**

Pascal A. Fernandez  
Vice President- Market Information & Consumer Research  
Altria Client Services (on behalf of Philip Morris USA)

Monica J. Graves  
Director- Marketing Operations  
Regulatory Oversight  
R.J. Reynolds Tobacco Company

Leonard H. Jones  
Director- Direct Marketing & Marketing Research  
Lorillard Tobacco Company

4:15 Clarifying Questions

5:00 Adjourn

**July 16, 2010**
8:00  Call to Order  
Jonathan Samet, M.D.  
Chair, TPSAC

8:05  Conflict of Interest Statement  
Cristi Stark, M.S.  
Acting Designated Federal Official  
FDA

8:15  Overview and Welcome  
Dr. Joshua Sharfstein, Principal Deputy Commissioner, FDA

8:25  Industry Presentations – *Population Effects*

Geoffrey M. Curtin, Ph.D.  
Director- Regulatory Science Development/Engagement  
Regulatory Oversight  
R.J. Reynolds Tobacco Company

Jennifer L. Hunter  
Vice President- Corporate Affairs  
Altria Client Services (on behalf of Philip Morris USA)

William R. True, Ph.D.  
Senior Vice President- Research & Development  
Lorillard Tobacco Company

9:25  Clarifying Questions

9:55  Break

10:10  **Open Public Hearing**

11:10  Committee Discussion

12:00  Lunch

1:00  Committee Discussion

2:30  Break

2:45  Committee Discussion

3:20  Closing remarks  
David L. Ashley, Ph.D.  
CTP

3:30  Adjourn