

**FOOD AND DRUG ADMINISTRATION**  
Center for Tobacco Products (CTP)

**Tobacco Products Scientific Advisory Committee (TPSAC)**

Center for Tobacco Products  
9200 Corporate Blvd.  
Rockville, MD 20850

**October 7, 2010**

These summary minutes for October 7, 2010 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on \_\_June 20, 2011\_\_\_\_.

I certify that I attended the October 7, 2010 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

\_\_\_\_\_/s/\_\_\_\_\_  
Karen M. Templeton-Somers, Ph.D.  
Acting Designated Federal Official

\_\_\_\_\_/s/\_\_\_\_\_  
Jonathan Samet, M.D., M.S.  
Chair, Menthol Report Subcommittee  
Tobacco Products Scientific Advisory Committee

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on October 7, 2010 at the Center for Tobacco Products, 9200 Corporate Boulevard, Rockville, Maryland. The meeting was called to order by Jonathan Samet, M.D., M.S. (Chair); the conflict of interest statement was read into the record by Karen M. Templeton-Somers, Ph.D. (Acting Designated Federal Official). There were approximately 50 persons in attendance. There were three speakers for the Open Public Hearing session.

**Proposed Agenda:** On October 7, 2010, the Committee received and discussed presentations on the publicly available industry documents as they relate to the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities

**Attendance:**

**Tobacco Products Scientific Advisory Committee Members Present:**

Jonathan Samet, M.D., M.S. (Chair)

Neal Benowitz, M.D.

Mark Clanton, M.D., M.P.H.

Gregory Connolly, D.M.D., M.P.H.

Karen DeLeeuw, M.S.W. (State/Local Government)

Dorothy Hatsukami, Ph.D.

Patricia Nez-Henderson, M.P.H., M.D. (Public Representative)

**Industry Representative Members Present:**

Luby Arnold Hamm (Tobacco Growers Representative)

Daniel Heck, Ph.D, D.A.B.T. (Tobacco Manufacturing Industry Representative)

John Lauterbach, Ph.D., D.A.B.T. (Small Business Tobacco Manufacturing Industry Representative)

**Ex Officio Members Present (Non-Voting):**

Ursula Bauer, Ph.D., M.P.H. (CDC)

Cathy Backinger, Ph.D., M.P.H. (NIH)

Susan Karol, M.D. (IHS)

**FDA Participants (Non-Voting):**

David Ashley, Ph.D.

Lawrence Deyton, M.S.P.H., M.D.

Corinne Husten, M.D., M.P.H.

**Designated Federal Official (Acting):** Karen M. Templeton-Somers, Ph.D.

**The Agenda proceeded as follows:**

Call to Order	Jonathan Samet, M.D. Chair, TPSAC
Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Acting Designated Federal Official FDA
Introduction of Committee Members	
FDA presentation: Status of TPSAC Information Requests	Corinne Husten, M.D., M.P.H. CTP  Allison C. Hoffman, Ph.D. CTP
Update on Menthol Report Subcommittee: Standards of Evidence	Jonathan Samet, M.D. Chair, TPSAC
Legacy Documents Presentations	Stacey J. Anderson, Ph.D. University of California, San Francisco  Valerie B. Yerger, N.D. University of California, San Francisco
Open Public Hearing	
William True – Lorillard Tobacco Company James Dillard – Altria	

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*The Committee received and discussed presentations on the publicly available industry documents from the Legacy database, and considered them as they relate to the issue of the impact of the use of menthol in cigarettes on the public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities.*

*This meeting also served as an introduction to the process of preparing the required report on the effects of menthol in cigarettes on the public health. The Committee reviewed the plans for the chapters of the menthol report, and the questions that should be addressed in the report. They also discussed their approach to gathering and reviewing evidence, and the system by which they planned to classify the evidence. Instructions were provided to allow the public to submit journal articles for consideration by the writing groups.*

The meeting adjourned at 4:47 p.m. on October 7, 2010.

**Please see the *verbatim* transcript for details of the discussion.**