FOOD AND DRUG ADMINISTRATION  
Center for Tobacco Products (CTP) 

Menthol Report Subcommittee  
of the  
Tobacco Products Scientific Advisory Committee (TPSAC)  

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

September 27, 2010  

These summary minutes for September 27, 2010 meeting of the Menthol Report Subcommittee 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 September 27, 2010 meeting of the Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.  

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

Jonathan Samet, M.D., M.S.  
Chair, Menthol Report Subcommittee  
Tobacco Products Scientific Advisory Committee
The Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on September 27, 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 60 persons in attendance. There were two speakers for the Open Public Hearing session.

**Proposed Agenda:** On September 27, 2010, the subcommittee will receive a presentation and discuss the timelines and structure of the Tobacco Products Scientific Advisory Committee’s required report to the Secretary of Health and Human Services regarding the impact of use of menthol in cigarettes on the public health.

**Attendance:** (* - participation by webcast/telecom)

**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)

**FDA Participants (Non-Voting):**
Glen D. Jones, Ph.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/CTP

Introduction of Committee Members

Charge to the Committee
Corinne Husten, M.D., M.P.H.
FDA/CTP

Menthol Report Writing Process
Karen M. Templeton-Somers, Ph.D.
FDA/CTP
Considerations with Regard to the Menthol Report          Jonathan Samet, M.D., Chair, TPSAC

Open Public Hearing

William R. True - Lorillard Tobacco Company

Jim Tozzi - Committee for Regulatory Effectiveness

Committee Discussion, Establishment of Timelines, and Writing Assignments

Closing Remarks                  Glen D. Jones, Ph.D.
                                   FDA/CTP

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This meeting mainly concerned the logistics of writing the Menthol Report, the structure of the Report and the timelines needed to complete the Report by the March 23, 2011 deadline.

The Subcommittee discussed the questions to be answered in the report regarding the effect of menthol cigarettes on individual smokers, and at the population level. The Chapters of the report were defined and Subcommittee Members assigned to each chapter.

For each chapter, the scientific evidence should be evaluated to determine:
  • The extent of the evidence available;
  • The strengths and limitations of the evidence;
  • Key gaps and uncertainties in the evidence;
  • The generalizability of study findings.

Questions to be addressed in the final report:

1. What is the impact of menthol cigarettes on public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities?

2. What recommendations, if any, does TPSAC have for FDA regarding menthol cigarettes?

The meeting adjourned at 12:00 on September 27, 2010.

Please see the verbatim transcript for details of the discussion.