February 11, 2011

These summary minutes for February 11, 2011 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 February 11, 2011 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.

/s/ Caryn Cohen, M.S.  
Designated Federal Official, TPSAC

/s/ Jonathan Samet, M.D., M.S.  
Committee Chair, TPSAC
Meeting of the Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee

February 11, 2011

The Menthol Report Subcommittee of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on February 11, 2011 at the Center for Tobacco Products, 9200 Corporate Blvd., Rockville, Maryland, 20850. Prior to the meeting, committee members and invited guests were provided copies of the background material from the FDA and the submissions from the public. The meeting was called to order by Jonathan Samet, M.D., M.S. (Committee Chair); the conflict of interest statement was read into the record by Caryn Cohen, M.S. (Designated Federal Official). There were approximately 100 persons in attendance. There were 7 speakers for the Open Public Hearing session.

**Agenda:** On February 11, 2011, the subcommittee received presentations and discussed 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:***

**Tobacco Products Scientific Advisory Committee (Voting):**
Jonathan Samet, M.D., M.S. (Committee Chair)
Neal Benowitz, M.D.
Mark Clanton, 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)
Melanie Wakefield, Ph.D. (*participating by telecom*)

**Industry Representative Members Present (Non-voting):**
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):**
David Ashley, Ph.D.
Lawrence Deyton, M.S.P.H., M.D.
Corinne Husten, M.D., M.P.H.

**Designated Federal Official:**
Caryn Cohen, M.S.
The agenda was as follows:

Call to Order
Jonathan Samet, M.D.
Chair, TPSAC

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

Introduction of Committee Members

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

Writing Group Presentations
Menthol Report, Chapter Presentations – Chapters 1-4:

Chapter 3 – Physiological Effects
Chapter 4 – Patterns of Smoking
Chapter 5 – Initiation, Cessation, & Marketing

Break

Menthol Report, Chapter Presentations – Chapters 5-7:

Chapter 6 – Risk Factors
Chapter 7 – Public Health Impact

Industry Perspective

Open Public Hearing

Committee Discussion

Adjourn

The session adjourned @ approximately 11:30 a.m.

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This meeting of the Menthol Report Subcommittee provided an opportunity for the writers of chapters 3 through 7 to present updates on the progress of their chapters (having discussed chapters 1 and 2 on the previous day). Each presenter provided information on the content of the chapters, the projected progress, and additional information required for completion. The entire Subcommittee provided feedback to the Writing Group members.

The session adjourned @ approximately 11:30 a.m.

Please see the verbatim transcript for details of the discussion.