These summary minutes for November 18, 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 November 18, 2010 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

_____/s/_____________    ________/s/_____________
Caryn Cohen, M.S.     Jonathan Samet, M.D., M.S.
Designated Federal Official, TPSAC   Committee Chair, TPSAC
The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on November 18, 2010 at the FDA White Oak Conference Center, Building 31, Room 1503, 10903 New Hampshire Ave., Building 31, Silver Spring, MD 20993-0002. 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 November 18, 2010, the Committee 1) received an update on the Menthol Report Subcommittee; and 2) received and discussed presentations regarding the data requested by the Committee at the March 30–31, 2010 meeting of the Tobacco Products Scientific Advisory Committee.

Attendance: (* - participation by webcast/telecom)

Tobacco Products Scientific Advisory Committee Members Present via Tele-Conference (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) *
Gregory Connolly, D.M.D., M.P.H *
Jack Henningfield, Ph.D. *
Melanie Wakefield, Ph.D. *

Industry Representative Members Present via Tele-Conference (Non-voting):
Luby Arnold Hamm (Tobacco Growers Representative) *
J. 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 via Tele-Conference (Non-Voting):
Timothy McAfee, M.D., M.P.H. (CDC) *
Cathy Backinger, Ph.D., M.P.H. (NIH) *
H. Westley Clark, M.D., J.D., M.P.H. (SAMHSA) *

Guest Speakers (Non-Voting) :
Brett Loomis (via Tele-Conference)
James Hersey, Ph.D. (Present)

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:

November 18, 2010

Call to Order and Introductions
Jonathan Samet, M.D., M.S.
Committee Chair
Tobacco Products Scientific Advisory Committee

Conflict of Interest Statement
Caryn Cohen, M.S.
Designated Federal Official
Tobacco Products Scientific Advisory Committee

FDA Presentation
Status of TPSAC Information
Corinne Husten, M.D., M.P.H.
Requests
Senior Medical Advisor, CTP, FDA

Questions to the Presenter

Chair Presentation
Jonathan Samet, M.D., M.S.
Update on Menthol Report
Committee Chair
Subcommittee
Tobacco Products Scientific Advisory Committee

Questions to the Presenter

Guest Speaker Presentation
James C. Hersey, Ph.D.
Secondary Analysis of the Effects
of Smoking Menthol Cigarettes
RTI International

Questions to the Presenter

Guest Speaker Presentation
Brett JR. Loomis
Trends in Menthol Cigarette Sales,
Price, and Promotion in the
United States
RTI International

Questions to the Presenter

Open Public Hearing
Jonathan Winickoff, M.D., M.P.H. - American Academy of Pediatrics
Frederick Flyer - Compass Lexecon
Gilbert Ross, M.D. - American Council on Science and Health
Bruce Levinson - Center for Regulatory Effectiveness
Lyle Beckwith - National Association of Convenience Stores
At this meeting the Committee continued to discuss the plans for writing the Menthol Report. The specific questions to be addressed by the Writing Groups were presented by the TPSAC Chair along with the general process for the Report; i.e., evidence-based decision making:

- Systematic reviews
- Evidence synthesis approaches
- Causal inference and classification of strength of evidence

The Committee discussed basing possible future recommendations gleaned from the evidence review around the concept of equipoise:

- The evidence is sufficient to conclude that a relationship is more likely than not.
- The evidence is sufficient to conclude that a relationship is at least as likely as not.
- The evidence is insufficient to conclude that a relationship is more likely than not.
- There is insufficient evidence to make a determination of strength of evidence.

Dr. James Hersey presented interim analysis based on his ongoing secondary analysis of the effects of smoking menthol cigarettes. Brett Loomis gave a presentation on trends in menthol cigarette sales, price, and promotion in the United States.

The session adjourned @ approximately 5:19 p.m.

Questions to the committee:

1. Are the questions proposed by the Chapters 1 and 2 writing workgroups the scientific questions that should be addressed in the report?

2. Does the Committee agree with the proposed approach for evaluating the scientific evidence?

Please see the verbatim transcript for details of the discussion.