These summary minutes for March 2, 2011 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 March 2, 2011 meeting 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 Tobacco Products Scientific Advisory Committee
March 2, 2011

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on March 2, 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 4 speakers for the Open Public Hearing session.

**Agenda:** On March 2, 2011, the Committee continued to 1) receive updates from 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 Advisory Committee.

**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. (via Tele-conference)
Karen DeLeeuw, M.S.W. (State/Local Government)
Dorothy Hatsukami, Ph.D.
Patricia Nez Henderson, M.P.H., M.D. (Public Representative)
Jack Henningfield, Ph.D.
Melanie Wakefield, Ph.D.

**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)

**Ex Officio Members Present (Non-Voting):**
Cathy Backinger, Ph.D., M.P.H. (NIH)
Timothy McAfee, M.D., M.P.H.

**Guest Speakers (Non-Voting):**
David Mendez, Ph.D.
Eric Johnson, Ph.D (via Tele-conference)
James Hersey, Ph.D.
Brian D. Thomas, Ph.D.

**FDA Participants (Non-Voting):**
David Ashley, Ph.D.
Lawrence Deyton, M.S.P.H., M.D.
Corinne Husten, M.D., M.P.H. (via Tele-conference)

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

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

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

Introduction of Committee Members

FDA presentation: Menthol Report
David L. Ashley, Ph.D.
FDA/CTP

Building a Population Dynamics Model of the
Consequences of Menthol Cigarettes for Smoking
Prevalence and Disease Risks
David Mendez, Ph.D.
Associate Professor
Department of Health
Management & Policy
University of Michigan
School of Public Health

Lunch

Presentation:
Rates of Users Switching to and from
Menthol and Non-menthol Cigarettes:
Answers to Follow-up Questions
Eric O. Johnson, Ph.D.
RTI International

Discussion:
Discussion of Draft Chapter 3
Neal Benowitz, M.D.

Discussion of Draft Chapter 6
Jonathan Samet, M.D., M.S.

Open Public Hearing
David T. Levy, Ph.D. - Pacific Institute for Research and Evaluation/Legacy
Dr. Jane Lewis - Altria Client Services
Jim Tozzi - Center for Regulatory Effectiveness
Niger Innis - Congress of Racial Equality (CORE)

Menthol Report – Industry Perspective
Daniel J. Heck, Ph.D., DABT

Updates of Chapters 4, 5, and 7

Break

Committee Discussion

Adjourn
The session adjourned @ approximately 3:00 p.m.

Dr. David Ashley provided brief opening comments. He explained that the FDA did not have a specific timeline within which to make determinations about possible actions to be taken - if an - related to menthol in cigarettes. He stated that the Menthol Report was only one of many pieces of information that would, in any event, be used by FDA to make decisions about such possible determinations.

Dr. David Mendez presented preliminary results from his model regarding the prevalence of menthol smoking. He explained the model’s structure, methods used for checking the accuracy of results, and the scenarios used to frame predictions. The Committee provided feedback on the model’s structure and content.

In response to the Committee’s requests for additional and clarifying information, Dr. Eric Johnson gave a follow-up presentation to his February 10 presentation on rates of user switching.

Members of the Menthol Report Subcommittee presented updates. Dr. Heck discussed the progress of the report referred to as the “Industry Perspective” and the Menthol Writing Group gave updates on chapters 3, 4, 5, 6, and 7 of the TPSAC report. In both cases much progress was reported and completion in time for the March 23 deadline was expected. Committee members provided input and feedback to the Writing Group regarding the content of the report.

The session adjourned @ approximately 3:00 p.m.

Questions to the Committee:

1. What comments do you have regarding the proposed model?

2. What feedback does the TPSAC have regarding draft chapters 3 and 6?

Please see the verbatim transcript for details of the discussion.