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

March 17-18, 2011

These summary minutes for March 17-18, 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 17-18, 2011 meeting 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/
Caryn Cohen, M.S.    Jonathan Samet, M.D., M.S.
Designated Federal Official, TPSAC    Committee Chair, TPSAC
Meeting of the Tobacco Products Scientific Advisory Committee  
March 17-18, 2011

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on March 17-18, 2011 at FDA White Oak Conference Center, Building 31, Room 1503, 10903 New Hampshire Ave., 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 4 speakers for the Open Public Hearing session.

Agenda: On March 17 and 18, 2011, the Committee continued to receive updates from the Menthol Report Subcommittee and discussed plans for finalizing the report 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)
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)
Jack Henningfield, Ph.D.
Melanie Wakefield, Ph.D. (via Tele-conference)
Neal Benowitz, M.D. (via Tele-conference)

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):
Timothy McAfee, M.D., M.P.H.

Guest Speakers (Non-Voting):
David Mendez, Ph.D.

FDA Participants (Non-Voting):
David Ashley, Ph.D.
Lawrence Deyton, M.S.P.H., M.D. (on March 18 only)
Corinne Husten, M.D., M.P.H.

Designated Federal Official:
Caryn Cohen, M.S.
The agenda on March 17 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  
Corinne Husten, M.D., M.P.H.  
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

Discussion of Menthol Report Chapters

Break

Open Public Hearing

Scott Ramminger - American Wholesale Marketers Association  
William R. True - Lorillard Tobacco Company  
Jim Tozzi - Center for Regulatory Effectiveness  
Harry C. Alford - National Black Chamber of Commerce

Discussion of Menthol Report Chapters (continued)

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

Adjourn for the day

The session adjourned @ approximately 5:00 p.m.

The agenda on March 18 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
Presentation and Discussion of Final Menthol Report and Recommendations

Break

Committee Discussion of Questions to the Committee

Adjourn

The session adjourned @ approximately 9:30 a.m.

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On the first day of the meeting, Dr. Corinne Husten outlined the agenda for the meeting, explaining that the menthol report and related recommendations would be deliberated on and finalized during the course of this two-day meeting. The report, once redacted, would be made available to the public on FDA’s website along with the industry perspective document. Once received by the FDA, the report would be considered along with the recommendations of the Committee, the industry perspective document, and other relevant scientific information and determinations would be considered about what actions, if any, may be warranted related to menthol in cigarettes.

Dr. David Mendez presented Results from his Population Dynamics Model of the Consequences of Menthol Cigarettes for Smoking Prevalence and Disease Risks and responded to questions and comments from the Committee.

Updates on Chapters 4-7 of the Menthol Report. The most extensive discussion was on Chapter 5, focusing on marketing. The relative importance of considering marketing practices of the past and how they may or may not continue to influence current attitudes, was among the issues discussed.

On the second day of the meeting redacted copies of the Menthol Report were distributed to the non-voting members of the Committee and made available to the public at the information tables in the lobby and were posted on CTP’s website. Unredacted copies of the Report were provided to the voting members of the Committee prior to the start of the meeting.

Dr. Dorothy Hatsukami led a detailed discussion of Chapter 6, which focuses on initiation, addiction, and cessation. The Committee discussed Chapter 8, which focuses on answering the “Questions to the Committee” that were established at the beginning of the Menthol Report process and guided the discussion at this meeting. Chapter 8 includes the Committees recommendations related to menthol in cigarettes; Dr. Mark Clanton led the discussion on the recommendations themselves. These recommendations can be found posted (in Chapter 8) on the CTP website and in the verbatim transcripts of this meeting (also posted on the web).

Dr. Jack Henningfield, who was not part of the Menthol Subcommittee, provided his comments on the report and the resulting recommendations, which he characterized as “succinct and appropriate.”

Dr. Lawrence Deyton closed the meeting by thanking the TPSAC for their work on the report. He delineated FDA’s next steps as they relate to the issue of menthol in cigarettes: Once the final report is received by FDA, it will undergo thorough expert review by FDA staff and FDA will assess all of the science related to menthol in cigarettes as outlined in the Tobacco Control Act. Dr. Deyton stated that there is no required deadline or timeline for FDA to act on the issue of menthol in cigarettes. He stated that FDA will continue to communicate the steps to be undertaken once it is determined what, if any, future regulatory actions are warranted.

The session adjourned @ approximately 9:30 a.m.
Questions to the Committee:

- What is the level of evidence that the availability of menthol cigarettes increases the likelihood of experimentation?
- What is the level of evidence that the availability of menthol cigarettes increases the likelihood of becoming a regular smoker?
- What is the level of evidence that inclusion of menthol in cigarettes increases the likelihood of the smoker becoming addicted?
- What is the level of evidence that inclusion of menthol in cigarettes increases the degree of addiction of the smoker?
- What is the level of evidence that smokers of menthol cigarettes less likely to quit successfully than smokers of non-menthol cigarettes?
- What is the level of evidence from biomarker studies that smokers of menthol cigarettes receive greater doses of harmful agents per cigarette smoked, in comparison with smokers of non-menthol cigarettes?
- What is the level of evidence that smokers of menthol cigarettes have increased risk for diseases caused by smoking in comparison with smokers of non-menthol cigarettes?
- What is the level of evidence that the availability of menthol cigarettes increases the prevalence of smoking in the population, beyond the anticipated prevalence if such cigarettes were not available? In subgroups within the population?
- What is the level of evidence that tobacco company marketing of menthol cigarettes increases the prevalence of smoking beyond the anticipated prevalence if such cigarettes were not available? In subgroups within the population?
- What are the overall conclusions of the Menthol Report?
- What are the conclusions of the Committee regarding the public health impact of the use of menthol in cigarettes?
- What are the recommendations of the Committee regarding the use of menthol in cigarettes?

Please see the verbatim transcript for details of the discussion.