

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

April 30, 2013

These summary minutes for April 30, 2013 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on ____May 24, 2013____.

I certify that I attended the April 30, 2013 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
April 30, 2013**

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on April 30, 2013 at the FDA Center for Tobacco Products (CTP), 9200 Corporate Boulevard, 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 6 speakers for the Open Public Hearing session.

Agenda: On April 30, 2013, the Committee convened to discuss review of the requirements for Modified Risk Tobacco Product Applications (MRTPAs) under section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Modified risk tobacco products (MRTPs) are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Before an MRTP can be introduced or delivered for introduction into interstate commerce, an order from FDA under section 911(g) (21 U.S.C. 387k(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) must be in effect with respect to the tobacco product. 21 U.S.C. 387k(a). Any person may submit an application seeking an order under section 911(g) of the FD&C Act. Section 911(f) of the FD&C Act (21 U.S.C. 387k(f)) requires FDA to refer modified risk tobacco product applications to the Tobacco Products Scientific Advisory Committee (TPSAC) for its recommendations. TPSAC is required to report its recommendations on an application to FDA no later than 60 days after the date the application is referred to them. 21 U.S.C. 387k(f)(2).

Attendance:

Tobacco Products Scientific Advisory Committee (Voting):

Jonathan M. Samet, M.D., M.S. (Committee Chair)

Warren K. Bickel, Ph.D.

Mark Stuart Clanton, M.D., M.P.H.

Joanna Cohen, Ph.D.

Thomas E. Eissenberg, Ph.D.

Patricia Nez Henderson, M.P.H., M.D. (*Representative of the General Public, Participated by Telecon*)

Philip P. Huang, M.D., M.P.H. (*Employee of a state or local government or of the Federal Government*)

Suchitra Krishan-Sarin, Ph.D.

Kurt M. Ribisl, M.A., Ph.D.

Industry Representative Members Present (Non-voting):

Hampton H. Henton (*Representative of the interests of tobacco growers*)

Daniel Heck, Ph.D., D.A.B.T. (*Representative of the tobacco manufacturing industry*)

David M. Johnson, Ph.D. (*Representative for the interest of small business tobacco manufacturing industry*)

Ex Officio Members Present (Non-Voting):

Timothy McAfee, M.D., M.P.H. (CDC)

Douglas Tipperman, M.S.W. (SAMHSA)

Mirjana Djordjevic, Ph.D. (NIH)

FDA Participants (Non-Voting):

Mitch Zeller, J.D.
David Ashley, Ph.D.
Conrad Choiniere, Ph.D.
Carolyn Dresler, M.D., M.P.A.

Designated Federal Official:

Caryn Cohen, M.S.

The agenda on April 30, 2013 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	
Welcome and Introduction	Mitch Zeller, J.D. Director Center for Tobacco Products
Opening Remarks	Carolyn Dresler, M.D., M.P.A. Associate Director for Medical and Health Sciences Office of Science, FDA/CTP
Draft Guidance on Modified Risk Tobacco Product Applications	Conrad J. Choiniere, Ph.D. Lead Social Scientist Office of Science, FDA/CTP
Journey of the Modified Risk Tobacco Product (MRTP) Application	Ii-Lun Chen, M.D. Supervisory Medical Officer Office of Science, FDA/CTP
The TPSAC Meeting for an MRTP Application	Karen Templeton-Somers, Ph.D. Director, Advisors and Consultants Staff Office of Science, FDA/CTP
Open Public Hearing	
	Gilbert Ross, M.D., The American Council on Science and Health Robert McMillen, Ph.D., American Academy of Pediatrics Dr. Neil Wilcox, Lorillard Tobacco Company Dennis Henigan, Campaign for Tobacco-Free Kids Bill Godshall, Smokefree Pennsylvania Dr. David Abrams, Legacy
Questions to the Committee	Carolyn Dresler, M.D., M.P.A. Associate Director for Medical and Health Sciences Office of Science, FDA/CTP
Committee Discussion	
Adjourn Open Session	

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The purpose of the meeting, as described in Carolyn Dresler's opening presentation, was to review the requirements for Modified Risk Tobacco Product Applications (MRTPAs) under section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and solicit recommendations from the Advisory Committee and comments from the public relevant to the processing of MRTPAs. The FD&C Act states:

**(f) Advisory Committee**

1. **In General.** The Secretary shall **refer** to the Tobacco Products Scientific Advisory Committee any application submitted under this section.
2. **Recommendations.** Not later than **60 days after** the date an application is referred to the Tobacco Products Scientific Advisory Committee under paragraph (1), the Advisory Committee shall report its **recommendations** on the application to the Secretary.

Conrad Choiniere described the Draft Guidance on Modified Tobacco Product Applications issued on March 30, 2012, which describes a 360 day review period from the date the application is received (day 0) to the anticipated FDA action (day 360).

Ii-lun Chen discussed the "journey" of an MRTPA – describing FDA's scientific review, conducted by CTP's scientific staff (including experts in chemistry, toxicology, medicine, addiction, social and behavioral science, epidemiology, and statistics). These FDA scientists evaluate the applications, focusing on the aspects relevant to their area of expertise in order to create summary evaluations. Summaries prepared by FDA scientists are provided to the advisory committee when there are specific questions regarding portions of the applications and the analyses therein, about which recommendations are deemed needed from the TPSAC and/or more generally, to provide the TPSAC with summary information about the application.

Karen Templeton-Somers presented information about the advisory committee meeting that would necessarily take place as the forum for TPSAC's discussion of their recommendation(s) on an MRTPA. After an application is received by CTP and prior to a TPSAC meeting on that application, a redacted copy of the MRTPA will be posted on the FDA/CTP website. Redacted versions of any summary materials prepared by FDA scientists and other background materials provided to the TPSAC by FDA (including comments from the public) to assist in their preparation for the meeting, will also be posted on the FDA/CTP website. At some point in this process the unredacted application itself, or some portion of it, may also be provided to the voting members of the TPSAC.

Following the presentations by Drs. Dresler, Choiniere, Chen and Templeton-Somers, the TPSAC asked clarifying questions, including:

- In what format does FDA expect MRTPAs to arrive?
- Will the TPSAC have only one change to provide feedback on an MRTPA?
- Will there be a third party governance requirement?
- Does FDA expect to make a decision about third party governance before the first MRTPAs are received?
- Will there be a requirement to provide information on special populations in MRTPAs?
- Is there guidance on timelines for pre-market and post market studies?
- Can there be a preliminary TPSAC discussion, prior to MRTPA referral?
- Will samples of the proposed MRTP be provided to the TPSAC?
- Is information about proposed pricing and advertising required as part of the MRTPA?
- Will TPSAC be involved of post-market review of MRTPs that go to market; how and when?
- What are the consequences if the TPSAC does not meet the 60 day deadline?

Further scientific, administrative and legal review will be needed for FDA to determine the processes to be used and to consider the questions raised by the TPSAC.

During committee discussion, two actions seemed likely options to initiate the referral to TPSAC: 1) the date review materials are sent to the TPSAC or 2) the date the TPSAC meeting is convened.

*The materials that may be provided to the TPSAC in preparation for committee discussion may include one or more of the following, the entire unredacted application, part of the application for which FDA is asking specific questions, parts of the application which different TPSAC members have requested based on expertise, and/or the FDA synthesis of the application.*

*The TPSAC recommendation regarding an MRTPA is likely to be a compilation of TPSAC meeting(s) materials (transcript, slides, etc.) and may include a brief written report. The TPSAC must meet at least once, but additional meetings may be convened to give the applicant and FDA and opportunity to present their findings regarding the MRTPA.*

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***Questions to the committee:***

1. What FDA action could initiate a referral that starts the 60-day period within which TPSAC must make its recommendations to FDA?
2. What materials should FDA provide in order for TPSAC to make its recommendations?
3. In what format could TPSAC report its recommendations to FDA?

**Please see the *verbatim* transcript for details of the discussion.**