FOOD AND DRUG ADMINISTRATION

Center for Tobacco Products (CTP)

Tobacco Products Scientific Advisory Committee (TPSAC)

Tommy Douglas Conference Center
10000 New Hampshire Avenue
Silver Spring, Maryland 20903

April 6, 2017

These summary minutes for the April 6, 2017 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on May 1, 2017.

I certify that I attended the April 6, 2017 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, MS
Designated Federal Official, TPSAC

_____/s/_____
Philip P. Huang, MD, MPH
Chair, TPSAC

Meeting of the Tobacco Products Scientific Advisory Committee
April 6, 2017

The Tobacco Products Scientific Advisory Committee (TPSAC) of the Food and Drug Administration, Center for Tobacco Products met on April 6, 2017 at the Tommy Douglas Conference Center, 10000 New Hampshire Avenue, Silver Spring, Maryland. Prior to the meeting, committee members and invited participants were provided copies of the background material from the FDA and the submissions from the public. The meeting was called to order by Philip P. Huang, MD, MPH (Chair); the conflict of interest statement was read into the record by Caryn Cohen, MS (Designated Federal Official). There were approximately 75 persons in attendance. There were two speakers for the Open Public Hearing session.

Agenda: *Under section 910(b)(2) (21 U.S.C. 387j(b)(2)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA may refer applications for premarket review of new tobacco products (PMTA) to the Tobacco Products Scientific Advisory Committee (Committee). The FD&C Act also provides for mandatory referral of modified risk tobacco product applications (MRTPA) to the Committee under section 911(f)(1). 21 U.S.C. 387k (f)(1). On April 6, 2017, FDA will present information to the Committee on the processes used in review of tobacco product applications, including premarket tobacco, substantial equivalence, and modified risk tobacco product applications. Topics will include the statutory standards applicable to the different types of applications, the scientific basis for review decisions, with a focus on PMTA and MRTPA, and the role of the Committee in the review process.*

Attendance:

TPSAC Members Present (Voting):
Philip P. Huang, MD, MPH (*Chair; Employee of a state or local government or of the Federal Government)*
Laura J. Bierut, MD
Pebbles Fagan, PhD, MPH (*Representative of the General Public)*
Gary A. Giovino, PhD
Robin J. Mermelstein, PhD
Richard J. O'Connor, PhD
Deborah J. Ossip, PhD
James F. Thrasher, PhD
Michael Weitzman, MD

Industry Representative Members Present (Non-voting):
William Andy Bailey, PhD *(Representative of the interests of tobacco growers)*
Willie McKinney, PhD, DABT *(Representative of the interests of the tobacco manufacturing industry)*
David M. Johnson, PhD *(Representative of the interests of small business tobacco manufacturing industry)*

Ex Officio Members Present (Non-Voting):
Brian King, PhD, MPH (CDC)
Melinda Campopiano, MD (SAMHSA)
Kay L. Wanke, PhD, MPH (NIH)

FDA Participants (Non-Voting):
David Ashley, PhD

Matthew R. Holman, PhD
Benjamin Apelberg, PhD
Ii-Lun Chen, MD

Designated Federal Official:
Caryn Cohen, MS

The agenda on April 6, 2017 was as follows:

Call to Order	Philip P. Huang, MD, MPH Chair, TPSAC
Conflict of Interest Statement	Caryn Cohen, MS Designated Federal Official Office of Science, FDA/CTP
Introduction of Committee Members	Philip P. Huang, MD, MPH Chair, TPSAC
Welcome and Introduction	David Ashley, PhD RADM (Ret.), U.S. Public Health Service Senior Advisor Office of the Director, FDA/CTP
Overview of Product Review Pathways	Matthew R. Holman, PhD Director Office of Science, FDA/CTP
The Substantial Equivalence Pathway: An Overview	Atasi Poddar, PhD Senior Regulatory Health Project Manager Office of Science, FDA/CTP
PMTA and MRPTA Review Process	Stephanie L. Redus, MS Senior Regulatory Health Project Manager Office of Science, FDA/CTP

Open Public Hearing

- Michael W. Ogden, PhD - RAI Service Company
- Jose Luis Murillo - Altria Client Services, LLC

Scientific Basis for Swedish Match NA Premarket Tobacco Product Authorization	Ii-Lun Chen, MD Director, Division of Individual Health Science Office of Science, FDA/CTP

Modified Risk Tobacco Product Marketing Decisions	Benjamin Apelberg, PhD Director, Division of Population Health Science Office of Science, FDA/CTP

Questions to the Committee

Committee Discussion

Adjourn

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***Questions to the Committee*:**

In relation to meeting preparation:

1. How was the information provided to the TPSAC prior to the 2015 meeting on the MRTPAs for the SMNA snus products helpful in preparing for the meeting?
2. How do you anticipate preparing for upcoming application review TPSAC meetings?
3. What information would be most useful to receive prior to an application review TPSAC meeting?
4. What information would likely be least useful prior to an application review TPSAC meeting?
5. How would having only an Executive Summary or only the sections of the application that FDA planned to discuss, compared to having the entire application, impact your ability to prepare for an application review TPSAC meeting and give advice to FDA?

In relation to the meeting itself:

6. How was the information provided during the presentations at the 2015 meeting on the MRTPAs for the SMNA snus products helpful in providing advice to FDA?
7. What information would be useful as part of the meeting presentations during an application review TPSAC meeting?
8. What information would not be useful as part of the meeting presentations during an application review TPSAC meeting?
9. How might the TPSAC meeting be structured so that the committee is best positioned to provide advice to FDA?

Committee Discussion:

***Question*:**

1. How was the information provided to the TPSAC prior to the 2015 meeting on the MRTPAs for the SMNA snus products helpful in preparing for the meeting?

Committee Discussion:

Those members that attended the 2015 TPSAC meeting indicated that the information provided by both FDA and the applicant was helpful and included the appropriate level of detail. Members suggested that, if feasible, hyperlinks to the background articles would be helpful. Those members who attended the
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2015 meeting stated that they had enough lead time to do the necessary work. Members stated that having access to the entire application for reference was helpful.

***Question*:**

2. How do you anticipate preparing for upcoming application review TPSAC meetings?

Committee Discussion:

Members expressed some apprehension about applications that may be as much as one-million pages long, and wondered if the amount of information given to the TPSAC would be proportional to the length of the application. FDA explained that FDA will do the initial review, and will provide the TPSAC with a document summarizing FDA's findings. The applicant will also provide a summary document. While entire MRTPA applications will be made available to the TPSAC for reference, members are not expected to read the entire application.

***Question*:**

3. What information would be most useful to receive prior to an application review TPSAC meeting?

Committee Discussion:

The Committee again voiced their approval of the information that was provided prior to the 2015 MRTP review meeting. Members suggested that a graphic representation of HPHCs in the product under review as compared to a currently marketed product would be useful. The Committee suggested that it could be useful to direct members to the areas within an application that are relevant to their particular expertise.

***Question*:**

4. What information would likely be least useful prior to an application review TPSAC meeting?

Committee Discussion:

The Committee expressed satisfaction with the content of the briefing materials for both the 2015 meeting and the April 6, 2017 meeting.

***Question*:**

5. How would having only an Executive Summary or only the sections of the application that FDA planned to discuss, compared to having the entire application, impact your ability to prepare for an application review TPSAC meeting and give advice to FDA?

Committee Discussion:

Members stated that, in general, executive summaries do not provide enough scientific information to be entirely useful.

***Question*:**

6. How was the information provided during the presentations at the 2015 meeting on the MRTPAs for the SMNA snus products helpful in providing advice to FDA?

Committee Discussion:

Members said the presentations helped reinforce the information provided in the background materials.

***Question*:**

7. What information would be useful as part of the meeting presentations during an application review TPSAC meeting?

Committee Discussion:

Members said the MRTP criteria, which were included in the briefing materials for the 2015 MRTP meeting, would be important to include in the briefing materials for future MRTP review meetings.

***Question*:**

8. What information would not be useful as part of the meeting presentations during an application review TPSAC meeting?

Committee Discussion:

Members pointed out that information extraneous to the application would not be useful.

***Question*:**

9. How might the TPSAC meeting be structured so that the committee is best positioned to provide advice to FDA?

Committee Discussion:

Members expressed support of a two-day meeting format, with presentations on the first day and Committee discussion on the second. FDA explained that in the future, more than one application may be considered within the context of a single meeting. Members also pointed out that as the Committee gains experience with applications, less time may be required.

Please see the verbatim transcript for details of the discussion.