Food and Drug Administration
Center for Biologics Evaluation and Research (CBER) Summary Minutes
29th Allergenic Products Advisory Committee (APAC) Meeting
October 27, 2016
OPEN SESSION

Allergenic Products Advisory Committee Members

Michael Nelson, M.D., Ph.D. (Chair)
Andrea J. Apter, M.D., M.Sc., M.A.
Amal Assa'ad, M.D.
Ira Finegold, M.D., M.S.
John M. Kelso, M.D. +
David Peden, M.D., M.S.
Jane Peterson, M.N., Ph.D..*
Gregory Plunkett, Ph.D.**

FDA Participants

Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research (CBER)
Carolyn Wilson, Ph.D., Associate Director for Research, CBER
Marion Gruber, Ph.D., Director, Office of Vaccines Research and Review (OVRR), CBER
Jay Slater, M.D., Director, Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), OVRR, CBER
Drusilla Burns, Ph.D., Deputy Director, DBPAP, OVRR
Ronald Rabin, M.D., Chief, Laboratory of Immuno-biochemistry (LIB), DBPAP, OVRR

FDA Administrative Team

Designated Federal Officer for APAC

Janie Kim, Pharm.D., DSAC, CBER, FDA

Committee Management Specialists

Denise Royster, DSAC, CBER, FDA
Joanne Lipkind, M.S., DSAC, CBER, FDA
Rosanna Harvey, DSAC, CBER, FDA

Director, DSAC, CBER, FDA
Prabhakara L. Atreya, Ph.D.

+ Not in attendance
* Acting Consumer Representative
** Industry Representative

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These summary minutes for the October 27, 2016 Allergenic Products Advisory Committee meeting were approved on 28 November 2016.

I certify that I participated in the October 27, 2016 Allergenic Products Advisory Committee (APAC) meeting and that these minutes accurately reflect what transpired.

/s/
Michael Nelson, M.D., Ph.D.
Chair, APAC

/s/
Janie Kim,Pharm.D.
Designated Federal Officer, CTGTAC

On October 27, 2016 at 1:00 p.m. Eastern Standard Time (EST), Dr. Michael Nelson, the Allergenic Products Advisory Committee (APAC) Chair, called the 29th APAC meeting to order. The partially closed meeting was held at the Food and Drug Administration (FDA) Conference Center Great Room in Silver Spring, Maryland.. The meeting is partially closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting began with a session open to members of the Public. APAC members participated via teleconference for the open and closed sessions

The topic of the meeting was the March 17, 2016 site visit of the intramural research programs of the Laboratory of Immunobiochemistry (LIB) in the Division of Bacterial, Parasitic, and Allergenic Products (DBPAP), Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER).

After the meeting was called to order by Dr. Nelson, the Designated Federal Officer (DFO) took a roll call of the APAC members for the public record during which members introduced themselves. The DFO made administrative remarks and read the conflict of interest meeting statement for the public record noting that the meeting topic was a non-particular matter and that the committee discussion presented no potential for conflicts of interest. CBER Center Director, Dr. Peter Marks, recognized the service of retired APAC members, Drs. Carla Davis, Michelle Gill, and Jane Peterson.

The Committee heard the following presentations in open session:

- Overview of Research Programs in the Center for Biologics Evaluation and Research (CBER), FDA by Dr. Carolyn Wilson
- Overview of Research Program in the Division of Bacterial, Parasitic and Allergenic Products (DBPAP), Office of Vaccine Research and Review (OVRR), CBER, FDA by Dr. Jay Slater
- Overview of Research Programs in the Laboratory of Immunobiochemistry, DBPAP, CBER, FDA by Dr. Ronald Rabin

Time was allotted during the meeting for public comment, but no individuals from the public registered to speak and none requested time at the meeting to address the Committee.

Dr. Michael Nelson, the Chair, adjourned the open session at 2:20 p.m.

For more detailed information concerning the open session presentations and committee discussions summarized above, please refer to the meeting transcripts available on the FDA website. Please submit all external requests to the FDA Freedom of Information Office.