Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)

SUMMARY MINUTES
28th ALLERGENIC PRODUCTS ADVISORY COMMITTEE MEETING
JANUARY 21, 2016

Allergenic Products Advisory Committee Members (Voting)
Michael Nelson, M.D., Ph.D. (Chair)
Andrea J. Apter, M.D., M.Sc., M.A.
Carla Davis, M.D. +
Ira Finegold, M.D., M.S.
Michelle A. Joubert Gill, M.D., Ph.D.
John M. Kelso, M.D.
David Peden, M.D., M.S.
Jane Peterson, M.N., Ph.D..*
Gregory Plunkett, Ph.D.**

Temporary Members (Voting)
Mark Dykewicz, M.D.
Richard Weber, M.D.

Guest Speaker
Thomas Platts-Mills, M.D.

FDA Participants
Marion Gruber, M.D., Director, Office of Vaccines Research and Review (OVRR)
Jay Slater, M.D., Director, Division of Bacterial, Parasitic, and Allergenic Products, OVRR
Kathleen Hise, M.D., Medical Officer, Division of Vaccines and Related Product Applications (DVRPA), OVRR
S. Tina Chang, M.D. Medical Officer, DVRPA, OVRR

Designated Federal Officer for CTGTAC
Janie Kim, Pharm.D., DSAC, CBER, FDA

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

+ Not in attendance
* Consumer Representative
** Industry Representative

These summary minutes for the January 21, 2016 Allergenic Products Advisory Committee meeting were approved on 24 Mar 2016.

I certify that I participated in the January 21, 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

The 28th Allergenic Products Advisory Committee (APAC) met at 8:30 AM on January 21, 2016 at the FDA White Oak Conference Center, Silver Spring, Maryland. The committee met in open session to discuss the data on the - safety and effectiveness including challenge study endpoints, for licensure of food allergy immunotherapy products, and the clinical development of aeroallergen immunotherapy products for the prevention of respiratory allergic disease.

Dr. Michael Nelson, the APAC Chair, called the meeting to order and invited the members and temporary members seated at the table to introduce themselves. The Designated Federal Officer (DFO) made administrative remarks and read the conflict of interest statement into the public record.

An introduction, background and discussion points were presented by Dr. Jay Slater, Director, Division of Bacterial, Parasitic, and Allergenic Products (DBPAP) in the Office of Vaccines Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER), FDA. Dr. Slater's presentation was followed by two FDA presentations, one onon clinical considerations for food allergy immunotherapy by Dr. Hise, and on clinical considerations for aeroallergen immunotherapy by Dr. Chang, and a presentation from a guest speaker Dr. Platts-Mills , on designing and assessing relevant intervention studies.

The committee reconvened after a lunch break to allow for the Open Public Hearing (OPH) session. During the OPH, Ms. Kimberly Turner of the Allergy & Asthma Network, Dr. Cary Sennett of Asthma and Allergy Foundation of America (AAFA), Ms. Margaret Dayhoff-Brannigan of National Center for Health Research, Mr. Scott Riccio and his eleven year old daughter, Dr. James R. (Jim) Baker of Food Allergy Research & Education (FARE), and Dr. Hendrik Nolte of Merck & Company provided oral comments.

The committee discussed and made recommendations on the following discussion points:

Treatment of Food Allergy; Discussion Point1
Regarding food challenge studies to assess effectiveness of immunotherapy in allergic individuals, please discuss:

- objective criteria for determining the eliciting dose (ED), particularly in children <5 years of age;
- clinically meaningful parameters, including amplitude of response and duration of time off therapy, that could be used to demonstrate the effectiveness of immunotherapy for:

- “desensitization”
- “sustained unresponsiveness” (i.e., maintenance of desensitization off therapy)
- safety considerations for the food challenge

Treatment of food allergy: Discussion Point 2
Please discuss approaches other than food challenge studies to demonstrate the effectiveness of immunotherapy products intended for use in food allergic individuals.

Treatment of food allergy: Discussion Point 3
Taking into account the route of administration of immunotherapy in food allergic subjects, and the age of study subjects, please discuss specific safety monitoring for signs and symptoms of allergic reactions.

Prevention of development of asthma: Discussion Point 1
Studies to demonstrate effectiveness of allergy immunotherapy to prevent the development of asthma will likely enroll a population at increased risk for the development of asthma, including children 6 months of age and older.
Please discuss:

- factors to consider in the identification of subjects at increased risk of developing asthma;
- the diagnosis of asthma in infants and young children;
- factors to consider regarding the timing of the assessment of asthma endpoints (e.g. age, time on therapy, time off therapy, others)

Prevention of development of asthma: Discussion Point 2
Please discuss the assessment of safety in infants and young children receiving aeroallergen immunotherapy to prevent the development of asthma.