

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
ALLERGENIC PRODUCTS ADVISORY COMMITTEE**

**SUMMARY MINUTES
May 12, 2011
DoubleTree Hotel, Bethesda, MD**

COMMITTEE MEMBERS

Robert G. Hamilton, Ph.D., D.ABMLI, Chair
Marianna C. Castells, M.D., Ph.D.
Sandra J. Fusco-Walker*
J. Andrew-Grant, Ph.D.
Bryan L. Martin, D.O.
Michael R. Nelson, M.D., Ph.D.
Greg Plunkett, Ph.D.**
Marc A. Riedl, M.D., M.S.
Vivian E. Sege Saper, M.D.
Richard W. Weber, M.D.

* Consumer Representative
** Industry Representative

TEMPORARY VOTING MEMBERS

Linda Cox, M.D.
Steven G. Self, Ph.D.

FDA PARTICIPANTS

Karen Midthun, M.D.
Norman Baylor, Ph.D.
Jay Slater, M.D.
Ronald Rabin, M.D.
Tammy Massie, Ph.D.
Sandra Menzies, M.S.
Carolyn Wilson, Ph.D.
Konstatin Chumakov, Ph.D.

The summary minutes for the May 12, 2011 meeting of the Allergenic Products Advisory Committee were approved on November 7, 2011.

I certify that I attended the May 12, 2011 meeting of the Allergenic Products Advisory Committee and that this report accurately reflects what transpired.

//s//
Gail Dapolito, Designated Federal Officer

//s//
Robert G. Hamilton, Ph.D., D. ABMLI, Chair

FDA ALLERGENIC PRODUCTS ADVISORY COMMITTEE
SUMMARY MINUTES
May 12, 2011

The Allergenic Products Advisory Committee (APAC) met on May 12, 2011 at the DoubleTree Hotel, Ballroom D, Bethesda, Maryland.

Robert G. Hamilton, Ph.D., D. ABMLI, Chair, called the meeting to order and introduced the members. The Designated Federal Officer read the conflict of interest statement into the public record. This statement identifies members of the Committee with an appearance of a financial conflict of interest, for whom FDA issued waivers to participate. FDA issued no waivers for the meeting.

Karen Midthun, M.D., Director, Center for Biologics Evaluation and Research recognized the Committee service of two Committee members: Drs. Linda Cox and J. Andrew Grant were presented with plaques and letters of appreciation for their service on the Committee.

In open session, the Committee received information on and discussed the following:

- Laboratory of Immunobiochemistry; Structure and Activities
- ISO 17025 Accreditation
- ELISA Replacement of RID Assays for Potency Determination of Cat and Ragweed Pollen Allergen Extracts
- Statistical Considerations for the Design and Interpretation of Phase III Clinical Trials of Allergenic Products
- Environmental Exposure Chambers for Phase III Studies of Allergenic Products

In open session, the Committee received the following updates:

- Research Program Overviews:
 - Center for Biologics Evaluation and Research, FDA
 - Office of Vaccines Research and Review
 - Division of Bacterial, Parasitic and Allergenic Products
 - Laboratory of Immunobiochemistry

Laboratory of Immunobiochemistry; Structure and Activities

FDA provided information on the regulatory activities of the Laboratory of Immunobiochemistry. The Laboratory is located within the Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA and is responsible for the regulation of biologics that pertain to the diagnosis and treatment of allergic diseases. The regulatory activities of the Laboratory include review of protocols, distribution of reference reagents and maintenance and replacement of reference reagents. Reference reagents replaced within the last year include extracts for house dust mite, cat pelt extract and short ragweed pollen. Additionally, Laboratory staff review investigational new drug applications. Research activities in the Laboratory include standardization and characterization of allergens; the relationship between respiratory viruses and asthma and the biological effects of subtypes of alpha interferon and beta interferon on gene expression and modulation of adaptive response to allergens.

ISO 17025 Accreditation

FDA provided an update on FDA's decision to seek accreditation of its official testing activities and the efforts of the Laboratory of Immunobiochemistry to obtain ISO 17025 accreditation. The Laboratory is working to accredit the confirmatory allergen lot release tests and the competition enzyme-linked immunosorbent assay (ELISA) and radial immunodiffusion (RID) assays for potency determination of allergen extracts.

FDA ALLERGENIC PRODUCTS ADVISORY COMMITTEE
SUMMARY MINUTES
May 12, 2011

ELISA Replacement of RID Assays for Potency Determination of Cat and Ragweed Pollen Allergen Extracts

The FDA provided an update on the developmental plan to replace the current radial immunodiffusion (RID) assay for measuring the potency of short ragweed pollen and cat allergen extracts with an enzyme-linked immunosorbent assay (ELISA). The current RID assay is more labor and time intensive and uses more reagents than the proposed ELISA. FDA provided data on proof of concept studies for potency determination of cat and ragweed allergen extracts by ELISA. FDA will proceed to prepare a validation program and invite manufacturers to participate in the program. The third phase of development following validation will be standardization/quality control and final replacement of RID with ELISA as the potency assay for cat and short ragweed pollen allergen extracts.

Statistical Considerations for the Design and Interpretation of Phase III Clinical Trials of Allergenic Products

FDA presented an overview of basic statistical concepts that the Agency applies to the review of studies of allergenic products. Statistical concepts such as covariates, meaningful differences and appropriate timeframes were discussed.

Environmental Exposure Chambers (EEC) for Phase III Studies of Allergenic Products

FDA provided background information on the advantages and disadvantages of natural exposure studies for seasonal allergens and the potential use of EECs to better control for variability. The Committee discussed the challenges of designing a controlled environmental study of sufficient size, as well as a natural exposure study during a low pollen season in which the difference between the placebo and treatment groups could be small. The Committee stated at this time, there is not as much experience with EEC challenge versus natural exposure to determine their relative utility in establishing efficacy. However, EECs may be more useful as an adjunct to natural exposure clinical trials.

Research Update

The FDA provided an update on the research projects, publications and research support for the Laboratory of Immunobiochemistry. Research projects include characterization of innate immune responses to respiratory syncytial virus, endotoxin in mite extracts and development of a multiplex allergen extract potency assay.

Following the Research Update the open session was adjourned.

For more detailed information concerning this session presentation and committee discussion summarized above, please refer to the meeting transcripts available on the FDA website at <http://www.fda.gov/ohrms/dockets>.