DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

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

SUMMARY MINUTES
September 13, 2006, Teleconference
National Institutes of Health, Bethesda, MD

COMMITTEE MEMBERS
Larry Borish, M.D., Chair
Fred M. Atkins, M.D.
Christy Olson, R.N.
Steven Ostrove, M.D.
Jay M. Portnoy, M.D.
Gillian Shepherd, M.D.
Marsha Wills-Karp, M.D.

CONSULTANT
Lynelle C. Granady, M.D.

FDA PARTICIPANTS
Jay E. Slater, M.D.
Ronald Rabin, M.D.
Richard Walker, M.D.
Milan S. Blake, Ph.D.
Michael J. Brennan, Ph.D.
Norman Baylor, Ph.D.

Executive Secretary
Gail Dapolito

Committee Management Specialist
Jane S. Brown

The summary minutes for the September 13, 2006 meeting of the Allergenic Products Advisory Committee were approved on May 7, 2007.

I certify that I attended the September 13, 2006 meeting of the Allergenic Products Advisory Committee and that this report accurately reflects what transpired.

//s//

Gail Dapolito, Executive Secretary

//s//

Larry Borish, M.D.

FDA ALLERGENIC PRODUCTS ADVISORY COMMITTEE
SUMMARY MINUTES
September 13, 2006

The Allergenic Products Advisory Committee (APAC) met on September 13, 2006 by teleconference at the National Institutes of Health, Bethesda, MD.

Larry Borish, M.D., Chair, called the meeting to order and introduced the members. The Executive Secretary read the conflict of interest statement into the public record. This statement identified members of the Committee with an appearance of a financial conflict of interest for whom FDA issued waivers to participate. Copies of the waivers are available from the FDA Freedom of Information Office.

Open Session

The Committee received updates on 1) the FDA strategy for the reclassification of Category IIIA allergenic products and 2) research programs in the Laboratory of Immunobiochemistry, Division of Bacteria, Parasitic and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA.

The FDA provided a summary of the information discussed at the April 2006 Allergenic Products Advisory Committee meeting, including a summary of the history of allergy, allergy treatment and allergen extract regulations, and the FDA's proposed process for the reclassification of Category IIIA allergenic products. Following this summary the FDA updated the Committee on the current status of the FDA reclassification effort:

The FDA has developed a database and is currently reviewing approximately 1300 allergen extracts. Approximately one-half of these extracts have been completely reviewed and are in the database. Evaluations and references in the database are based on published data. The database includes safety information obtained from case reports and internet searches. To date, no safety issues have been identified. When reviewing efficacy, the FDA requires 2 or more supporting, published case reports. FDA projects the review of the remaining extracts will be completed within 6 months.

In the following question and answer session, the Committee suggested the FDA scan MedWatch reports for adverse events reports and that the FDA database, when completed, could be an important resource for physicians. The Committee also asked questions concerning how the reclassification strategy relates to dosing measurements of extract products, and product standardization. FDA stated that the goal of the efficacy review was to review the literature and reclassify Category III allergenic products in an organized manner. FDA intends this to be a separate process that does not include setting extract standards or establishing methods to measure allergens in extracts. This does not affect existing FDA requirements for compliance with manufacturing standards.

The Open Public Hearing followed this Committee discussion. There were no public speakers.

Following the Open Public Hearing, the FDA provided an update of research programs in the Laboratory of Immunobiochemistry. The open portion of the meeting was adjourned after the research update.

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.