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

SUMMARY MINUTES
April 7, 2005
Holiday Inn Select, Bethesda, MD

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Marsha Wills-Karp, Ph.D.

FDA PARTICPANTS
Kathryn M. Carbone, M.D.
Mary A. Foulkes, Ph.D.
Ronald Rabin, M.D.
Jay E. Slater, M.D.

EXECUTIVE SECRETARY
Gail Dapolito

COMMITTEE MANAGEMENT SPECIALIST
Jane S. Brown

The summary minutes for the April 7, 2005 meeting of the Allergenic Products Advisory Committee were approved on _____.

I certify that I attended the April 7, 2005 meeting of the Allergenic Products Advisory Committee and that this report accurately reflects what transpired.

_____//S//_____
Gail Dapolito, Executive Secretary

_____//S//_____
Melvin Berger, M.D., Ph.D. Chair

FDA ALLERGENIC PRODUCTS ADVISORY COMMITTEE
SUMMARY MINUTES
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The Allergenic Products Advisory Committee (APAC) met on April 7, 2005 at the Holiday Inn Select, Bethesda, MD.

Melvin Berger, 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.

In open session, the Committee discussed a proposed strategy for the reclassification of Category IIIA allergenic products. The Committee also received a progress report on the cockroach allergen standardization project, updates on individual research programs in the Laboratory of Immunobiochemistry and information related to the FDA Critical Path Initiative.

Research Overview

The FDA provided an introduction and overview of the regulatory and research activities within the Laboratory of Immunobiochemistry, Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research. Regulatory activities include lot release and, reference standards maintenance and distribution. Research projects include studies on the role of multi-drug resistance proteins in T cell activation and, the regulation of T cell responses by respiratory syncytial virus.

Cockroach Allergen Standardization Project

The FDA reported on testing methods and approaches to determine the biological potency of several extracts from "german" cockroaches and to identify highly allergic individuals who can be asked to volunteer for skin testing to compare extracts. Future studies have been proposed to determine the appropriate surrogate tests for standardization and to develop an appropriate set of reference standards.

Reclassification of Category IIIA Allergenic Products

The FDA provided information on 1) the history of allergy, allergy treatment, and allergen extract regulation and, 2) the completion of the FDA process for the classification of allergenic products. The FDA proposes to review data available, since 1972, on allergenic products originally classigfied into category IIIA, and implement conversion of category IIIA products into category I or II in a step wise fashion:

- Collect data on products since 1972
- Establish criteria for reviewing data
- Review data and identify products for conversion to category I or II
- Publish in the Federal Register full list of reclassification products and call for public comment

- Publish in the Federal Register final classifications and provisions for the revocations of licenses of products reclassified into category II

Following the FDA overview the Committee engaged in a general discussion of the FDA proposed reclassification strategy. The Committee did not address specific questions or provide specific advice at this meeting.

Critical Path Initiative

The FDA provided an update on the Critical Path Initiative. The FDA Critical Path Initiative is proposed to better enable FDA to facilitate product development and more efficiently evaluate safety, efficacy and quality of products regulated by the Agency.

This completed the open session and the meeting 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.