

**FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
ALLERGENIC PRODUCTS ADVISORY COMMITTEE
APRIL 7, 2005
Holiday Inn, Bethesda, MD**

AGENDA

Open Committee Discussion:

Topic I: FDA Proposed Strategy for the Reclassification of Class IIIA Allergenic Products

- 8:30 a.m.** Welcome and Administrative Remarks
Melvin Berger, M.D., Ph.D., Chair
- 8:40** Meeting Statement
Executive Secretary
- 8:45** FDA Perspective
Introduction and Overview
Jay Slater, M.D., Division of Bacterial, Parasitic and Allergenic Products, CBER, FDA
- 9:00** Cockroach Allergen Standardization
Jay Slater, M.D.
- 9:45** Q&A
- 10:00** Research Overview
Ronald Rabin, M.D., Division of Bacterial, Parasitic and Allergenic Products, CBER, FDA
- 10:30** Q&A
- 10:45** Break
- 11:00** Reclassification of IIIA Allergenic Products
Jay Slater, M.D.
- 11:45** Q&A
- 12 noon** Open Public Hearing
- 1:00 p.m.** Lunch
- 2:00** Committee Discussion
- Topic II: FDA Critical Path Initiative Update**
- 3:30** FDA's "Critical Path" Initiative
Kathryn Carbone, M.D., Office of the Director, CBER, FDA
- Clinical Trial Design and Other Statistical Issues
Mary Foulkes, Ph.D., Office of Biostatistics and Epidemiology, CBER, FDA
- 4:20 p.m.** Adjourn

