

DRAFT AGENDA (revised 3/05/02)

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

March 15, 2002

*Versailles I and II
Bethesda Holiday Inn
Bethesda, Maryland 20814*

- 8:00 a.m. Administrative Remarks
- 8:10 Opening Remarks
Samuel Lehrer, Ph.D., Committee Chair

COMMITTEE UPDATES (Open Session)

- 8:15 **Overview of the Division of Bacterial, Parasitic & Allergenic Products (DBPAP)**
Richard Walker, Ph.D., Division Director
- 8:30 **Overview of the Laboratory of Immunobiochemistry: Personnel, organizational, and lot release activities**
Jay E. Slater, M.D., DBPAP, Laboratory Chief
- 8:45 Discussion
- 8:50 **Research Updates**
Jay E. Slater, M.D.
Ronald Rabin, M.D., DBPAP, FDA
- 9:35 Discussion
- 9:50 Break
- 10:05 **Particulates in Allergen Extracts and Compliance Overview**
Jay E. Slater, M.D.
Teddi Lopez, OCBQ, FDA
- 10:35 Discussion
- 10:50 **Reduction of Possible Exposure to TSE Agents in Allergen Extracts**
Jay E. Slater, M.D.
- 11:05 Discussion
- 11:15 **Open Public Hearing**
- 11:45 Lunch

APAC AGENDA (Continued)

REGULATORY DISCUSSION TOPICS (Open Session)

12:45 p.m. **Considerations for the Regulation of Recombinant Allergens for the Diagnosis and Treatment of Allergic Disease**
Jay E. Slater, M.D

1:15 Discussion

1:30 **Glycerol in Allergen Extracts**
Jay E. Slater, M.D

1:45 Discussion

2:00 **Open Public Hearing**

CLOSED SESSION

2:30 **Presentation and Discussion of Site Visit Report**

3:30 p.m. Adjourn