

AGENDA
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