

**DRAFT**

DRAFT of 1/24/00

**PUBLIC AGENDA**

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)**

**ALLERGENIC PRODUCTS ADVISORY COMMITTEE MEETING**

**February 10, 2000**

*Holiday Inn Bethesda  
8120 Wisconsin Avenue  
Bethesda, MD 20184*

8:30 am Opening remarks

8:40 Laboratory of Immunobiochemistry (LIB) Jay E. Slater, M.D.  
Organizational changes  
New division structure  
Current staffing  
Regulatory activities  
Reference replacement  
Lot release statistics

9:00 Research report Jay E. Slater, M.D.  
Publications/abstracts/presentations  
Allergen structure and function  
Hyaluronidase mutants  
MALDI-TOF and SDS PAGE analysis of allergens  
Enzyme activity/allergenicity correlations  
Immunomodulation  
Hev b 5 mutants  
Role of LPS exposure and murine hyperreactivity  
Mite stability

9:45 [Break]

10:00 Regulatory proposals Richard Pastor, Ph.D.  
Potency limits for standardized allergen vaccines

## **Allergenic Product Advisory Committee**

Agenda (page 2)

Wednesday, February 10, 2000 (continued)

- 10:45 Regulatory proposals  
Allergen standardization Jay E. Slater, M.D.  
Evaluation of previous standardization program  
Impact criteria for the selection of new standardization targets  
Three year plan
- 11:30 [Lunch]
- 12:30 OPEN PUBLIC HEARING
- 1:30 COMMITTEE DISCUSSION
- 3:30 ADJOURN

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ALLERGENIC PRODUCTS ADVISORY COMMITTEE  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH  
February 10, 2000

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