DRAFT AGENDA (Draft version of 2/20/01)

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

ALLERGENIC PRODUCTS ADVISORY COMMITTEE MEETING

March 5, 2001

Holiday Inn Bethesda
Versailles I and II
8120 Wisconsin Avenue
Bethesda, MD 20184

8:30 a.m. Opening remarks
Dennis R. Ownby, Chairman

8:40 **I. REPORTS**

8:40 Laboratory of Immunobiochemistry Personnel Update
Jay E. Slater, M.D., DBPAP
Division of Bacterial, Parasitic and Allergenic Products (DBPAP)
OVRR, FDA

8:45 Lot Release Statistics

8:50 New Guidance Documents

9:00 Research Update

9:20 Cockroach Standardization

9:40 Compliance Report,
Mary Anne Malarkey, OCBQ, FDA

10:00 BREAK

10:10 a.m. **II. REGULATORY UPDATES**

Discussion of whether master seed stocks of mold strains used for allergenic extracts should be rederived to reduce a theoretical risk of Transmissible Spongiform Encephalopathy (TSE) transmission.

10:10 TSE as it affects allergens, Jay E. Slater, M.D., DBPAP

10:40 Committee discussion

11:10 Open Public Hearing

Allergenic Product Advisory Committee

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Monday March 5, 2001 (continued)

II. REGULATORY UPDATES (continued)

Discussion of the statistical power of clinical studies used to assess bioequivalence as it applies to allergen extract studies.

11:40 Statistical power of clinical studies comparing allergen extracts
Peter A. Lachenbruch, Ph.D., OBE, FDA
and Jay E. Slater, M.D., DBPAP
12:10 Committee Discussion

12:40 p.m. Lunch

Discussion of particulates that appear in allergen extracts and the effect of these particulates on the safety and efficacy of these products

1:40 Particulates in allergen extracts
Jennifer Bridgewater, MPH, DBPAP
2:00 Invited comments from the Allergenic Products Manufacturers Association
2:20 Open Public Hearing
2:50 Committee Discussion

3:30 p.m. ADJOURN