AGENDA

FOOD AND DRUG ADMINISTRATION '01 OCT -3 P1:25
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, M.D., Chairman

8:40 a.m. **I. REPORTS**

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

8:45 Lot Release Statistics

8:50 New Guidance Documents

9:00 Research Update

9:30 Cockroach Standardization

9:50 Compliance Report,
Mary Anne Malarkey, Office of Compliance and Biologics Quality (OCBQ), FDA

10:15 a.m. BREAK

10:30 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.

10:30 TSE as it affects allergens, Jay E. Slater, M.D., DBPAP, FDA

11:00 Committee discussion

11:30 Open Public Hearing

This is the final Agenda

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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.

12:00 Statistical power of clinical studies comparing allergen extracts
Peter A. Lachenbruch, Ph.D., OBE, FDA
and Jay E. Slater, M.D., DBPAP, FDA
12:30 Committee discussion

12:50 p.m. Lunch

Discussion of the effect of particulates on allergen extracts.

1:50 Particulates in allergen extracts
Jennifer Bridgewater, MPH, DBPAP, FDA
2:10 Invited comments from the Allergenic Products Manufacturers Association
Shirley Williamson, President, APMA,
2:30 Open Public Hearing
3:00 Committee Discussion

3:45 p.m. ADJOURN