

BLOOD PRODUCTS ADVISORY COMMITTEE  
73rd Meeting - June 13-14, 2002  
Gaithersburg Holiday Inn  
2 Montgomery Village Avenue  
Gaithersburg, MD 20877

Thursday, June 13, 2002

8:00 a.m. Welcome, Statement of Conflict of Interest,  
Announcements

8:10 a.m. Committee Updates

- Current IGIV Supply - Mark Weinstein, Ph.D.

8:45 a.m. Open Committee Discussion

- Recent Western Blot Shortage (Informational) - Paul Mied, Ph.D.
- Electronic Submission of Applications (Informational) - Michael Fauntleroy

10:30 a.m. BREAK

11:00 a.m. Open Committee Discussion

I. Standards for Recovered Plasma

- A. Introduction and Background - Elizabeth Callaghan, Deputy Director, Division of Blood Applications, OBRR
- B. Presentation - Sharon O'Callaghan, Consumer Safety Officer, OCBQ  
Kay Lewis, Chief, Blood and Tissue Compliance Branch, OCBQ
- C. Industry Presentations
  - PPTA - Barbara Whitaker
  - AABB - Kay Gregory
  - ABC - Celso Bianco
  - ARC - Don Fipps

12:30 p.m. OPEN PUBLIC HEARING

1:00 p.m. Open Committee Discussion

- D. Questions for the Committee
- E. Committee Discussion and Recommendations

1:30 p.m. LUNCH

2:30 p.m. *Open Committee Discussion*

II. Uniform Donor History Questionnaire (UDHQ)

- A. Introduction and Background - Alan Williams, Ph.D., Director, Division of Blood Applications, OBRR
- B. Overview of AABB Task Force UDHQ Project - Joy Fridey, MD, Senior VP, Medical Affairs Blood Bank of San Bernardino and Riverside County, Chair, AABB UDHQ Task Force
- C. UDHQ Cognitive Studies - Paul Beatty, Cognitive Methods Staff, National Center for Health Statistics
- D. FDA Status of Review of the AABB Task Force UDHQ - Judy Ellen Ciaraldi, BS, MT(ASCP) SBB, Consumer Safety Officer, Division of Blood Applications, OBRR

4:00 p.m. OPEN PUBLIC HEARING

4:30 p.m. BREAK

4:45 p.m. *Open Committee Discussion*

- E. Questions for the Committee- Alan Williams, Ph.D.
- F. Committee Discussion and Recommendations

5:30 p.m. RECESS (until 8:00 a.m., Friday, June 14, 2002)

Friday, June 14, 2002

8:00 a.m. Committee Updates

- Summary of FDA/PPTA Workshop on Comparability of Plasma Derivatives - Andrew Chang, Ph.D.
- Summary on AABB Conference on Oxygen Therapeutics - Toby Silverman, M.D.

8:30 a.m. Open Committee Discussion

- Requirements for Premarket Submissions: In-vitro Diagnostic Software and Instruments (Informational) -
  1. Diane Gubernot, DETTD, OBRR
  2. Sheryl Kochman, DBA, OBRR
  3. James Callaghan, DCLD, ODE, CDRH

10:00 a.m. BREAK

10:30 a.m. Open Committee Discussion

III. Reported Association of 6% Hetastarch with Excess Bleeding in Open Heart Surgery

- A. Introduction and Background - Laurence Landow, M.D., Medical Officer, Clinical Review Branch, DH, OBRR
- B. Presentation - Charles C. Canver, M.D.
- C. Presentation - William J. Sibbald, M.D.
- D. Presentation - Gary R. Haynes, M.D., Ph.D

12 NOON OPEN PUBLIC HEARING

12:30 p.m. Open Committee Discussion

- E. FDA summary and questions for the Committee
- F. Committee Discussion and Recommendations

1:30 p.m. ADJOURNMENT