

BLOOD PRODUCTS ADVISORY COMMITTEE
81st Meeting - October 21-22, 2004
Gaithersburg Holiday Inn, 2 Montgomery Village Avenue
Gaithersburg, MD 20877

Thursday, October 21, 2004

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

8:45 a.m. Committee Updates

- Summary of TSEAC Discussion of vCJD Transmission by
Transfusion in the United Kingdom - David Asher, MD (15')
- Supplemental Testing for HIV and HCV - Martin Ruta, PhD (15')

9:15 a.m. *Open Committee Discussion*

- I. FDA's Current Thinking on Re-entry of Donors Previously
Deferred for Anti-HBc Reactivity
 - A. Introduction and Background - Gerardo Kaplan, PhD,
Chief, Laboratory of Hepatitis and Related Emerging
Agents, DETTD (10')
 - B. Serological course of HBV - Blaine Hollinger, MD,
Baylor College of Medicine (20')
 - C. Studies of Deferred Donors - Susan Stramer, PhD,
American Red Cross - (20')
 - D. Studies of Deferred Donors - Thomas Clement, Roche
Diagnostics (20')

10:30 a.m. OPEN PUBLIC HEARING

- manufacturers

11:00 a.m. BREAK

11:30 a.m. *Open Committee Discussion*

- E. FDA Perspective and Questions for the Committee
- F. Committee Discussion and Recommendations

12:30 p.m. LUNCH

1:30 p.m. *Open Committee Discussion*

- II. Potential Risk of Transmission of Simian Foamy Virus (SFV)
by Blood Transfusions

- A. Introduction and Background - Edward Tabor, MD,
Associate Director for Medical Affairs, OBRR (10')

- B. Simian Foamy Virus Epidemiology - Walid Heneine, MD - Centers for Disease Control and Prevention (20')
- C. Simian Foamy Virus Transmission Studies - Arifa Kahn, PhD, Office of Vaccine Research and Review, CBER (20')
- D. Recent Research Results - Dr. James Brooks, Health Canada (15')
- E. Regulatory Considerations - Dr. Peter R. Ganz, Director, Centre for Biologics Evaluation, Health Canada (10')
- F. Demographics of Primate Handlers - Nicholas W. Lerche, DVM, MPVM, University of California, Davis (20')

3:45 p.m. BREAK

4:00 p.m. OPEN PUBLIC HEARING

4:30 p.m. Open Committee Discussion

G. Questions for the Committee

H. Committee Discussion and Recommendations

5:30 p.m. RECESS (until 8:30 a.m. Friday, October 22, 2004)

Friday, October 22, 2004

8:30 a.m. Committee Updates

- Summary of Plasma Workshop held on 8/31-9/1/04 - Mark Weinstein, PhD (15')
- Draft UDHQ Acceptance Guidance: Review of Public Comments Judy Ciaraldi, BS, MT(ASCP) SBB(15')
- FDA's Current Thinking on Monitoring Weight in Source Plasma Donors - Linda Alms, BS (10')

9:15 a.m. Open Committee Discussion

III. FDA's Current Thinking on Donor Deferral for Potential or Documented Infection with West Nile Virus

- A. Introduction and Background - Hira Nakhasi, PhD, Director, Division of Emerging and Transfusion Transmitted Diseases, OBRR (10')
- B. Summary of 2004 Epidemic - Theresa Smith, MD, MPH, FACP, FIDSA, Centers for Disease Control and Prevention (15')
- C. Duration of Viremia/Experience with ID NAT
 1. Michael Busch, MD, PhD, Blood Centers of the Pacific (15')
 2. Susan Stramer, PhD, American Red Cross (15')

D. Current Thinking on Donor Deferral - Alan Williams,
PhD, Director, Division of Blood Applications, OBRR
(10')

E. Questions for the Committee - Alan Williams, Ph.D.

10:30 a.m. BREAK

11:00 a.m. OPEN PUBLIC HEARING
- Manufacturers

11:45 a.m. *Open Committee Discussion*
F. Committee Discussion and Recommendations

1:00 p.m. ADJOURNMENT