BLOOD PRODUCTS ADVISORY COMMITTEE
78th Meeting - December 11-12, 2003
Hilton Gaithersburg, 620 Perry Parkway
Gaithersburg, MD 20877

Thursday, December 11, 2003

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

8:05 a.m. Update

- Use of Secure E-Mail - Michael Fauntleroy (10')

8:15 a.m. Open Committee Discussion

I. American Association for Blood Banks (AABB) Abbreviated Questionnaire
   A. Introduction and Background - Judy Ciaraldi, MT (ASCP)SBB, Consumer Safety Officer, OBRR (15')
   B. AABB UDHQ Task Force Perspective on Abbreviated Questionnaires - Mary Townsend, MD, Chair, UDHQ Task Force, AABB (15')
   C. FDA Regulatory and Review Issues
      - Judy Ciaraldi, MT (ASCP) SBB, Consumer Safety Officer, OBRR (15')
      - Sharon O'Callaghan, MT (ASCP), Consumer Safety Officer, OCBQ (15')
   D. Experiences Using Abbreviated Questionnaires
      - Mary Beth Bassett, MS, MT(ASCP) SBB, Vice President, Quality Management and Regulatory Affairs, Blood Systems, Inc.(15')
      - Stacy Sime, MS, MT (ASCP) SBB, The Blood Center of Iowa (15')
   E. Can Abbreviated Questionnaires Be Studied/Tested? - Paul Beatty, PhD, NCHS,CDC (15')
   F. Validation of Donor Screening Procedures - Alan Williams, PhD, Director, Division of Blood Applications, OBRR (10')

10:00 a.m. BREAK

10:30 a.m. OPEN PUBLIC HEARING

A-4014

11:00 a.m *Open Committee Discussion*

G. FDA Current Thinking and Questions for the Committee

H. Committee Discussion and Recommendations

11:30 a.m. II. Potential Recommendations on Blood Donor Deferral for Leishmaniasis and Its Exposure

A. Introduction and Background - Robert Duncan, PhD, Staff Scientist, DETTD, OBRR (20')

B. Leishmania Pathogenesis and Epidemiology - Barbara Herwaldt, MD, M.P.H., Medical Epidemiologist, Centers for Disease Control (25')

C. Department of Defense Leishmaniasis Donor Deferral Policy - Ruth D. Sylvester, Lt Col, USAF, BSC, Director of Operations, Armed Services Blood Program, DoD (25')

D. Impact of Leishmaniasis Donor Deferral Policy on the Blood Supply - Sharyn Orton, PhD, Acting Chief, Blood and Plasma Branch, DBA, OBRR (20')

1:00 p.m. LUNCH

2:00 p.m. OPEN PUBLIC HEARING

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

E. FDA Current Thinking and Questions for the Committee

F. Committee Discussion and Recommendations

3:00 p.m. III. Update on West Nile Virus Epidemic and Donor Testing in 2003

A. Introduction and Background - Hira Nakhasi, PhD, Director, Division of Emerging and Transfusion Transmitted Diseases, OBRR, CBER (20')

B. Update on Epidemiology Including Reports of Transfusion-Transmitted Cases - Anthony Marfin, MD, Acting Deputy Director, Division of Vector-Borne Infectious Diseases, Centers for Disease Control (20')

3:40 p.m. BREAK

3:55 p.m. *Open Committee Discussion*

C. Updates on WNV Testing Under IND and Plans for 2004
   1. American Red Cross - Susan Stramer, PhD Executive Scientific Director, The American Red Cross (15')
   2. GenProbe - Jeff Linnen (15')
   3. Roche - James Gallarda (15')

D. Status Reports
   1. Prospective and Retrospective Testing Using ID-NAT and Update on Relative Sensitivity Study for WNV NAT Testing - Michael Busch, MD, PhD, Blood Centers of the Pacific (25')
   2. Prospective and Retrospective Testing Using ID-NAT - Susan Stramer, PhD (15')
   3. Follow-up Testing of Canadian Donors who Tested Positive for WNV RNA by Routine Screening/ Establishment of a Reference Reagent for WMV NAT Assays - John Saldanha, Executive Director, Infectious Diseases, Canadian Blood Services (10')
   4. Update on Infectivity Study - Indira Hewlett, PhD, Chief, Molecular Virology Branch, DETTD, OBRR (10')

5:30 p.m. OPEN PUBLIC HEARING

6:00 p.m. *Open Committee Discussion*

E. Committee Discussion

6:30 p.m. RECESS (8:00 a.m. Friday, December 12, 2003)

Friday, December 12, 2003

8:00 a.m. Committee Updates

- Medical Device User Fee and Modernization Act of 2002 Update - Mary E. Jacobs, PhD (10')
- Summary of Factor VIII Inhibitor Workshop -Jay Lozier, MD, PhD (15')
- Platelet Testing and Evaluation Guidance - Jaro Vostal, MD, PhD (15')
- Freezing and Storage Temperatures for Source Plasma and Fresh Frozen Plasma - Elizabeth Callaghan, MS, SBB (5')

9:30 a.m. OPEN PUBLIC HEARING

10:15 a.m. BREAK

10:45 a.m. IV. Review of Plasma Collection Nomograms

A. Introduction and Background - Les Holness, MD, Medical Officer, Blood and Plasma Branch, DBA, OBRR (15')

B. Review of Nomogram Volumes - Laurence Landow, MD, Medical Officer, Clinical Review Branch, DH, OBRR (20')

C. Review of Statistical Data - Timothy R. Coté, MD, MPH, OBE, Chief, Therapeutics and Blood Safety Branch, OBE, CBER (15')

D. Experience in Other Countries - Prof. Peter Hellstern, Institute of Hemostaseology and Transfusion Medicine, Academic City Hospital Ludwigshafen, Germany (20')

12 Noon Lunch

1:00 p.m. Open Public Hearing

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

F. FDA Current Thinking and Questions for the Committee

G. Committee Discussion

3:00 p.m. ADJOURNMENT