BLOOD PRODUCTS ADVISORY COMMITTEE
79th Meeting - March 18-19, 2004
Gaithersburg Holiday Inn, 2 Montgomery Village Avenue
Gaithersburg, MD 20877

Thursday, March 18, 2004

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

8:05 a.m. *Open Committee Discussion*

I. Clinical Trials for Licensing Hepatitis B Immune Globulin Intravenous as Treatment to Prevent HBV Liver Disease Following Liver Transplantation in HBV+ Recipients (3.5 hrs)

A. Introduction and Background - Basil Golding, MD, Director, Division of Hematology, OBRR (15')

B. Presentation - Anna S. Lok, MD, Director of Clinical Hepatology, University of Michigan Medical Center (70')

9:30 a.m. OPEN PUBLIC HEARING

10:00 a.m. BREAK

10:30 a.m. *Open Committee Discussion*

C. FDA Current Thinking and Questions for the Committee

D. Committee Discussion and Recommendations

11:15 a.m. Committee Updates

- Current Thinking on Variances to Address the Specificity Issues of Ortho HBsAg 3.0 Assays - Gerardo Kaplan, PhD (15')
- Summary of Meeting of PHS Advisory Committee on Blood Safety Availability - Jerry Holmberg, MD (15')
- Summary of Meeting of Transmissible Spongiform Encephalopathies Advisory Committee Meeting - David Asher, MD (15')

4025 A

- Current Thinking on Draft Guidance for Nucleic Acid Testing (NAT) for HIV and HCV: Testing, Product Disposition, and Donor Deferral and Re-entry - Paul Mied, PhD (15')
- Current Thinking on Final Guidance for Use of Nucleic Acid Testing (NAT) on Pooled and Individual Samples from Donors of Whole Blood and Blood Components to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV - Pradip Akolkar, PhD and Judy Ciaraldi, BS, MT (15')

12:30 p.m. LUNCH

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

II. Supplemental Testing for Human Immune Deficiency Virus (HIV) and Hepatitis C Virus (HCV) (3.5 hrs)

A. Introduction and Background - Robin Biswas, MD and Indira Hewlett, PhD, DETTD, OBRR, FDA (30')

B. Performance of HIV and HCV Supplemental Assays

1. Wendi L.Kuhnert, PhD, Chief, Hepatitis Reference Laboratory, Division of Viral Hepatitis, CDC - (15')
2. Dale J. Hu, MD, MPH, Acting Associate Director for Science , Division of AIDS, STD and TB Laboratory Research, CDC - (15')
3. Susan L. Stramer, PhD, Executive Scientific Officer, American Red Cross - (20')
4. Michael Busch, MD, PhD, Director, Blood Systems Research Institute, University of California, San Francisco - (20')

3:30 p.m. BREAK

3:45 p.m. OPEN PUBLIC HEARING

4:15 p.m. *Open Committee Discussion*

C. Questions for the Committee

D. Committee Discussion and Recommendations

5:00 p.m. RECESS (8:00 a.m. Friday, March 19, 2004)

Friday, March 19, 2004

8:00 a.m. Open Committee Discussion (3.5 hrs)

III. FDA's Current Thinking on Product Standards, Quality Assurance, and Submission Requirements for Platelets, Pheresis

A. Introduction and Background - Alan E. Williams, PhD, Director, Division of Blood Applications, OBRR (15')

B. FDA Update: Collection of Platelets Pheresis by Automated Methods: Current Thinking: Including Quality Control - Sharyn Orton, PhD, Acting Chief, Blood and Plasma Branch, Division of Blood Applications (20')

C. Laboratory Evaluation of Platelet Components Submitted to CBER - Betsy Poindexter, Biologist, Division of Hematology (20')

D. Strategies for Quality Assurance Monitoring - Alan E. Williams, PhD (20')

E. Blood Center Perspective on Plateletpheresis Quality Control - German F. Leparc, MD, Chief Medical Officer, Florida Blood Services, Inc. (20')

9:30 a.m. OPEN PUBLIC HEARING

10:00 a.m. BREAK

10:30 a.m. Open Committee Discussion

F. FDA Current Thinking and Questions for the Committee

G. Committee Discussion and Recommendations

11:30 a.m. LUNCH

12:30 p.m. Open Committee Discussion

IV. Review of Site Visit of the Laboratory of Hepatitis and Related Emerging Agents and the Laboratory of Bacterial, Parasitic, and Unconventional Agents, Division of Emerging and Transfusion Transmitted Diseases, OBRR, CBER

A. Introduction and Overview - Kathryn Carbone, MD, Acting Associate Director for Research, CBER

B. Overview of Office of Blood Research and Review - Jay Epstein, MD, Director, Office of Blood Research and Review

C. Overview of Division of Emerging Transfusion Transmitted Diseases, OBRR - Hira Nakhasi, PhD, Director, Division of Emerging and Transfusion Transmitted Diseases, OBRR

D. Summary Presentation - Edward Tabor, MD, Viral Pathogenesis Section, Laboratory of Hepatitis and Related Emerging Agents, DETTD, OBRR

E. Summary Presentation - Gerardo Kaplan, PhD, Laboratory of Hepatitis and Related Emerging Agents, DETTD, OBRR

F. Summary Presentation - David Asher, MD, Laboratory of Bacterial, Parasitic and Unconventional Agents

2:15 p.m. CLOSED SESSION

3:00 p.m. ADJOURNMENT