BLOOD PRODUCTS ADVISORY COMMITTEE

83rd Meeting
Gaithersburg Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, MD 20877

Thursday, July 21, 2005

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

8:10 a.m. Committee Updates

- **Summary of May 2005 Meeting of the DHHS Advisory Committee on Blood Safety and Availability – Jerry Holmberg, Ph.D., Executive Secretary, Advisory Committee on Blood Safety and Availability (10')**

- **Disseminated Intravascular Coagulation Associated with Acute Hemoglobinemia Following Anti-D IGIV Administration for Idiopathic Thrombocytopenic Purpura – Ann Gaines, Ph.D., OBE, FDA (15')**

- **Update on Safety of Albumin – Laurence Landow, M.D., OBRR, FDA (5')**

- **Summary of June 2005 Workshop on Biological Therapeutics for Rare Plasma Protein Disorders – Mark Weinstein, Ph.D., OBRR, FDA (10')**

- **Summary of July 2005 Workshop on Leukoreduction - Alan Williams, Ph.D., OBRR, FDA (10')**

- **Update on West Nile Virus Guidance – Alan Williams, Ph.D., Maria Rios, Ph.D., OBRR, FDA and CDR Matthew Kuehnert, Ph.D, CDC (15')**

9:30 a.m. *Open Committee Discussion*

I. Management of Donors and Units that Test Positive for Hepatitis B Virus (HBV) DNA by Nucleic Acid Tests (NAT)

A. Introduction and Background – Robin Biswas, M.D., OBRR, FDA (15')

B. HBV Seroconversion Panel Results and HBV NAT Positive/Serology Negative Donors - Larry Pietrelli, Roche Molecular Diagnostics (10')

C. Temporal Association of HBV NAT and HBsAg Reactivity in Prospectively Screened Source Plasma Donations and Retrospectively Screened Seroconversion Panels – Richard Smith, Ph.D., National Genetics Institute (10')

D. Window Period Detection of HBV with the Procleix

Ultrio Assay - Larry Mimms, Ph.D., Gen-Probe (10')

10:15 a.m. BREAK

10:30 a.m. OPEN PUBLIC HEARING

11:00 a.m. *Open Committee Discussion*

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

12:00 p.m. LUNCH

1:00 p.m.

II. Scientific Basis for Review of Varicella Zoster Immune Globulin

A. Background - Dorothy Scott, M.D., OBRR, FDA (15')
B. VZIG Manufacture, Potency Testing and Current Supply Status - Donna Ambrosino, M.D., MPHBL; Catherine A. Hay, Ph.D, MPHBL (15')
C. Severe Varicella Zoster Disease, Correlates of Protection and Post-Exposure Prophylaxis Options - Philip La Russa, M.D., Professor Clinical Pediatrics, Columbia University (45')
D. Advisory Committee for Immunization Practices Recommendations for Post-Exposure Prophylaxis of Severe Varicella Infections - Mona Marin, M.D., Medical Epidemiologist, National Immunization Program, Center for Disease Control (15')

2:30 p.m. OPEN PUBLIC HEARING

3:00 p.m. *Open Committee Discussion*

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

3:45 p.m. Break
4:00 p.m.

III. Dextran 1 Pre-treatment For Safe Use of Dextran 40/70

A. Introduction and Background - Laurence Landow, M.D., OBRR, FDA (10')
B. Prevention of Adverse Reactions to Dextran - Karl-Gösta Ljungström M.D., Ph.D., Consultant Vascular Surgeon, Associate Professor of Surgery, Karolinska Institute, Department of Surgery, Danderyd Hospital, Sweden (25')

5:00 p.m. OPEN PUBLIC HEARING

5:30 p.m. *Open Committee Discussion*

C. FDA Perspective and Questions for the Committee

D. Committee Discussion and Recommendations

6:30 p.m. **Adjournment**