BLOOD PRODUCTS ADVISORY COMMITTEE

82nd Meeting – March 17-18, 2005
Gaithersburg Holiday Inn, 2 Montgomery Village Avenue
Gaithersburg, MD 20877

Thursday, March 17, 2005

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

8:30 a.m. Committee Updates

- **Meeting Summary of DHHS Advisory Committee on Blood Safety and Availability – Jerry Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability (15')**
- **Summary of TSEAC Meeting – David Asher, MD, OBRR, FDA (15')**
- **Update on West Nile Virus Guidance – Alan Williams, PhD, OBRR, FDA (10)**
- **Critical Path Initiative Workshop Summary**
  - **A. CBER Overview - Kathryn Carbone, MD, OD, CBER, FDA (10')**
  - **B. OBRR Summary – Paul Mied, PhD, OBRR, FDA (10')**
  - **C. Clinical Trial Design – Mary Foulkes, PhD., OBE, FDA (10')**

9:40 a.m. *Open Committee Discussion*

I. Safety of Albumin Revisited
- **A. Introduction and Background – Laurence Landow, MD, OBRR, FDA (5')**
- **B. Review of the Cochrane Report – Paul Hebert, MD, Vice Chair of Research, Ottawa Health Research Institute Ontario, Canada (20')**
- **C. Review of the SAFE Study - Simon Finfer, MD, Senior Staff Specialist in Intensive Care, University of Sydney, Australia (35')**

10:40 a.m. BREAK

11:00 a.m. OPEN PUBLIC HEARING

12:00 p.m. *Open Committee Discussion*
- **D. FDA Perspective and Questions for the Committee**
- **E. Committee Discussion and Recommendations**

1:00 p.m. LUNCH

BLOOD PRODUCTS ADVISORY COMMITTEE

2:00 p.m. Committee Updates
- **Update on International Agreements – Mark Weinstein, PhD, OBRR, FDA (15')**
- **Sharing Information with the Public – Kathleen Swisher, RN JD, OD, FDA (15')**

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

II. Review of Standards for Plasma Products for Transfusion
A. Introduction and Review of the Literature - Mark Weinstein, PhD (40')
B. Presentation (clinical use of plasma) – Irma O. Szymanski, MD. Professor Emerita of Pathology, University of Massachusetts (20')

3:30 p.m. BREAK

3:50 p.m. OPEN PUBLIC HEARING

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

C. FDA Perspective and Questions for the Committee
D. Committee Discussion and Recommendations

5:30 p.m. RECESS (until 8:30 a.m. Friday, March 18,2005)

DAY TWO
BLOOD PRODUCTS ADVISORY COMMITTEE

Friday, March 18, 2005
8:30 a.m. ***Open Committee Discussion***

III. Study Design for Abbreviated Uniform Donor History Questionnaire
A. Background and Introduction - Sharyn Orton, PhD, OBRR FDA (5')
B. Study Design - Debra Kessler, RN, MS, Donor History Task Force & Director Regional Services, New York Blood Center (40')
C. Experience with an Abbreviated Donor History Questionnaire - Mary Beth Bassett, BS Medical Technology (ASCP) and Microbiology, Vice President of Quality Assurance & Regulatory Affairs, Blood Systems Inc.(15')

9:30 a.m. OPEN PUBLIC HEARING

10:00 a.m. ***Open Committee Discussion***
D. FDA Perspective and Questions for the Committee
E. Committee Discussion and Recommendations

11:00 a.m. BREAK

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

IV. Review of Site Visit Report for the Laboratory of Molecular Virology, DETTD

A. **Introduction and Background - Hira Nakhasi, PhD, Director, Division of Emerging and Transfusion Transmitted Diseases, OBRR (5')**
B. **Overview of Laboratory and Diagnosis and Pathogenesis of HIV variant: a progress report - Indira Hewlett Chief, Laboratory of Molecular Virology OBRR, FDA PhD (15')**
C. **The Molecular Biology of HIV Infection of Primary Human Macrophages - Andrew Dayton, MD, PhD, Section Head, LMV, OBRR, FDA (10')**
D. **Viral and Host Factors in the Pathogenesis of HIV-1 Infection: an overview - Subhash Dhawan, PhD, Section Head, LMV, OBRR, FDA (10')**
E. **West Nile Virus: pathogenesis and diagnostic tools - Maria Rios, Ph.D., Senior Staff Fellow, LMV, OBRR, FDA PhD (10')**

12:30 a.m. LUNCH

1:30 p.m. ***Closed Committee Discussion***
Committee Discussion and Recommendations

2:30 p.m. ADJOURNMENT