

**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

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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')

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Friday, March 18, 2005 (page 3)

- 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