

BLOOD PRODUCTS ADVISORY COMMITTEE

80<sup>th</sup> Meeting - July 22-23, 2004

Gaithersburg Holiday Inn, 2 Montgomery Village Avenue

Gaithersburg, MD 20877

Thursday, July 22, 2004

- 8:00 a.m. Welcome, Statement of Conflict of Interest, Announcements
- 8:05 a.m. Committee Updates
- FDA Current Thinking on TRALI - Leslie Holness, MD (15')
  - Donor Blood Pressure Determination - Alan Williams, PhD (15')
- 8:35 a.m. OPEN PUBLIC HEARING
- 9:00 a.m. Open Committee Discussion
- I. Dating of Irradiated Red Blood Cells
    - A. Introduction and Background - Ping He, MD, Senior Staff Fellow, Laboratory of Cellular Hematology, DH, OBRR, FDA (15')
    - B. Presentation - Gary Moroff, PhD, Director, Blood Development, Holland Laboratory, American Red Cross (20')
    - C. Presentation - Larry Dumont, Scientist, Gambro BCT Inc. (20')
    - D. Presentation - Dean Elfath, MD, VP Global Medical & Scientific Affairs, Baxter Healthcare Corp. (20')
    - E. Presentation - Jessica Kim, PhD, Mathematical Statistician, DB, OBE, CBER, FDA (15')
- 10:30 a.m. BREAK
- 11:00 a.m. OPEN PUBLIC HEARING
- 11:30 a.m. Open Committee Discussion
- E. FDA Current Thinking and Questions for the Committee - Jaro Vostal, MD, PhD, Chief, Laboratory of Cellular Hematology, DH, OBRR, FDA (15')
  - F. Committee Discussion and Recommendations

12:30 p.m. LUNCH

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

II. New Standard for Platelet Evaluation

- A. Introduction and Background - Salim Haddad, MD, Medical Officer, Laboratory of Cellular Hematology, DH, OBRR, FDA (15')
- B. Presentation - James AuBuchon, MD, Chair of Pathology, Dartmouth-Hitchcock Medical Center (15')
- C. Presentation - Edward Snyder, MD, Director, Department of Laboratory Medicine, Yale-New Haven Hospital (15')

2:15 p.m. OPEN PUBLIC HEARING

2:45 p.m. *Open Committee Discussion*

- D. FDA Current Thinking and Questions for the Committee - Jaro Vostal, MD, PhD (15')
- E. Committee Discussion and Recommendations

3:30 p.m. BREAK

3:45 p.m. *Open Committee Discussion*

III. Experience with Monitoring of Bacterial Contamination of Platelets

- A. Introduction and Background - Jaro Vostal, MD, PhD (20')
- B. Summary of ACBSA Meeting: Bacterial Contamination - Jerry A. Holmberg, PhD, Senior Advisory for Policy, Executive Secretary, DHHS Advisory Committee on Blood Safety and Availability, OS, OPHS, DHHS (20')
- C. Presentation - Steven Kleinman, MD, American Association of Blood Banks (AABB) Task Force (20')

4:45 p.m. OPEN PUBLIC HEARING

5:15 p.m. *Open Committee Discussion*

- D. Committee Discussion and Recommendations

6:15 p.m. RECESS (8:00 a.m. Friday, July 23, 2004)

Friday, July 23, 2004

8:00 a.m. Committee Updates

- Update on West Nile Virus - Hira Nakhasi, PhD (15')

8:15 a.m. Open Committee Discussion

IV. Hepatitis B Virus Nucleic Acid Testing (NAT) for Donors of Whole Blood

A. Introduction and Background - Gerardo Kaplan, PhD, Chief Laboratory of Hepatitis and Related Emerging Viruses, DETTD, OBRR, FDA (15')

B. Serological Course of Hepatitis B - F. Blaine Hollinger, MD, Professor of Medicine, Baylor College of Medicine (20')

C. Pre-clinical and Clinical data for HBV MP NAT -

1. Steven Herman, PhD, Director, Blood Screening Development, Roche Molecular Systems (20')

2. Allan Frank, MD, MS, Senior, Director, Clinical Affairs, Roche Molecular Systems (20')

D. FDA Perspective on HBV MP NAT and Questions for the Committee - Gerardo Kaplan, PhD (15')

9:45 a.m. Break

10:15 a.m. Open Public Hearing

11:15 a.m. Open Committee Discussion

E. Committee Discussion and Recommendations

12:15 p.m. LUNCH

1:15 p.m. Open Committee Discussion

V. Current Trends in Plasma Product Manufacturing (Informational)

A. Introduction and Background - Mark Weinstein, PhD, Associate Deputy Director, OBRR, FDA (20')

B. Presentation - Jan M. Bult, CEO, Plasma Protein Therapeutics Association (25')

2:00 p.m. Open Public Hearing

2:30 p.m. Open Committee Discussion

C. Committee Discussion

3:00 p.m. ADJOURNMENT