

Draft Agenda: 7/14/2004

BLOOD PRODUCTS ADVISORY COMMITTEE

80th 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

- Donor Blood Pressure Determination - Alan Williams, PhD

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

B. Presentation - Gary Moroff, PhD, Director, Blood Development, Holland Laboratory, American Red Cross

C. Presentation - Larry Dumont, Scientist, Gambro BCT Inc.

D. Presentation - Dean Elfath, MD, VP Global Medical & Scientific Affairs, Baxter Healthcare Corp.

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

F. Committee Discussion and Recommendations

12:30 p.m. LUNCH

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

II. New Standard for Platelet Evaluation

2004-4057A1 - DRAFT

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

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

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
- 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
- C. Presentation - Steven Kleinman, MD, American Association of Blood Banks (AABB) Task Force

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

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

B. Serological Course of Hepatitis B - tba

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

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

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, IOD, OBRR, FDA

B. Presentation - Jan M. Bult, Plasma Protein Therapeutics Association

2:00 p.m. Open Public Hearing

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

C. Committee Discussion

3:00 p.m. ADJOURNMENT

