

BLOOD PRODUCTS ADVISORY COMMITTEE
72nd Meeting - March 14-15, 2002
Gaithersburg Holiday Inn
2 Montgomery Village Avenue
Gaithersburg, MD 20877

Thursday, March 14, 2002

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

8:10 a.m. Committee Updates

- Nucleic Acid Testing for Whole Blood: Including Standards for HIV-1 and HCV RNA - Indira Hewlett, Ph.D.
- Nucleic Acid Testing for Parvovirus B19 - Mei-ying Yu, Ph.D.
- Nucleic Acid Testing for Hepatitis A Virus - Gerardo Kaplan, Ph.D.
- Draft "Guidance for Industry on Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts" - Andrew Dayton, M.D., Ph.D.
- Announcement of Planned FDA Workshops

9:45 a.m. BREAK

10:00 a.m. Open Committee Discussion

I. Emergency Preparedness - Informational Presentation

- A. OBRR Strategic Plan - Richard Lewis, Ph.D.
- B. Supply Management - Karen Lipton, Esq., AABB Task Force
- C. Summary of PHS Advisory Committee on Blood Safety and Availability Meeting, January 31-February 1, 2002 - Stephen Nightingale, M.D.
- D. OBRR Divisional Initiatives
 - Division of Hematology - Basil Golding, M.D.
 - Division of Emerging and Transfusion Transmitted Diseases - Hira Nakhasi, Ph.D.
 - Division of Blood Applications - Manette Niu, M.D.

12:30 p.m. OPEN PUBLIC HEARING

1:00 p.m. Open Committee Discussion

E. Committee Discussion

1:30 p.m. LUNCH

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

II. Discussion on Percutaneous Exposure of Blood and Plasma Donors: Tattoos and Body Piercing

- A. Introduction and Background - Alan Williams, Ph.D., Director, Division of Blood Applications, OBRR, FDA
- B. Epidemiological Studies Evaluating Risk of Viral Hepatitis Infection from Tattoos and Body Piercing - Miriam Alter, Ph.D., Chief, Epidemiology Branch, Division of Viral Hepatitis, CDC
- C. Prevalence and Characterization of Deferrals for Tattoo, Accupuncture and Skin/Body Piercing Who Fail to Self-Defer - Sharyn Orton, Ph.D. Regulatory Project Manager, Division of Blood Applications
 - i) Donor Deferral Estimates
 - ii) REDS Survey Data

3:30 p.m. BREAK

3:45 p.m. OPEN PUBLIC HEARING

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

- D. Questions for the Committee - Alan Williams, Ph.D.
- E. Committee Discussion and Recommendations

5:30 p.m. RECESS (until 8:00 a.m., Friday, March 15, 2002)

Friday, March 15, 2002

8:00 a.m. *Open Committee Discussion*

III. Review of Data Supporting Extension of Dating Period
for Platelets

- A. Introduction and Background -Jaro Vostal, M.D.,
Ph.D., Chief, Laboratory of Cellular Hematology,
Division of Hematology OBRR, CBER
- B. Presentation - Sherrill Slichter, M.D., Executive
Vice President of Research, Puget Sound Blood
Center, Seattle, WA
- C. Presentation - James AuBuchon, M.D., Professor
and Chair of Pathology, Dartmouth-Hitchcock
Medical Center, Lebanon, NH

9:30 a.m. OPEN PUBLIC HEARING

10:00 a.m. BREAK

10:30 a.m. *Open Committee Discussion*

D. Committee Discussion

11:30 a.m. LUNCH

12:30 p.m. *Open Committee Discussion*

IV. Bacterial and Fungal Contamination of Human Tissue
Intended for Transplantation

- A. Introduction and Background - Ruth Solomon,
M.D., Director, Human Tissue Staff, OBRR, CBER
- B. Microbial Contamination and Cross Contamination
Concerns During Processing of Tissue - Mary
Malarkey, Director, Division of Case Management,
OCBQ, CBER, FDA
- C. Preliminary Findings From an Investigation of
Allograft-Associated Infections - Marion A.
Kainer, MBBS, MPH, FRACP, Epidemic Intelligence
Service Officer, Division of Healthcare Quality
Promotion, NCID, CDC

- D. Reducing the Risk of Tissue Transplant-
Transmitted Bacterial and Fungal Infections:
Tissue Banks Perspective - D. Ted Eastland,
M.D., Head, Division of Transfusion Medicine,
Dept. of Laboratory Medicine, University of
Minnesota Medical School
- E. Adverse Reactions (Endophthalmitis) After
Corneal Transplantation: Eye Banks Perspective -
Michael A. Lemp, M.D., EBAA

2:30 p.m. OPEN PUBLIC HEARING

3:00 p.m. Open Committee Discussion

F. Committee Discussion

4:00 p.m. ADJOURNMENT