

BLOOD PRODUCTS ADVISORY COMMITTEE
76th Meeting - March 13-14, 2003
Hilton Gaithersburg, 620 Perry Parkway
Gaithersburg, MD 20877

Thursday, March 13, 2003

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

8:10 a.m. Committee Updates

?? CBER Update - Mark Elengold, Deputy Director for Operations,
Center for Biologics Evaluation and Research, FDA - 15'

?? Medical Device User Fee and Modernization Act (MDUFMA) - Mary
Elizabeth Jacobs, PhD - 10'

?? CLIA Waiver for the OraQuick® Rapid HIV-1 Antibody Test -
Elliot Cowan, PhD - 10'

?? Trans Net Pilot Program - Alan Williams, PhD - 15'

9:15 a.m. OPEN PUBLIC HEARING

9:45 a.m. *Open Committee Discussion*

I. West Nile Virus (WNV) Donor Testing

A. Introduction and Update of Previous Activities
- Hira Nakhasi, PhD, Director, Division
of Emerging and Transfusion Transmitted
Diseases, OBRR - 15'

B. Industry Presentations

Update on NAT Testing:

1. Jim Gallarda, PhD, Roche (Whole Blood) -
10'
2. Cristina Giachetti, PhD, Gen-Probe (Whole
Blood)-10'
3. Bruce Phelps, PhD, Chiron (supplemental
test) - 10'

10:30 a.m. Break

11:00 a.m. *Open Committee Discussion*

4. Andrew Conrad, PhD, National Genetics
Institute (NGI) (Source Plasma) - 10'
5. Chip Stevens, MS, Sanochemia - 10'
6. John Callaghan, MS, Tetracore - 10'

Serological Tests:

1. George Dawson, PhD, Abbott Laboratories -
10'

- Virus
Petersen,
2. Steven Alexander, PhD, Ortho Diagnostics - 10'
 - C. CDC Update on Investigations of West Nile Transfusion Transmitted Cases - Lyle MD, CDC - 20'
 - D. Donor Serologic Studies of WNV 2002 Outbreak - Susan Stramer, PhD, ARC - 20'

12:40 p.m. *Open Committee Discussion*

- Update)
Ruta, JD,
10'
20'
- E. Regulatory Pathway for WNV Testing (FDA
 1. Guidance for Industry - Martin PhD - 10'
 2. Approval Criteria - Robin Biswas, MD -
 3. Clinical Study Design, Unit and Donor Management - Indira Hewlett, PhD -
 4. Panel Development and In-house Testing - Maria Rios, PhD - 10'

1:30 p.m. LUNCH

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

- 20'
of
- F. Blood Supply Management and Triggers for West Nile Virus Testing - Alan Williams, PhD -
 - G. Testing Source Plasma Donations and Clearance West Nile Virus in Plasma Derived Products - Mahmood Farshid, PhD - 15'
- Chris Healy, PPTA Presentation - 20'

3:30 p.m. OPEN PUBLIC HEARING

4:30 p.m. BREAK

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

- H. Questions for the Committee
- I. Committee Discussion and Recommendations

6:00 p.m. RECESS (until 8:30 a.m. Friday, March 14, 2003)

Friday, March 14, 2003

8:30 a.m. Committee Update

?? Anticoagulants, Irradiation and Freezing of Blood Components -
Judy Ciaraldi, M.T., (ASCP), Blood and Plasma Branch, DBA,
OBRR

?? Bar Code Label Requirement For Human Drug Products and Blood -
Richard Lewis, PhD

9:00 a.m. OPEN PUBLIC HEARING

9:30 a.m. *Open Committee Discussion*

II. Discussion on Extension of the Storage Period for
Pooled Platelets

A. Introduction and Background - Jaro Vostal, MD,
PhD,
DH, OBRR
Chief, Laboratory of Cellular Hematology,

B. Clinical Performance of Pre-storage Pooled
Platelet Products - Edward Snyder, MD, Yale
University

10:15 a.m. BREAK

10:45 a.m. *Open Committee Discussion*

C. European Experience with Extended Storage of
Platelet Pools - Ruby Pietersz, MD, PhD

D. Bacterial Detection in Platelet Products - Mark
Brecher, MD, University of North Carolina

11:30 a.m. OPEN PUBLIC HEARING

12:00 Noon LUNCH

1:00 p.m. *Open Committee Discussion*

E. Questions for the Committee

F. Committee Discussion and Recommendations

2:00 p.m. Update on Particulates in Blood Bags - Informational

A. Introduction - Richard Lewis, PhD, Deputy
Director,
10' Office of Blood Research and Review -

B. Discovery, ADR Investigation, Conditions of
Collections Investigation - Peter Page, MD -
American Red Cross - 15'

C. Chronology and Field Overview - Jerome Davis,
Office of Compliance, CBER - 10'

D. Testing

- FDA Findings - Division of Hematology, OBRR -

10'

- Industry Investigations - Steve Binion, Baxter

