Revised Draft V5.0 3/11/03

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'**

2. Steven Alexander, PhD, Ortho Diagnostics - 10'
3. Christopher Bentsen, PhD. Bio-Rad – 10'

C. CDC Update on Investigations of West Nile Virus Transfusion Transmitted Cases – Lyle Petersen, MD, CDC – 20'

D. Donor Serologic Studies of WNV 2002 Outbreak – Susan Stramer, PhD, ARC – 20'

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

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

1:30 p.m. LUNCH

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

F. Blood Supply Management and Triggers for West Nile Virus Testing – Alan Williams, PhD – 20'

G. Testing Source Plasma Donations and Clearance of 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 – Elizabeth Callaghan, MS**

9:00 a.m. OPEN PUBLIC HEARING

9:30 a.m. O*pen Committee Discussion*

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

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

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, Office of Blood Research and Review – 10'

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

Labs. – 10'

E. Follow-up ADR Monitoring

- Clinical Studies – Sharyn Orton, PhD, DBA, OBRR – 10'

- Centers for Disease Control (CDC) and Georgia State Division of Public Health – Matthew Kuehnert, MD, CDC – 10'

4:00 p.m. ADJOURNMENT