

AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE
100th Meeting, April 28-29, 2011

The Hilton Washington DC North/Gaithersburg
620 Perry Parkway
Gaithersburg, MD 20877

Thursday, April 28, 2011

8:30 a.m. Opening Remarks, Blaine Hollinger, M.D., Chair

Statement of Conflicts of Interest, Announcements

8:40 a.m. Topic I: Testing Source Plasma for Hepatitis B Virus by Nucleic Acid Testing

A. Introduction, Susan A. Zullo, Ph.D., DETTD, OBRR, FDA (20')

B. PPTA's Voluntary Standards/HBV NAT Testing, Joshua Penrod, J.D., M.P.H., M.B.A., Source Division, Plasma Protein Therapeutics Association (15')

C. Safety of Plasma Protein Therapies with Respect to HBV, Douglas C. Lee, Ph.D., Talecris, on behalf of PPTA's Pathogen Safety Steering Committee (15')

D. Source Plasma Testing for HBV by NAT

i. Richard Smith, Ph.D. National Genetics Institute (20')

ii. John Saldanha, Ph.D., Roche Molecular Systems, Inc. (20')

iii. Gerold Zerlauth, Ph.D. Biolife Plasma Services (20')

E. Summary, Susan A. Zullo, Ph.D. (10')

10:45 a.m. Break

11:00 a.m. Open Public Hearing

11:30 a.m. Open Committee Discussion

Questions for the Committee

12:30 p.m. Lunch

1:30 p.m. Topic II: Current Considerations on Use of Plasma Obtained from Whole Blood Donors for Further Manufacturing

A. Introduction and Regulatory Perspective, Alan Williams, Ph.D., OBRR, FDA (30')

B. Considerations for Concurrent and Component Plasma Product Standards, Mark Weinstein, Ph.D., OBRR, FDA (40')

3:15 p.m. Break

3:30 p.m. Open Public Hearing

4:00 p.m. Open Committee Discussion

Questions for the Committee

5:00 p.m. Adjournment

Friday, April 29, 2011

8:00 a.m. Opening Remarks, Blaine Hollinger, M.D., Chair

Statement of Conflicts of Interest, Announcements

8:10 a.m. Topic III: Written Statement of Understanding for Blood Donors

A. Introduction and Background, Oriji Illoh, M.D., DBA, OBRR, FDA (20')

B. Informed Consent – An Overview, Christine Grady, MSN, Ph.D., NIH Clinical Center (30')

C. Evaluation of Informed Consent Forms for Whole Blood Donation, Beth Shaz, M.D., New York Blood Center (30')

D. The Informed Consent Process in Whole Blood Donation, Ronald Domen, M.D., Penn State Milton S. Hershey Medical Center/ Penn State University College of Medicine (30')

E. Summary, Oriji Illoh, M.D. (15')

10:15 a.m. Break

10:30 a.m. Open Public Hearing

11:00 a.m. Open Committee Discussion

Questions for the Committee

12:00 p.m. Break

12:15 p.m. Committee Updates

- Planned FDA Public Workshops (40')

(i) Thrombotic Adverse Events Associated with Immune Globulin, Dorothy Scott, M.D., DH, OBRR, FDA (10')

(ii) Quarantine Release Errors, Teresita Mercado, DBA, OBRR, FDA (10')

(iii) Measurement of Hemoglobin in Blood Donors, Richard Davey, M.D., DBA, OBRR, FDA (10')

(iv) Toxicities of Hydroxyethyl Starch Solution, Laurence Landow, M.D., DH, OBRR, FDA (10')

1:15 p.m. Adjournment