

# DRAFT AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE  
92<sup>nd</sup> Meeting – September 10-11, 2008  
Hilton Hotel, 1750 Rockville Pike, Rockville, MD

Wednesday, September 10, 2008

8:00 a.m. Opening Remarks, Frederick P. Siegal, M.D., Medical Director, Comprehensive HIV Center, Saint Vincent's Catholic Medical Centers, New York, NY, Chairperson, BPAC

Statement of Conflicts of Interest, Acknowledgement of Members, Announcements

8:15 a.m. Committee Update

- Summary of May 29-30, 2008 Meeting of the DHHS Advisory Committee on Blood Safety and Availability, Jerry Holmberg, Ph.D., Executive Secretary, Advisory Committee on Blood Safety and Availability (15')

8:30 a.m. Topic I. Strategies to Enhance Bacterial Safety of 7 Day Platelets for Transfusion

- A. Introduction, Jaro Vostal, M.D., DH, OBRR, FDA (10')
- B. Issues in Detection of Bacterially Contaminated Platelet Products, Mark Brecher, M.D., University of North Carolina School of Medicine, Chapel Hill (30')
- C. Bacterial Detection in Blood Components, Thomas Montag-Lessing, M.D., Paul Ehrlich Institute, Germany (20')
- D. Redesign of PASSPORT Study for 7 Day Platelets, Louis Katz, M.D., Mississippi Valley Regional Blood Center (40')
- E. FDA Perspective on Re-introduction of 7 Day Platelets and Redesign of PASSPORT Study, Salim Haddad, M.D., DH, OBRR, FDA (40')

10:50 a.m. Break

11:00 a.m. Open Public Hearing

11:45 a.m. Open Committee Discussion

- F. Questions for the Committee
- G. Committee Discussion

12:45 p.m. Lunch

1:45 p.m. Topic II: Iron Status in Blood Donors

- A. Introduction, Leslie Holness, M.D., DBA, OBRR, FDA (10')
- B. Overview of Iron Metabolism and Impact of Iron Deficiency on Blood Donors, Gary Brittenham, M.D.,

Columbia University (40')

- C. Normal Values for Hemoglobin and Iron Stores, Sarah Cusick, Ph.D., Centers for Disease Control and Prevention (15')
- D. European Studies on Iron Replacement for Blood Donors, Karin Magnussen, M.D., Copenhagen University Hospital (30')
- E. Management of Iron Status in Blood Donors, Barbara Bryant, M.D., University of Texas, Medical Branch, Galveston (30')
- F. A U.S. Blood Center Experience with Iron Replacement, Dan Waxman, M.D., Indiana Blood Center (15')
- G. REDS Studies on Iron Stores and Implications for Blood Donors, Ritchard Cable, M.D., American Red Cross (10')

4:15 p.m. Open Public Hearing

4:45 pm Break

5:00 p.m. H. Questions for the Committee

I. Committee Discussion

6:00 p.m. Adjournment

Thursday, September 11, 2008

8:00 a.m. Opening Remarks, Frederick P. Siegal, M.D., Medical Director, Comprehensive HIV Center, Saint Vincent's Catholic Medical Centers, New York, NY, Chairperson, BPAC

Statement of Conflicts of Interest, Acknowledgement of Members, Recognition of Retiring Members

8:15 a.m. Committee Updates

- Summary of April 29-30, 2008 Workshop on Hemoglobin Based Oxygen Carriers: Current Status and Future Directions, Paul Buehler, Pharm.D., Ph.D., DH, OBRR, FDA and Toby Silverman, M.D., DH, OBRR, FDA (15')
- Summary of July 10-11, 2008 Blood Establishment Computer Software Conference, Sheryl Kochman, DBA, OBRR, FDA (15')
- Development of an Automated Biologics License Application Submission System, Elizabeth Callaghan, M.S., DBA, OBRR, FDA (15')
- "Draft Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)," Robin Biswas, M.D., DETTD, OBRR, FDA (15')

9:15 a.m. Open Public Hearing

9:45 a.m. Break

10:00 a.m. Topic III: Options for Blood Donor Screening and Reentry for Malaria

- A. Introduction and Background, Sanjai Kumar, Ph.D., DETTD, OBRR, FDA (30')
- B. Risk Analysis for Malaria Exposure in Blood Donors and Its Effect on Blood Safety and Availability, Hong Yang, Ph.D. and Mark Walderhaug, Ph.D., OBE, FDA (35')
- C. Evaluating Risk for Malaria Infection in United States Donors Deferred for Travel to Malaria-Endemic Areas, Bryan Spencer, M.P.H., American Red Cross (15')
- D. Donor Deferrals Due to Travel to Malarial Areas Among Members of America's Blood Centers, Celso Bianco, M.D., America's Blood Centers (15')
- E. Risk of Malaria in Travelers to Mexico, Paul Arguin, M.D., CDC (30')
- F. Serologic Testing of Malaria Deferred Blood Donors: Ferreting Out the At-Risk Donors, David Leiby, Ph.D., American Red Cross (15')

12:30 p.m. Lunch

1:30 p.m. Open Public Hearing

2:30 p.m. Open Committee Discussion

E. Questions for the Committee

F. Committee Discussion

3:30 p.m. Adjournment