

AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE
87th Meeting – July 13, 2006
Hilton Hotel, Washington DC North / Gaithersburg
620 Perry Parkway, Gaithersburg, MD 20877

Thursday, July 13, 2006

8:00 a.m. Welcome – James R. Allen, MD, MPH, Chair, BPAC

Statement of Conflict of Interest, Acknowledgement of New Members, Announcements

8:15 a.m. Committee Updates

- Summary of May 9-10, 2006 Meeting of the DHHS Advisory Committee on Blood Safety and Availability – Jerry Holmberg, PhD, Executive Secretary, Advisory Committee on Blood Safety and Availability (10')
- Summary of July 12, 2006 FDA Workshop on Testing for Malarial Infections in Blood Donors - Sanjai Kumar, PhD, DETTD, OBRR, FDA (10')
- Committee Report on the Office of Blood Research and Review Site visit, Review of Intramural Research - James Allen, MD, MPH, Chairman, Review Committee and Blood Products Advisory Committee (15')
- West Nile Virus Update – Maria Rios, PhD, DETTD, OBRR, FDA (10')

9:10 a.m. Topic I.

FDA Review of Nabi Biopharmaceuticals' Hepatitis B IGIV for Prevention of Recurrent HBV Disease after Orthotopic Liver Transplantation

- A. Introduction – Charles Maplethorpe, MD, PhD, CRB, DH, OBRR, FDA (5')
- B. Sponsor presentation – Henrik S. Rasmussen, M.D., Ph.D.
Senior Vice President, Clinical Research, Medical & Regulatory Affairs
Nabi Biopharmaceuticals (30')
- C. FDA clinical review – Charles Maplethorpe, MD, PhD, CRB, DH, OBRR, FDA (30')
- D. FDA statistical review - Jessica Kim, PhD, DB, OBE, CBER (30')

10:45 a.m. Break

11:00 a.m. Open Public Hearing

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Thursday, July 13, 2006 (continued)

11:30 p.m. Open Committee Discussion

E. Questions for the Committee

F. Committee Discussion and Recommendations

12:30 p.m. Lunch

1:30 p.m. Topic II.

Review of the Research Programs in the Laboratory of Bacterial, Parasitic and Unconventional Agents, Division of Emerging and Transfusion Transmitted Diseases, OBRR, CBER (May 25, 2006)

A. Overview of CBER Research, Kathryn M. Carbone, MD, Associate Director for Research, CBER, FDA (20')

B. Overview of OBRR Research, C.D. Atreya, PhD, Associate Director for Research, OBRR (5')

C. Overview of the Division of Emerging and Transfusion Transmitted Diseases Research Program - Hira Nakhasi, PhD, Director, DETTD, OBRR (10')

D. Overview of the Laboratory of Bacterial, Parasitic and Unconventional Agents, David Asher, MD, Chief, LBPUA, DETTD, OBRR (5')

E. Review of Laboratory of Bacterial, Parasitic and Unconventional Agents Scientific Program

- David Asher, MD (5')
- Pedro Piccardo, MD (5')
- Hira Nakhasi, PhD (5')
- Robert Duncan, PhD (5')
- Angamuthu Selvapandiyan, PhD (5')
- Alain Debrabant, PhD (5')
- Sanjai Kumar, PhD (5')
- Questions - 15'

3:00 p.m. OPEN PUBLIC HEARING

3:30 p.m. Closed Committee Discussion

Discussion of the DETTD program site visit report

4:30 p.m. Adjournment