

AGENDA

BLOOD PRODUCTS ADVISORY COMMITTEE

88th Meeting – December 14, 2006
Crown Plaza, 8777 Georgia Avenue, Silver Spring, MD

Thursday, December 14, 2006

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

Opening Remarks

- Frederick P. Siegal, M.D., Medical Director, Comprehensive HIV Center,
Saint Vincent's Catholic Medical Centers, New York, NY, Chairperson, BPAC

- Jay Epstein, M.D., Director, OBRR, FDA

8:05 a.m. Committee Update

Summary of October 11, 2006 Public Hearing on Emergency Research (21CFR50.24)

- Overview of 21 CFR 50.24, Toby Silverman, M.D., Chief, CRB, DH, OBRR, FDA
(10')

- Summary of October 11, 2006 Public Hearing on Emergency Research,
Diane Maloney, J.D., Associate Director for Policy, IOD, CBER, FDA (15')

TOPIC: Review of a Proposed Clinical Trial of HBOC-201 in Trauma

8:30 a.m. Background Presentations

A. Overview of Hemoglobin-based Oxygen Carriers, Abdu I. Alayash, Ph.D., Chief, LBVB, DH,
OBRR, FDA (15')

B. Introduction, Laurence Landow, M.D., Medical Officer, CRB, DH, OBRR, CBER (10')

8:55 a.m. Sponsor Presentations

C. Introductory Remarks, Dan Freilich, M.D, CDR, MC, USN, Head, Hematomimetics
Program, NMRC (2')

D. Importance of RESUS to the Navy and Marines, John Mateczun, M.D., RADM, MC, USN,
Navy Deputy Surgeon General, Senior Healthcare Executive (5')

E. Hemorrhagic Shock: Pathophysiology, Clinical Presentation and Current Treatment, Lewis
Kaplan, M.D., Director of the SICU and Surgical Critical Care Fellowship, Yale University
School of Medicine, Section of Trauma Surgical Critical Care and Surgical Emergencies
Center (8')

- F. Overview of RESUS Study, Rick Dutton, M.D., R. Adams Cowley Shock Trauma Center, University of Maryland Medical Center, Baltimore, M.D. (10')
- G. All Preclinical HS/Traumatic Brain Injury Studies, Susan Stern, M.D., Associate Professor, Associate Chair - Education, Department of Emergency Medicine, University of Michigan, Ann Arbor, MI (11')
- H. HBOC-201 Clinical Studies Analysis, Gerson Greenberg, M.D., Vice President of Medical Affairs, Biopure Corp. (15')

9:45 a.m. BREAK

9:55 a.m. Sponsor Presentations (Continued)

- I. Overview of the HBOC-201 RESUS IND and Discussion of Benefit:Risk, Dan Freilich, M.D, CDR, MC, USN, Head, Hematomimetics Program, NMRC (50')
- J. Concluding Remarks, Joe Acker, EMT-P, MPH, Executive Director, Birmingham Regional EMS, Birmingham, AL (3')
- K. Concluding Remarks, Lewis Kaplan, M.D., Director of SICU and Surgical Critical Care Fellowship, Yale University School of Medicine, Section of Trauma Surgical Critical Care and Surgical Emergencies Center (3')

10:45 a.m. Presentations by Special Government Employees engaged by FDA as outside consultants

- J. Studies of HBOC-201 in Animal Models of Hemorrhagic Shock
 - John Hess, M.D., M.P.H., Medical Director, Cancer Center Laboratory, Associate Medical Director, Blood Bank, Department of Pathology, University of Maryland Medical School (10')
 - Thomas Hintze, Ph.D., Professor, Department of Physiology, New York Medical College, (10')
 - Carl Hauser, M.D., Visiting Professor of Surgery, Department of Surgery, Beth Israel Deaconess Medical Center (10')

11:15 a.m. K. FDA Assessment – Toby Silverman, M.D., Chief, CRB, DH, OBRR, FDA

12:15 p.m. LUNCH

1:15 p.m. Open Public Hearing

2:15 p.m. BREAK

2:30 p.m. Committee Discussion

L. FDA Questions for the Committee - Laurence Landow, M.D., Medical Officer, DH, OBRR, CBER

M. Committee discussion and recommendations

6:00 p.m. Adjournment