

DRAFT

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

8:05 a.m. Committee Update

Summary of October 11, 2006 Public Hearing on Emergency Research (21CFR50.24) – Diane Maloney, J.D., IOD, CBER, FDA (15')

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

8:20 a.m. Background Presentations

- A. Introduction – Laurence Landow, M.D., Clinical Review Branch, Division of Hematology, OBRR, CBER (15')
- B. Standards Applicable to Proposed Clinical Trial, Toby Silverman, M.D., DH, OBRR, FDA (10')
- C. Overview of Hemoglobin-based Oxygen Carriers, Abdu Alayash, Ph.D., LBVB, DH, OBRR, FDA (15')

9:00 a.m. Sponsor Presentations

- 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. Overview of the HBOC-201 RESUS IND and Discussion of Benefit:Risk, Dan Freilich, M.D, CDR, MC, USN, Head, Hematomimetics Program, NMRC (50')

9:55 a.m. BREAK

10:10 a.m. Sponsor Presentations (Continued)

- F. 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 (10')
- G. Preclinical HBOC-201 HS/Traumatic Brain Injury Studies, Susan Stern, M.D., Associate Professor, Associate Chair - Education, Department of Emergency Medicine, University of Michigan, Ann Arbor, MI (15')

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- H. Synopsis of HBOC-201 Clinical Studies, Gerson Greenberg, M.D., Vice President of Medical Affairs, Biopure Corp. (10')
- I. Overview of RESUS Study, Rick Dutton, M.D., R. Adams Cowley Shock Trauma Center, University of Maryland Medical Center, Baltimore, M.D. (10')
- J. 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 (5')

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

- K. Studies of HBOC-201 in Animal Models of Hemorrhagic Shock
 - John Hess, M.D., M.P.H., University of Maryland Medical Center (10')
 - Thomas Hintze, Ph.D., New York Medical College, (10')
 - Carl Hauser, M.D., UMDNJ/New Jersey Medical School (10')

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

12:15 p.m. M. LUNCH

1:15 p.m. Open Public Hearing

2:15 p.m. BREAK

2:30 p.m. Committee Discussion

N. FDA Questions for the Committee - Laurence Landow, M.D., DH, OBRR, CBER

O. Committee discussion and recommendations

6:00 p.m. Adjournment