FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
104th Meeting of the Blood Products Advisory Committee
FDA Fishers Lane Building
5630 Fishers Lane, Room 1066
Rockville, Maryland
September 20-21, 2012

DRAFT AGENDA

Thursday, September 20, 2012

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	F. Blaine Hollinger, M.D. Chair, BPAC
	Recognition of Retiring Committee Members	Karen Midthun, M.D. Director, CBER
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC
Topic I:	**Hepatitis E Virus and Blood Transfusion Safety**	
8:05 a.m.	Introduction	Susan A. Zullo, Ph.D. (10') DETTD, OBRR, FDA
8:15 a.m.	HEV Global Experience	Robert Purcell, M.D. (20') NIAID, NIH
8:35 a.m.	Surveillance Studies for HEV Seroprevalence in the U.S.	Scott D. Holmberg, M.D., MPH Saleem Kamili, Ph.D. (20') CDC
8:55 a.m.	HEV Prevalence and Risk in U.S. Blood Donors and Recipients: Current Study and Proposed Study Designs	Harvey J. Alter, M.D. (20') Department of Transfusion Medicine, NIH
9:15 a.m.	Questions for speakers (10')	
9:25 a.m.	HEV Serological Assay Validation; Development of Reference Panels	Harry Dalton, DPhil (20') Royal Conwall Hospital, UK
9:45 a.m.	HEV Nucleic Acid Test (NAT) Validation; Development of Standards	Sally Baylis, Ph.D. (20') Paul-Ehrlich-Institut
10:05 a.m.	Summary	Susan A. Zullo, Ph.D. (10')
10:10 a.m.	Questions for speakers (5')	
10:15 a.m.	Break (15')	

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10:30 a.m.	Open Public Hearing	
11:15 a.m.	Open Committee Discussion Questions for the Committee	
12:15 p.m.	Lunch	
Topic II:	**Octapharma's Biologics License Application for Pooled Plasma (Human, Solvent/Detergent Treated)**	
1:00 p.m.	Introduction	Nancy Kirschbaum, Ph.D. DH, OBRR, FDA (15')
1:15 p.m.	Octapharma Presentations (60')	
2:15 p.m.	European Experience with Octaplas	Bjarte G. Solheim MD, Ph.D. Olso, Norway (30')
2:45 p.m.	Questions for Speakers (15')	
3:00 p.m.	FDA Analysis	Mitchell Frost, M.D. DH, OBRR, FDA (30')
3:30 p.m.	Post-licensure Safety Review	Michael D. Nguyen, Ph.D. OBE, FDA (15')
3:45 p.m.	Questions (10')	
3:55 p.m.	Break	
4:10 p.m.	Open Public Hearing	
4:30 p.m.	Open Committee Discussion Questions for the Committee	
5:30 p.m.	Adjournment	

<u>Friday, September 21, 2012</u>

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	F. Blaine Hollinger, M.D. Chair, BPAC
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC

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Topic III: Considerations for Strategies to Further Reduce the Risk of Bacterial Contamination in Platelets

8:10 a.m.	Overview and Options for Consideration	Salim Haddad, M.D. DH, OBRR, FDA (45')
8:55 a.m.	Microbiology of Platelets for Transfusion	Michael Jacobs, M.D., Ph.D. Case Western Reserve University (30')
9:25 a.m.	Experience of the Irish Blood Transfusion Service	William Murphy, M.D. (45') Blood Transfusion Clinical Programmes, Ireland
10:15 a.m.	Questions for speakers (15')	
10:30 a.m.	Break (15')	
10:45 a.m.	Transfusion Service Perspectives	Larry Dumont, M.B.A., Ph.D, Dartmouth Hitchcock Medical Center (20') Mark Yazer, M.D. Institute for Transfusion Medicine, Pittsburgh (20')
11:30 a.m.	Questions for speakers (15')	
11:45 a.m.	Lunch	
12:45 p.m.	Open Public Hearing	
2:00 p.m.	Open Committee Discussion Questions for the Committee	
3:15 p.m.	Break	

Committee Updates

3:30 p.m.	September 6-7, 2012 FDA Public Workshop: Risks and Benefits of Hydroxyethyl Starch Solutions	Laurence Landow, M.D. DH, OBRR, FDA (20')
4:00 p.m.	Adjournment	

8-20-12