FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
116th Meeting of the Blood Products Advisory Committee
Great Room, Building 31
FDA White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

November 30 – December 1, 2017

DRAFT AGENDA

Thursday, November 30, 2017

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	Christopher Stowell, M.D. Chair, BPAC
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC
Topic I:	**Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion**	
8:10 a.m.	Introduction and FDA's Current Considerations	Salim Haddad, M.D. OBRR, FDA (40')
8:50 a.m.	Summary of Public Comments on FDA's Draft Guidance Document	Jennifer Scharpf OBRR, FDA (10')
9:00 a.m.	BSI data	Ralph R. Vassallo, M.D. Blood Systems, Inc. (40')
9:40 a.m.	UK data	Carl McDonald National Health Service Blood and Transplant, UK (40')
10:20 a.m.	Irish Data	Stephen Field Irish Blood Transfusion Service (40')
11:00 a.m.	Break (15')	
11:15 a.m.	Questions for Speakers (20')	
11:35 a.m.	Open Public Hearing (45')	
12:20 p.m.	Lunch (45')	
1:05 p.m.	Open Committee Discussion (75')	

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	Questions for the Committee	
2:20 p.m.	Break (10')	
Topic II:	**Classification of Human Leukocyte Antigen, Human Platelet Antigen and Human Neutrophil Antigen Devices**	
2:30 p.m.	Classification of Medical Devices	Julia Lathrop, Ph.D. OBRR, FDA (20')
2:50 p.m.	Classification of HLA Devices	Jason Liu, Ph.D. (40') OBRR, FDA
3:30 p.m.	Classification of HPA and HNA Devices	Sharmila Shrestha (20') OBRR, FDA
3:50 p.m.	Questions for Speakers (10')	
4:00 p.m.	Break (15')	
4:15 p.m.	Open Public Hearing (30')	
4:45 p.m.	Open Committee Discussion Questions for the Committee	Teresita Mercado, M.S. OBRR, FDA (60')
5:45 p.m.	Adjournment	

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Friday, December 1, 2017

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	Christopher Stowell, M.D. Chair, BPAC
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC
Topic III:	**Strategies to Reduce the Risk of Transfusion-Transmitted Zika Virus**	
8:10 a.m.	Introduction	Anne Eder, M.D, Ph.D. OBRR, FDA (15')
8:25 a.m.	Update on the Current Status of the ZIKV Epidemic	Carolyn Gould, MD, MSCR CDC (45')
9:10 a.m.	Update on ZIKV Nucleic Acid Testing in Blood Donors	Anthony Hardiman Roche Molecular Systems, Inc. (20')
		Jeffrey Linnen, PhD. Grifols Diagnostic Solutions Inc. (20')
9:50 a.m.	Current Consideration for Reducing the Risk of Transfusion Transmitted ZIKV	Anne Eder, M.D, Ph.D. OBRR, FDA (25')
10:15 a.m.	Questions for Speakers (15')	
10:30 a.m.	Break (15')	
10:45 a.m.	Open Public Hearing	(45')
11:30 p.m.	Open Committee Discussion Questions for the Committee	(75')

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12:45 p.m. Lunch (60')

Topic IV: Informational Session on the Transfusion Transmissible Infections Monitoring System

1:45 p.m.	Transfusion Transmissible Infections Monitoring System	Alan Williams, Ph.D. OBE, FDA (10')
		Whitney Steele American Red Cross (20')
		Brian Custer, Ph.D. Blood Systems Research Institute (20')
		Alan Williams, Ph.D. OBE, FDA (5')

Committee Update

2:45 p.m.	Summary of the Public Workshop on Tick-Borne Diseases and Blood Safety	David Leiby, Ph.D. OBRR, FDA (15')
3:00 p.m.	Open Public Hearing (30')	
3:30 p.m.	Adjournment	