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

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8:50 a.m.	Summary of Public Comments on FDA's Draft Guidance Document	Jennifer Scharpf, M.P.H. OBRR, FDA (15')
9:05 a.m.	Platelet Bacterial Contamination Risk Mitigation: Another Successful Approach	Ralph R. Vassallo, M.D. Blood Systems, Inc. (40')
9:45 a.m.	Experience of the United Kingdom National Health Service, Blood and Transplant	Carl McDonald, Ph.D., MSc, BSc National Health Service Blood and Transplant, UK (40')
10:25 a.m.	Screening of Platelets for Bacterial Contamination: Experience of the Irish Blood Transfusion Service 2005-16	Stephen Field, MBChB, MA, MMed, FCPath(SA) Irish Blood Transfusion Service (40')
11:05 a.m.	Break (10')	
11:15 a.m.	Questions for Speakers (15')	
11:30 a.m.	Open Public Hearing (50')	
12:20 p.m.	Lunch (45')	

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1:05 p.m.	Open Committee Discussion (75') 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, HPA and HNA Devices	Jason Liu, M.D, Ph.D. OBRR, FDA Sharmila Shrestha, M.B.A., MT(ASCP) 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., MT(ASCP) 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.	Zika Virus Epidemiology Update	Carolyn Gould, M.D., M.S. CDC (45')
9:10 a.m.	Update on Zika Virus Nucleic Acid Testing in Blood Donors	Anthony Hardiman Roche Molecular Systems, Inc. (20')
		Jeffrey Linnen, Ph.D. Grifols Diagnostic Solutions Inc. (20')
9:50 a.m.	Current Consideration for Reducing the Risk of Transfusion Transmitted Zika Virus	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.	Progress Update – Introduction	Alan Williams, Ph.D. OBE, FDA (10')
	TTIMS: Donation Database Coordinating Center	Whitney Steele, Ph.D., M.P.H. American Red Cross (20')
	Proportion of HIV Seropositive Donors with Recently-Acquired Infection in the USA and Updates on Other LRCC Activities	Brian Custer, Ph.D. Blood Systems Research Institute (20')
	Progress Update – Summary	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	