FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
119th Meeting of the Blood Products Advisory Committee
Great Room, Building 31
FDA White Oak Campus
10903 New Hampshire Avenue
Silver Spring, MD 20993

Meeting Link:
https://collaboration.fda.gov/bpac0718/

DRAFT AGENDA

July 18, 2018

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	James Allen, M.D., Ph.D. Acting Chair
8:10 a.m.	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer
8:15 a.m.	Introduction To the Topic	Emily Storch, M.D. OBRR, FDA (15')
8:30 a.m.	Bacterial Culture Testing Strategy	Mary Beth Anheuser bioMerieux (20')
	Questions for the Speaker	(10')
9:00 a.m.	Primary Culture, and Secondary Culture on Day 3 Testing Strategy, with Dating to Day 5	Evan Bloch, M.B., Ch.B. Johns Hopkins University School of Medicine (20')
	Questions for the Speaker	(10')
9:30 a.m.	Primary Culture, and Secondary Culture on Day 4 Testing Strategy, with Dating to Day 7	Stephen Field, MBChB, MA, MMed, FCPath (SA) Irish Blood Service (20')
	Questions for the Speaker	(10')
10:00 a.m.	Break (15')	
10:15 a.m.	Minimal Proportional Sampling Volume Testing Strategy, with Dating to Day 5	Ralph Vassallo, M.D. Blood Systems, Inc. (20')
	Questions for the Speaker	(10')
10:45 a.m.	Large Volume and Delayed Sampling Testing Strategy, with Dating to Day 7	Carl McDonald, Ph.D., MSC, BSc National Health Service Blood and Transplant, UK (20')

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	Questions for the Speaker	(10')
11:15 a.m.	Bacterial Rapid Testing Strategy	Michael R. Jacobs, MD, PhD, FRCPath, D(ABMM), F(AMM) Case Western Reserve University On behalf of Verax and Immunetics (40')
	Questions for the Speaker	(20')
12:15 p.m.	Pathogen Reduction Technology Strategy	Richard Benjamin, M.D., Ph.D. Cerus Corporation (20')
	Questions for the Speaker	(10')
12:45 p.m.	Lunch (60')	
1:45 p.m.	Open Public Hearing	
2:45 p.m.	Question for the Committee	Nicole Verdun, M.D. OBRR, FDA (5')
2:50 p.m.	Open Committee Discussion	
4:30 p.m.	Adjournment	

July 19, 2018

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	Angela M. Caliendo, M.D., Ph.D. Acting Chair
8:10 a.m.	Conflict of Interest Statement	Bryan Emery, LCDR

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		Designated Federal Officer
Topic II:	**Device Reclassification of Human Immunodeficiency Virus (HIV) Point of Care and Laboratory-Based Serological and Nucleic Acid Diagnostic Devices**	
8:20 a.m.	Welcome and Introduction to the Topic	J. Peyton Hobson, Ph.D. OBRR, FDA (5')
8:25 a.m.	HIV Diagnosis: A Review of the Past and Prospects for the Future	S. Michele Owen, Ph.D. CDC (40')
9:05 a.m.	Clinical Application of HIV Testing Technology: How They Are Really Used in the Community	David Hardy, M.D. Whitman-Walker Health (30')
9:35 a.m.	Questions for the Speakers	(15')
9:50 a.m.	Break	(15')
10:05 a.m.	Overview of Device Classification	Julia Tait Lathrop, Ph.D. OBRR, FDA (20')
10:25 a.m.	Current Status of HIV Diagnostic Devices	Anne Eder, M.D., Ph.D. OBRR, FDA (20')
10:45 a.m.	Overview of Proposed Special Controls	Julia Tait Lathrop, Ph.D. OBRR, FDA (30')
11:15a.m.	Questions for the Speakers	(15')
11:30 p.m.	Lunch	(60')
12:30 p.m.	Open Public Hearing	(60')
1:30 p.m.	Question for the Committee	J. Peyton Hobson, Ph.D. OBRR/FDA (5')
1:35 p.m.	Open Committee Discussion	

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3:00 p.m. Adjournment

6/15/18