

# FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research  
117<sup>th</sup> Meeting of the Blood Products Advisory Committee  
Joint Meeting with the Medical Devices Advisory Committee (Microbiology Devices Panel)  
Great Room, Building 31  
FDA White Oak Campus  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

March 21, 2018

## DRAFT AGENDA

March 21, 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 Designated Federal Officer
<b>Topic I:</b>	<b>Device Reclassification of Human Immunodeficiency Virus (HIV) Point of Care and Laboratory-Based Serological and Nucleic Acid Diagnostic Devices</b>	
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.	[HIV Diagnostic Testing in the Community]	David Hardy, M.D. Whitman-Walker Health (30')
9:35 a.m.	Questions for the Speakers	(5')
9:40 a.m.	Break	(15')
9:55 a.m.	Overview of Device Classification	Julia Tait Lathrop, Ph.D. OBRR, FDA (30')
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')

3/9/18

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12:30 p.m.	Open Public Hearing	(60')
1:30 p.m.	Open Committee Discussion Question to the Committee	J. Peyton Hobson, Ph.D. OBRR/FDA (90')
3:00 p.m.	Chairperson Summation	Angela M. Caliendo, M.D., Ph.D. Acting Chair (5')
3:05 p.m.	Break	(10')
<b>Topic II:</b>	<b>Review of the Research Programs in the Laboratories of Emerging Pathogens, Bacterial and Transmissible Spongiform Encephalopathy Agents, and Molecular Virology, Division of Emerging Transfusion-Transmitted Diseases, OBRR</b>	
3:15 p.m.	Overview of CBER Research Programs	Carolyn Wilson, Ph.D. CBER, FDA (10')
3:25 p.m.	Overview of OBRR Research Programs	CD Atreya, Ph.D. OBRR, FDA (10')
3:35 p.m.	Overview of the Division of Emerging Transfusion-Transmitted Diseases Research Programs	Hira Nakhasi, Ph.D. OBRR, FDA (40')
4:15 p.m.	Questions for the Speakers	(10')
4:25 p.m.	Open Public Hearing	(15')
4:40 p.m.	Closed Committee Discussion	(35')
5:15 p.m.	Adjournment	