

# FOOD AND DRUG ADMINISTRATION

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

November 17-18, 2016

## DRAFT AGENDA

Thursday, November 17, 2016

<b>Time</b>	<b>Presentation</b>	<b>Presenter/Duration</b>
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
<b>Topic I:</b>	<b>Iron Deficiency in Blood Donors</b> (Proposed TVM: Gary Brittenham, MD )	
8:10 a.m.	Introduction and Background	Orieji Illoh/Wendy Paul OBRR, FDA (30')
8:40 a.m.	Iron Deficiency in Blood Donors: The REDS-II Donor Iron Status Evaluation (RISE) Study	Ritchard Cable, M.D. American Red Cross (20')
9:00 a.m.	Oral Iron Supplementation after Blood Donation: A Randomized Clinical Trial	Joseph Kiss, M.D. Institute for Transfusion Medicine (20')
9:20 a.m.	Strategies to Reduce Iron Deficiency in Blood Donors: A Randomized Trial	Bryan Spencer, M.P.H. American Red Cross (20')
9:40 a.m.	Questions for Speakers	(10')
9:50 a.m.	Break	(20')
10:10 a.m.	Ferritin Testing and Iron Supplementation: A Feasibility Study	Jed Gorlin, M.D. (20')
10:30 a.m.	AABB Proposed Algorithm	TBD
10:50 a.m.	Questions for Speakers	(10')

# FOOD AND DRUG ADMINISTRATION

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

November 17-18, 2016

## DRAFT AGENDA

11:00 a.m.	Open Public Hearing	(45')
11:45 a.m.	Open Committee Discussion Questions for the Committee	(60')
12:45 p.m.	Lunch	(60')

### **Topic II: Blood Collection and Adverse Events in Teenage (16-18 years) Blood Donors** (Proposed TVMs: Cassandra Josephson, MD and adolescent medicine pediatrician)

<b>Time</b>	<b>Presentation</b>	<b>Presenter/Duration</b>
1:30 p.m.	Introduction and Background	Emily Storch, M.D. OBRR, FDA (25')
1:55 p.m.	Overview of Teen Donation and Adverse Reactions in Teens	[Anne Eder, M.D.] OBRR, FDA (30')
2:25 p.m.	Experience with Mitigation Strategies	[Peter Tomasulo, M.D.] Blood Systems, Inc. (20')
2:45 p.m.	Predicting and Preventing Syncopal and Presyncopal Reactions among Young Donors	Christopher France, Ph.D. Ohio University (20')
3:05 p.m.	Iron Loss/Deficiency in Teenage Donors; CHILL Study	Bryan Spencer, M.P.H. American Red Cross (20')
3:25 p.m.	Break	(20')
3:45 p.m.	Questions for the Speakers	(15')
4:00 p.m.	Open Public Hearing	(30')
4:30 p.m.	Open Committee Discussion Questions for the Committee	(60')
5:30 p.m.	Adjournment	

# FOOD AND DRUG ADMINISTRATION

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

November 17-18, 2016

## DRAFT AGENDA

Friday, November 18, 2016

<b>Time</b>	<b>Presentation</b>	<b>Presenter/Duration</b>
8:30 a.m.	Call to Order and Opening Remarks	Christopher Stowell, M.D. Chair, BPAC
	Introduction of Committee	
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC

### **Topic III: Informational Session: Zika Virus and Blood Safety in the United States**

<b>Time</b>	<b>Presentation</b>	<b>Presenter/Duration</b>
8:40 a.m.	Current Status of the Epidemic	Ingrid Rabe CDC (20')
9:00 a.m.	FDA Guidance and Efforts with Respect to Blood Safety	Hira Nakhasi, Ph.D. OBRR, FDA (20')
9:20 a.m.	Update on IND Testing in Puerto Rico and Continental U.S.	CTS/Roche (40') Hologics
10:00 a.m.	[Placeholder presentation]	(15')
10:15 a.m.	Questions for Speakers	(15')
10:30 a.m.	Open Public Hearing	(30')
11:00 a.m.	Break	(15')

# FOOD AND DRUG ADMINISTRATION

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

November 17-18, 2016

## DRAFT AGENDA

### Committee Updates:

<b>Time</b>	<b>Presentation</b>	<b>Presenter/Duration</b>
11:15 a.m.	Update on the Transfusion Transmissible Infections Monitoring System [update on submission of data to docket on individual risk assessment]	Alan Williams, Ph.D. OBRR, FDA (30')
11:45 a.m.	Summary of the FDA Workshop on New Methods to Predict the Immunogenicity of Therapeutic Coagulation Proteins	Zuben Sauna, Ph.D. OBRR, FDA (15')
12:00 p.m.	Summary of the FDA Workshop on Pre-Clinical Evaluation of Red Blood Cells for Transfusion	Jaro Vostal, M.D. OBRR, FDA (15')
12:15 p.m.	Questions for Speakers	(15')
12:30 p.m.	Open Public Hearing	(30')
1:00 p.m.	Adjournment	