

FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
115th Meeting of the Blood Products Advisory Committee
Thomas Douglas Conference Center
10000 New Hampshire Avenue
Silver Spring, MD 20993

April 4-5, 2017

DRAFT AGENDA

April 4, 2017

8:30 a.m.	Call to Order and Opening Remarks Introduction of Committee	Christopher Stowell, M.D., Ph.D., Chair, BPAC
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC

Topic I: Recombinant Human Coagulation Factor IX, GlycoPEGylated

8:40 a.m.	Introduction to Topic	Wilson Bryan, M.D. OTAT, FDA (20')
9:00 a.m.	Novo Nordisk presentation	Shawn Hoskin Stephanie Seremetis Lars Wichmann Madsen Guy Young, M.D. (45')
9:45 a.m.	FDA presentation	Becky Robinson-Zeigler, Ph.D. Megha Kaushal, M.D. OTAT, FDA (45')
10:30 a.m.	Break	(15')
10:45 a.m.	Questions for Novo Nordisk and FDA	(30')
11:15 a.m.	Open Public Hearing	(30')
11:45 a.m.	Choroid Plexus Biology	Maria Lehtinen, Ph.D. Boston Children's Hospital (20')
12:05 p.m.	Questions for Speaker	(10')
12:15 p.m.	Lunch	(60')

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1:15 p.m. Open Committee Discussion (120')
 Discussion Questions for the Committee

3:15 p.m. Break (15')

Committee Update:

3:30 p.m. Summary of Responses to Docket FDA-2016-N-1502: Jennifer Scharpf, M.P.H.
 Blood Donor Deferral Policy for Reducing the Risk of OBRR, FDA (30')
 Human Immunodeficiency Virus Transmission by
 Blood and Blood Products

4:00 p.m. Open Public Hearing (30')

4:45 p.m. Adjourn

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Wednesday, April 5, 2017

8:30 a.m.	Call to Order and Opening Remarks Introduction of Committee	Christopher Stowell, M.D. Ph.D., Chair, BPAC
	Conflict of Interest Statement	Bryan Emery, LCDR Designated Federal Officer, BPAC
Topic II:	Review of the Research Programs in the Laboratory of Emerging Pathogens, Division of Emerging Transfusion-Transmitted Diseases, OBRR	
8:40 a.m.	Overview of CBER Research Programs	Carolyn Wilson, Ph.D. CBER, FDA (20')
9:00 a.m.	Overview of OBRR Research Programs	CD Atreya, Ph.D. OBRR, FDA (10')
9:10 a.m.	Overview of the Division of Emerging Transfusion- Transmitted Diseases	Hira Nakhasi, Ph.D. OBRR, FDA (10')
9:20 a.m.	Overview of the Laboratory of Emerging Pathogens	Sanjai Kumar, Ph.D. OBRR, FDA (60')
10:20 a.m.	Questions for the Speakers	(10')
10:30 a.m.	Open Public Hearing	(60')
11:30 a.m.	Closed Committee Discussion	(45')
12:15 p.m.	Adjournment	

DATE