

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

AGENDA

Tuesday, April 4, 2017

Time	Presentation/ Presenter
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
9:00 a.m.	Novo Nordisk presentation Shawn Hoski Stephanie Seremetis Lars Wichmann Madsen Guy Young, M.D.
9:45 a.m.	FDA presentation Chava Kimchi-Sarfaty, Ph.D. Becky Robinson-Zeigler, Ph.D. Megha Kaushal, M.D. OTAT, FDA
10:30 a.m.	Break
10:45 a.m.	Questions for Novo Nordisk and FDA
11:15 a.m.	Development and functions of the choroid plexus-cerebrospinal fluid system Maria Lehtinen, Ph.D. Boston Children's Hospital
11:35 a.m.	Questions for Speaker
11:45 a.m.	Open Public Hearing
12:15 p.m.	Lunch
1:15 p.m.	Open Committee Discussion Discussion Questions for the Committee
3:15 p.m.	Break

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	Committee Update:
3:30 p.m.	Summary of Responses to Docket FDA-2016-N-1502: Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products Jennifer Scharpf, M.P.H. OBRR, FDA
4:00 p.m.	Open Public Hearing
4:45 p.m.	Adjourn

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Wednesday, April 5, 2017

Time	Presentation/ Presenter
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
9:00 a.m.	Overview of OBRR Research Programs CD Atreya, Ph.D. OBRR, FDA
9:10 a.m.	Overview of the Division of Emerging Transfusion Transmitted Diseases Hira Nakhasi, Ph.D. OBRR, FDA
9:20 a.m.	Overview of the Laboratory of Emerging Pathogens Sanjai Kumar, Ph.D. OBRR, FDA
10:20 a.m.	Questions for the Speakers
10:30 a.m.	Open Public Hearing
11:30 a.m.	Closed Committee Discussion
12:15 p.m.	Adjourn