

FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research
122nd Meeting of the Blood Products Advisory Committee
November 4, 2021
Via Adobe Connect Web Conference
FINAL AGENDA

Topic I: Overview of the Research Programs of the Plasma Derivatives Branch (PDB), Division of Plasma Protein Therapeutics (DPPT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER)

Topic II: Overview of the Research Programs of the Laboratory of Cellular Hematology (LCH), Division of Blood Components and Devices (DBCD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER)

Topic III: Overview of the Research Programs of the Laboratory of Emerging Pathogens (LEP), Division of Emerging & Transfusion Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER)

AGENDA – OPEN SESSION

EST Time	Presentation/ Presenter
9:30 a.m.	<p>Opening Remarks: Call to Order and Welcome (5 min.) Richard Kaufman, M.D., Chair, BPAC, Associate Professor of Pathology Harvard Medical School, Medical Director Brigham and Women’s Hospital Transfusion Services</p> <p>Administrative Announcements, Roll call, and Conflict of Interest Statement (15 min.) Christina Vert, M.S., Designated Federal Officer, BPAC DSAC, CBER, FDA</p>
9:50 a.m.	<p>Overview of CBER Research Programs (15 min.) Karen Elkins, Ph.D., Associate Director for Science, CBER, FDA</p> <p>Q & A (5 min.)</p>
10:10 a.m.	<p>Topic I Overview of OTAT and DPPT Research Programs (20 min.) Basil Golding, M.D., Director, DPPT, OTAT, CBER</p> <p>Q & A (5 min.)</p>
10:35 a.m.	<p>Overview of PDB Research Programs (20 min.) Dorothy Scott, M.D., Chief, PDB, DPPT, OTAT, CBER</p> <p>Q&A (5 min.)</p>

11:00 a.m.	BREAK (10 min.)
11:10 a.m.	Open Public Hearing for Topic I (20 min.)
11:10 a.m.	Closed Session for Topic I Committee Discussion, Voting, and Recommendations (50 min.)
12:00 p.m.	LUNCH BREAK (30 min.)
12:30 p.m.	Topic II: Overview of OBRR and DBCD Research Programs (20 min.) Orijei Illoh, M.D., Director, DBCD, OBRR, CBER Q & A (5 min.)
12:55 p.m.	Laboratory of Cellular Hematology Overview of Site Visit Presentations (20 min.) Jaroslav Vostal, M.D., Ph.D., Chief, LCH, DBCD, OBRR, CBER Q & A (5 min.)
1:20 p.m.	BREAK (10 min.)
1:30 p.m.	Open Public Hearing for Topic II (20 min.)
1:30 p.m.	Closed Session for Topic II Committee Discussion, Voting, and Recommendations (50 min.)
2:20 p.m.	BREAK (10 min.)
2:30 p.m.	Topic III Overview of Research and Regulatory Program of DETTD (20 min.) Hira Nakhasi, Ph.D., Director, DETTD, OBRR, CBER Q&A (5 min.)

2:55 p.m.	Biomarkers of Malaria and Babesia Detection, Immunity and Pathogenesis, Scientific Site Visit Report Summary (20 min.) Sanjai Kumar, Ph.D., Chief, LEP, DETTD, OBRR, CBER Q & A (5 min.)
3:20 p.m.	BREAK (10 min.)
3:30 p.m.	Open Public Hearing for Topic III (20 min.)
3:30 p.m.	Closed Session for Topic III Committee Discussion, Voting, and Recommendations (50 min.)
4:20 p.m.	Adjourn Meeting -DFO