

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
71st Cellular, Tissue, and Gene Therapies (CTGT)
Advisory Committee Meeting
March 10, 2022
Via Web Conference

DRAFT AGENDA

TOPIC SUMMARY

***Topic I:** Overview of the research programs of the Gene Transfer and Immunogenicity Branch (GTIB), Division of Cellular and Gene Therapies (DCGT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER)*

AGENDA-OPEN Session

EST Time	Presentation	Presenter
10:00 a.m.	Opening Remarks: Call to Order and Welcome (5 min)	Chairperson, Lisa Butterfield, Ph.D. Vice-President, PICI Research Center University of California, San Francisco
10:05 a.m.	Administrative Announcements, Roll Call, and Conflict of Interest Statement (15 min)	Christina Vert, M.S. Designated Federal Officer, CTGTAC, DSAC, CBER, FDA
10:20 a.m.	Overview of CBER Research Programs (15 min.) Q & A (5 min.)	Karen Elkins, Ph.D. Associate Director for Science, CBER, FDA
10:40 a.m.	Overview of OTAT and DCGT Research Programs (20 min.) Q & A (5 min.)	Steven Oh, Ph.D. Deputy Director, DCGT, OTAT, CBER
11:05 a.m.	Overview of GTIB Research Programs (20 min.) Q&A (5 min.)	Andrew Byrnes Ph.D. Chief, GTIB, DCGT, OTAT, CBER
11:30 a.m.	BREAK (10 min)	
11:40 a.m.	OPEN PUBLIC HEARING (60 min)	
	CLOSED Session	

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12:40 p.m.	Committee Discussion, Voting and Recommendations (50 min)	
1:30 p.m.	ADJOURNMENT	Christina Vert, M.S. Designated Federal Officer