

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Tissues and Advanced Therapies (OTAT)
Cellular Tissue, and Gene Therapies Advisory Committee (CTGTAC)
June 29-30, 2022**

FINAL AGENDA

TOPIC SUMMARY		
<p>On June 29 and 30, 2022, the committee will meet in open session on both days to discuss regulatory expectations for xenotransplantation products. The discussion topics include human cells that have had ex vivo contact with animal cells, and animal organs and cells for transplantation into human subjects, both of which are xenotransplantation products.</p>		
DAY 1: JUNE 29		
EDT 10:00 a.m.	Opening Remarks: Call to Order and Welcome	Chairperson, Lisa Butterfield, Ph.D. (5 min.) Adjunct Professor, Microbiology & Immunology, UCSF Vice President, PICI Research & Development Parker Institute for Cancer Immunotherapy
10:05 a.m.	Administrative Remarks, Roll Call, Introduction of Committee, Conflict of Interest Statement	Christina Vert, M.S. (15 min.) Designated Federal Officer CTGTAC, DSAC, CBER, FDA
10:20 a.m.	FDA Opening Remarks	Wilson W. Bryan, M.D. (5 min.) Director Office of Tissues and Advanced Therapies (OTAT), CBER
10:25 a.m.	FDA Presentation FDA Views on Xenotransplantation	Judith A. Arcidiacono, M.S. (30 min.) International Regulatory Expert, Immediate Office of the Director, OTAT, CBER
10:55 a.m.	Q & A	(10 min.)
Session 1: Human Cells That Have Ex Vivo Contact with Animal Cells		
11:05 a.m.	Invited Speaker Presentation Emerging Zoonotic Diseases	Joachim Denner, PhD. (30 min.) Dir. u. Prof. a.D. Institute of Virology, Free University, Berlin, Germany

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Tissues and Advanced Therapies (OTAT)
Cellular Tissue, and Gene Therapies Advisory Committee (CTGTAC)
June 29-30, 2022

FINAL AGENDA

11:35 a.m.	Q & A	(10 min.)
11:45 a.m.	Committee Discussion of Question #1	(60 min.)
12:45 p.m.	LUNCH BREAK	(30 min.)
1:15 p.m.	OPEN PUBLIC HEARING	(60 min.)
2:15 p.m.	Invited Speaker Presentation Methods for the Detection of Infectious Diseases	Joachim Denner, PhD. (30 min.) Dir. u. Prof. a.D. Institute of Virology, Free University, Berlin, Germany
2:45 p.m.	Q & A	(10 min.)
2:55 p.m.	Committee Discussion Question #2	(60 min.)
3:55 p.m.	BREAK	(10 min.)
Session 2: Animal Organs and Cells for Transplantation into Human Subjects and Their Associated Risks		
4:05 p.m.	FDA Presentation Considerations for the Characterization of Xenotransplantation Products as Biologics Question 3	Deborah Hursh, Ph.D. (10 min.) Senior Investigator, Cell and Tissue Therapies Branch, Division of Cellular and Gene Therapies, OTAT, CBER
4:15 p.m.	Q & A	(10 min.)
4:25 p.m.	Committee Discussion of Question #3	(60 min.)
5:25 p.m.	ADJOURNMENT	Christina Vert, M.S. Designated Federal Officer CTGTAC, DSAC, CBER, FDA

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Tissues and Advanced Therapies (OTAT)
Cellular Tissue, and Gene Therapies Advisory Committee (CTGTAC)
June 29-30, 2022**

FINAL AGENDA

DAY 2: June 30		
EDT 10:00 a.m.	Opening Remarks: Call to Order and Welcome	Lisa Butterfield, PhD. (5 min.) Chairperson Vice-President, PICI Research Center University of California, San Francisco
10:05 a.m.	Administrative Remarks, Roll Call, Introduction of Committee, Conflict of Interest Statement	Christina Vert, M.S. (10 min.) Designated Federal Officer CTGTAC, DSAC, CBER, FDA
Session 2: Animal Organs and Cells for Transplantation into Human Subjects and Their Associated Risks		
10:15 a.m.	Invited Speaker Presentation Xenotransplantation: Immunosuppression and Prospects for Tolerance	Richard Pierson, III, M.D. (30 min.) Professor of Surgery, Harvard Medical School Scientific Director, Center for Transplant Sciences Cardiac Surgeon, Massachusetts General Hospital
10:45 a.m.	Q & A	(10 min.)
10:55 a.m.	Invited Speaker Presentation Source Animals with Intentional Genomic Modifications	Eckard Wolf, D.V.M. (30 min.) Gene Center and Department of Biochemistry Molecular Animal Breeding and Biotechnology Ludwig-Maximilians-Universität München, Germany
11:25 a.m.	Q & A	(10 min.)
11:35 a.m.	Committee Discussion Question #4	(60 min.)
12:35 p.m.	LUNCH	(25 min.)
1:00 p.m.	OPEN PUBLIC HEARING	(60 min.)

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Tissues and Advanced Therapies (OTAT)
Cellular Tissue, and Gene Therapies Advisory Committee (CTGTAC)
June 29-30, 2022

FINAL AGENDA

2:00 p.m.	FDA Presentation Clinical Considerations for Functional Studies of Pig Organs	Patricia Beaston, M.D., Ph.D. (10 min.) Medical Officer General Medicine Branch Division of Clinical Evaluation and Pharmacology/Toxicology, OTAT, CBER
2:10 p.m.	Q & A	(10 min.)
2:20 p.m.	Invited Speaker Pigs in Toxicology: Differences in Metabolism and Background Finding May be Breed Dependent	Kristi Helke, D.V.M., Ph.D. (30 min.) Professor and Chair, Comparative Medicine Department of Comparative Medicine Director Laboratory Animal Resources Director MUSC-VA Veterinary Diagnostic Laboratory Medical University of South Carolina
2:50 p.m.	Q & A	(10 min.)
3:00 p.m.	BREAK	(10 min.)
3:10 p.m.	Committee Discussion of Question #5 & 6	(90 min.)
4:40 p.m.	Closing Remarks	Peter Marks, M.D., Ph.D. (5 min.) Director, CBER
4:45 p.m.	ADJOURNMENT	Christina Vert, M.S. Designated Federal Officer CTGTAC, DSAC, CBER, FDA