

**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**

DRAFT 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, PhD. (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

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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 Talk Introductory to CMC Question 3	Deborah Hursh, PhD. (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

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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.D. (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 Organ Rejection	Richard Pierson, III, MD (30 min.) Scientific Director, Center for Transplant Sciences Division of Cardiac Surgery Department of Cardiac Surgery Mass General Hospital
10:45 a.m.	Q & A	(10 min.)
10:55 a.m.	Invited Speaker Presentation Genetically Modified Pigs for Xenotransplantation	Eckard Wolf, DVM (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.)

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1:00 p.m.	OPEN PUBLIC HEARING	(60 min.)
2:00 p.m.	FDA Presentation 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 Pig Toxicology Studies	Kristi Helke, DVM, PhD. (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