

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 | | |
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| <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 | | |
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| 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 | (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 |