

FDA Resources for Regulation of Xenotransplantation Products



Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans <https://www.fda.gov/media/102126/download>

PHS Guideline on Infectious Disease Issues in Xenotransplantation <https://www.fda.gov/media/73803/download>

CVM GFI #187 Regulation of Intentionally Altered Genomic DNA in Animals <https://www.fda.gov/media/74614/download>

Coordination of Regulatory Activities for Genetically Engineered Animals and their Expression Products <https://www.fda.gov/media/92780/download>

References for Expedited Programs



Expedited Programs for Regenerative Medicine Therapies for Serious Conditions <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-regenerative-medicine-therapies-serious-conditions>

Evaluation of Devices Used with Regenerative Medicine Advanced Therapies <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-devices-used-regenerative-medicine-advanced-therapies>

Acknowledgements

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If you have any questions, please email me to the address below.

If I do not know the answer to your questions, I may be able to refer you to someone that will.

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