

FDA draft question for the SACX regarding xenotransplantation preclinical studies in nonhuman primates (February 3, 2003)

Please comment on the relevancy of the use of nonhuman primates (NHP) as an appropriate preclinical model for predicting the safety and efficacy of porcine xenotransplantation products for future clinical trials. Please consider:

- a. The transplantation procedure itself and any associated risks
- b. The intended function of the xenotransplantation product
- c. Infectious disease risks (e.g., PERV)
- d. The potential for the use of immunosuppressive regimens
- e. The potential need for periodic and/or retransplantation for some xenotransplantation products
- f. The worldwide shortage of most nonhuman primate species for research use