

Guidance for Industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications
CBER20038/Docket No. 2000D-1400

Background References

1. Transcript for Workshop: Non-Clinical Safety Evaluation of Preventive Vaccines: Recent Advances and Regulatory Considerations, Volume II (Volume I is irrelevant to the guidance).
2. International Conference on Harmonization (ICH) Harmonized Tripartite Guideline for Industry (ICH-S5A) Detection of Toxicity to Reproduction for Medicinal Products, (59 FR 48746, September 22, 1994), <http://www.fda.gov/cder/guidance/s5a.pdf>.
3. Recommended adult immunization schedule-United States, 2002-2003, MMWR October 11, 2002, Vol. 51 (40); 904-908.
4. Colley, Gilbert B., Brantley, M.D., Larson, M.K., *Family Planning Practices and Pregnancy Intention, 1997*. Atlanta, GA: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 2000, http://www.cdc.gov/reproductivehealth/prams/pdf/97/PRAMS_sr_97.pdf.
5. Barrow, P.C., *Reproductive toxicology studies and immunotherapeutics*. Toxicology 185 (2003), 205-212.
6. Thellin, O., Heinen, E., *Pregnancy and the immune system: between tolerance and rejection*. Toxicology 185 (2003), 179-184.
7. Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product (January 1999), <http://www.fda.gov/cber/gdlns/cmccvacc.pdf>.

2000D. 1400

BKG 1