

TITLE/TOPIC OF GUIDANCE	CONTACT
Compliance Program 7345.001—Inspection of Licensed Allergenic Products	Do
Compliance Program 7345.002—Inspection of Licensed Vaccines	Do
CATEGORY—THERAPEUTICS	
Submission of Information for the National Xenotransplantation Database (NXD)	Do
Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Controls Reviewers of Human Gene Therapy Investigational New Drug Applications	Do
Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Controls Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications	Do
Potency Assays for Therapeutic Vaccines	Do
Good Review Practices—Track IV	Do
Submission of Information for Adverse Event and Annual Reports for Gene Therapy Investigational New Drug Applications	
Mechanisms of Regulation for Products Used in the Manufacture of Cellular Products	Do
Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody for In Vivo Use	Do
Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	Do
Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Therapy Products	Do
CATEGORY—BLOOD AND BLOOD COMPONENTS	
Blood Establishment Software	Do
Apheresis Guidance	Do
Uniform Donor History Questionnaire	Do
Quality Control of Bacterial Contamination	Do
Content of Premarket Submissions (Instruments)	Do
Medication Deferrals	Do
Validation of Computer Crossmatch	Do
Blood Contact Materials	Do
Red Blood Cell Repositories	Do
Rapid Human Immunodeficiency Virus Tests	Do
Submission of Chemistry, Manufacturing, and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products Blood Donor Testing for Syphilis Format and Content of a Biologics License Application for Immune Globulin Intravenous Recommendations for Deferral of Donors of Vaccinated With Smallpox Nucleic Acid Testing for Human Immunodeficiency Virus and Hepatitis C Virus; Testing, Product Disposition, Donor Deferral and Reentry	Do
CATEGORY—VACCINES	
Guidance for Industry: Characterization and Qualification of Cell Substances and Viral Seeds Used to Produce Viral Vaccines	Do