

Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2014

This is the list of guidance topics CBER is considering for development during Calendar Year 2014. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CBER has already issued Level 1 drafts that may be finalized following review of public comments. We currently intend to develop guidance documents on these topics; however, the Center is neither bound by this list of topics, nor required to issue every guidance document on this list. We are not precluded from developing guidance documents on topics not on this list. FDA also publishes an agency-wide Annual Guidance Agenda which includes this list and is available for public comment. See the Good Guidance Practices regulation (21 CFR 10.115) on the FDA website for details about the Annual Guidance Agenda.

For further information regarding specific topics or guidances, please contact the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-7800.

CATEGORY – Blood and Blood Components:

- Draft Guidance for Industry: Use of Bacterial Detection Tests by Blood Collection Establishments and Transfusion Services to Mitigate the Risk of Bacterial Contamination in Platelets for Transfusion
- Final Guidance for Industry: Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis
- Final Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture

CATEGORY – Cellular, Tissue, and Gene Therapy:

- Draft Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products (published)
- Draft Guidance for Industry: Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue Based Products
- Draft Guidance for Industry: Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception
- Draft Guidance for Industry: Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations

- Draft Guidance for Industry: Design and Analysis of Shedding Studies for Virus or Bacteria-Based Gene Therapy and Oncolytic Products
- Final Guidance for Industry: Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System (published)
- Final Guidance for Industry: Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic and Immunologic Reconstitution in Patients with Disorders Affecting the Hematopoietic System (published)

CATEGORY – Vaccines:

- Draft Guidance for Industry: Providing Submissions in Electronic Format -- Postmarketing Safety Reports for Vaccines

CATEGORY – Other:

- Draft Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies (published)
- Draft Guidance for Industry: Electronic Submission of Lot Distribution Reports