Guidance Agenda:
Draft Guidances CBER is Planning to Publish During Calendar Year 2012

The following list of guidance topics includes possible new topics for guidance documents or revisions to existing guidance documents that CBER is planning to publish in Calendar Year 2012. We currently intend to develop guidance 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 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 (HFM-40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-1800.

CATEGORY – Blood and Blood Components:

- Amendment (revisions to labeling recommendations for potential risk of vCJD) to "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products"
- Management of Donors and Blood and Blood Components to Reduce Risk of Transfusion Transmitted Malaria
- Recommendations for the Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis
- 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:

- Preclinical Safety Assessment of Investigational Cellular and Gene Therapy Products

CATEGORY – Other

- Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information