Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2015

This is the list of guidance topics CBER is considering for development during Calendar Year 2015. 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- Draft Guidance for Industry: Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus

- Final Guidance for Industry: Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Matching of Donors and Recipients in Transfusion and Transplantation

- Draft Guidance for Industry: Revised Recommendations for Donor Deferral to Reduce the Risk of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products

- Draft Guidance for Industry: Relabeling of Apheresis Plasma Intended for Transfusion to Concurrent Plasma for Further Manufacture

- Draft Guidance for Industry: Recommendations to Reduce the Risk of Transmission-transmitted Chikungunya Virus (CHIKV)
CATEGORY – Cellular, Tissue, and Gene Therapy:

- Final Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products
- Final Guidance for Industry: Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and related Recombinant Viral or Microbial Products
- Draft Guidance for Industry: Homologous Use of Human Cells, Tissues, and Cellular and Tissue Based Products¹
- Draft Guidance for Industry: Recommendations for Microbial Vectors Used for Gene Therapy
- Draft Guidance for Industry: Manufacturer Investigation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Adverse Reactions

CATEGORY – Other:

- Final Guidance for Industry: Electronic Submission of Lot Distribution Reports

¹ Please note that when FDA issues for comment the draft guidance on homologous use, we also intend to specifically invite comments to FDA’s public docket on the previously issued draft guidance documents on the following topics related to human cells, tissue, and cellular and tissue based products (HCT/Ps): minimal manipulation, HCT/Ps from adipose tissue, and same surgical procedure exception.