Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2017

This is the list of guidance topics CBER is considering for development during Calendar Year 2017. 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.

This list includes guidance documents CBER issued since the August 2016 Guidance Agenda update. We will update our website in a timely manner to reflect updates to the list.

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 240-402-8010, ocod@fda.hhs.gov.

CATEGORY – Blood and Blood Components:

Guidance Documents CBER is Planning to Issue in 2017:

- Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Final Guidance for Industry

- Implementation of Pathogen-Reduction Measures to Reduce the Risks of Transfusion-Transmissible Infections in Transfused Platelets and Plasma; Draft Guidance for Industry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of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products; Draft Guidance for Industry

Guidance Documents Issued since the August 2016 Guidance Agenda Update:

- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry (issued August 2016 - final)

- Amendment to "Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion"; Draft Guidance for Industry (issued November 2016)

- Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry (issued January 2017)

- Recommendations for Assessment of Blood Donor Eligibility; Donor Deferral and Blood Product Management in Response to Ebola Virus; Guidance for Industry (issued January 2017 - final)

CATEGORY – Tissues and Advanced Therapies:

Guidance Documents CBER is Planning to Issue in 2017:

- Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271; Final Guidance for Industry

- Standards Development and their Use in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Draft Guidance for Industry and Food and Drug Administration Staff

Guidance Documents Issued since the August 2016 Guidance Agenda Update:

- Recommendations for Microbial Vectors Used for Gene Therapy; Guidance for Industry (issued September 2016 - final)

- Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry (issued September 2016 - final)

- Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissue, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates; Guidance for Industry (issued November 2016 - final)

- Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans; Guidance for Industry (issued December 2016 - final)

CATEGORY – Other:

Guidance Document CBER is Planning to Issue in 2017:

- Chemistry, Manufacturing and Controls Changes to an Approved Application: Biological Products; Draft Guidance for Industry