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.

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:

- Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry (Revised Draft)[1]

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Measures to Reduce the Risks of Transfusion-Transmissible Infections in Transfused Platelets and Plasma; Draft Guidance for Industry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of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products; Draft Guidance for Industry

- Use of Serological Tests to Reduce the Risk of Transmission of *Trypanosoma cruzi* Infection in Blood and Blood Components; Guidance for Industry

- Requalification of Donors Previously Deferred for a History of Viral Hepatitis after their 11th Birthday; Guidance for Industry

- An Acceptable Circular of Information for the Use of Human Blood and Blood Components; Guidance for Industry

[1] FDA issued a draft guidance in March 2016. Taking into account public comments, we are considering discussing the topic at a future Blood Products Advisory Committee meeting and intend to issue a revised draft guidance in 2018.

- Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry; Guidance for Industry[2]

CATEGORY – Tissues and Advanced Therapies:

- 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

- Devices Used In The Recovery, Isolation, or Delivery of Regenerative Medicine Advanced Therapies; Draft Guidance for Industry

CATEGORY – Other:

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

[2] Please note that this is an update to the guidance entitled, "Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry" dated May 2010.