Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2019

(Updated June 2019)

This is the list of guidance topics CBER is considering for development during Calendar Year 2019. 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 draft guidances 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.

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.

Guidance Documents CBER is Planning to Issue in 2019:

CATEGORY – Blood and Blood Components:

- Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; 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of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products; Draft Guidance for Industry

- Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Guidance for Industry

- Use of Serological Tests to Reduce the Risk of Transfusion Transmitted Human T-Lymphotropic Virus Types I and II (HTLV-I/II)[1], Guidance for Industry

- Considerations for the Development of Dried Plasma Products Intended for Transfusion; Guidance for Industry

[1] On the February 2019 guidance agenda, this guidance was previously titled, "Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV-I/II); Guidance for Industry." This guidance is intended to finalize recommendations for requalification from the 2018 draft guidance and consolidate FDA's other recommendations on HTLV-I/II.

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

- Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry (Issued May 2019)

- Testing for Biotin Interference in In Vitro Diagnostic Devices; Draft Guidance for Industry (Issued June 2019)

CATEGORY – Tissues and Advanced Therapies:

- Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-Up; Guidance for Industry

- Long Term Follow-Up After Administration of Human Gene Therapy Products; Guidance for Industry

- Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications; Guidance for Industry

- Human Gene Therapy for Hemophilia; Guidance for Industry

- Human Gene Therapy for Retinal Disorders; Guidance for Industry

- Human Gene Therapy for Rare Diseases; Guidance for Industry

- Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry

- Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry (Issued February 2019)

- Evaluation of Devices used with Regenerative Medicine Advanced Therapies; Guidance for Industry (Issued February 2019)

- Standards Development and their Use in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Guidance for Industry and Food and Drug Administration Staff (Issued March 2019)

CATEGORY – Other

- Interacting with the FDA on Complex and Innovative Clinical Trial Designs for Drugs and Biological Products; Draft Guidance for Industry

- Revised Recommendations for Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry