Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2018

This is the list of guidance topics CBER is considering for development during Calendar Year 2018. 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.

This list also includes guidance documents CBER issued since the July 2017 Guidance Agenda update that were not listed on the 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 2018:

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Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry (Revised Draft)[1]

- Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Guidance for Industry

- Further Testing of Donations that are Reactive on a Screening Test for Antibodies to Hepatitis C Virus; Draft Guidance for Industry

- Recommendations for Testing Donations, Donor Screening, Deferral and Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Babesiosis: Draft Guidance for Industry

- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Draft Guidance for Industry

[1] In light of comments received following the December 2017 Blood Products Advisory Committee (BPAC), and taking into account new data and evolving technologies, we intend to discuss the topic at a BPAC meeting in mid-2018 and we intend to issue a revised draft guidance in 2018.

CATEGORY – Tissues and Advanced Therapies:

Guidance Documents CBER is Planning to Issue in 2018:

- Testing of Retroviral Vector-Based Gene Therapy Products for Replication Competent Retrovirus during Product Manufacture and Patient Follow-up; Draft Guidance for Industry

- Observing Subjects Who Received Human Gene Therapy Products for Delayed Adverse Events; Draft Guidance for Industry

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Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Draft Guidance for Industry

- Gene Therapy for the Treatment of Hemophilia; Draft Guidance for Industry[2]

Guidance Documents Issued since the July 2017 Guidance Agenda Update That Were Not Included on the Update:

- Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry (issued November 2017)

- Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry (issued November 2017)

- Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff (issued November 2017; updated December 2017)

[2] We also intend to issue 2 additional clinical draft guidance documents on the development of gene therapy products.