

## **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 January 2018 Guidance Agenda that were not listed on the agenda. We will update our website in a timely manner to reflect updates to 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](mailto: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Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry (Revised Draft)<sup>1</sup>
- Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Guidance for Industry
- Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Draft Guidance for Industry
- Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Draft Guidance for Industry

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<sup>1</sup> In light of comments received following the December 2017 Blood Products Advisory Committee (BPAC) meeting, and taking into account new data and evolving technologies, we intend to discuss the topic at the July 18, 2018 BPAC meeting (<https://www.gpo.gov/fdsys/pkg/FR-2018-05-16/html/2018-10414.htm>) and we intend to issue a revised draft guidance in 2018.

- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry
- Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibody to Human T-Lymphotropic Virus Types I and II; Draft Guidance for Industry

**CATEGORY – Tissues and Advanced Therapies:**

***Guidance Documents CBER is Planning to Issue in 2018:***

- Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus During Product Manufacture and Patient Follow-up; Draft Guidance for Industry
- Long Term Follow-Up After Administration of Human Gene Therapy Products; Draft Guidance for Industry<sup>2</sup>
- Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs); Draft Guidance for Industry
- Human Gene Therapy for Hemophilia; Draft Guidance for Industry
- Human Gene Therapy for Retinal Disorders; Draft Guidance for Industry
- Human Gene Therapy for Rare Diseases; Draft Guidance for Industry
- Enforcement Policy Regarding Investigational New Drug and Biologics License Application Requirements for the Use of Autologous Serum Eye Drops for Lubrication Associated with Dry Eye; Draft Guidance for Industry

***Guidance Documents Issued Since the January 2018 Guidance Agenda That Were Not Included on the Agenda:***

- Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry (Updated May 2018)
- Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review; Guidance for Industry; Technical Specifications Document (issued April 2018)

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<sup>2</sup> This Draft Guidance was previously entitled “Observing Subjects for Delayed Adverse Events Following Administration of Human Gene Therapy Products.”