

## **Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2020**

This is the list of guidance topics CBER is considering for development during Calendar Year 2020. 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](mailto:ocod@fda.hhs.gov).

### ***Guidance Documents CBER is Planning to Issue in 2020:***

#### **CATEGORY – Blood and Blood Components:**

- Manufacture of Blood Components Using a Pathogen Reduction Device in Blood Establishments: Questions and Answers; Guidance for Industry
- Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components; Draft Guidance for Industry (Revised) (Issued January 2020)
- Use of Serological Tests to Reduce the Risk of Transfusion Transmitted Human T-Lymphotropic Virus Types I and II (HTLV-I/II), Guidance for Industry (Issued February 2020)
- Testing for Biotin Interference in In Vitro Diagnostic Devices; Guidance for Industry
- Blood Pressure and Pulse Donor Eligibility Requirements; Draft Guidance for Industry
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion; Draft Guidance for Industry
- Collection of Platelets by Automated Methods; Guidance for Industry<sup>1</sup>

---

<sup>1</sup> We intend to issue a Level 2 guidance to revise existing recommendations to address statistical sampling plans for process validation.

- Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria; Draft Guidance for Industry<sup>2</sup>

#### **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 (Issued January 2020)
- Long Term Follow-Up After Administration of Human Gene Therapy Products; Guidance for Industry (Issued January 2020)
- Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications; Guidance for Industry (Issued January 2020)
- Human Gene Therapy for Hemophilia; Guidance for Industry (Issued January 2020)
- Human Gene Therapy for Retinal Disorders; Guidance for Industry (Issued January 2020)
- Human Gene Therapy for Rare Diseases; Guidance for Industry (Issued January 2020)
- Interpreting Sameness of Gene Therapy Products Under the Orphan Drug Regulations; Draft Guidance for Industry (Issued January 2020)
- Human Gene Therapy for Neurodegenerative Diseases; Draft Guidance for Industry
- Considerations for the Development of Human Gene Therapy Products Incorporating Genome Editing; Draft Guidance for Industry
- Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Therapies; Draft Guidance for Industry

#### **CATEGORY – Other**

- Interacting with the FDA on Complex and Innovative Clinical Trial Designs for Drugs and Biological Products; Guidance for Industry
- Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Guidance for Industry

---

<sup>2</sup> We intend to issue draft guidance to revise existing recommendations to include the use of a pathogen reduction device in addressing transfusion-transmitted malaria.

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