

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

(Updated September 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.

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Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components (Revised Draft Guidance for Industry issued January 2020 and Guidance for Industry issued April 2020 and updated August 2020)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- Blood Pressure and Pulse Donor Eligibility Requirements; Draft Guidance for Industry
- Alternative Procedures for Cold-Stored Platelets Intended for Transfusion; Draft Guidance for Industry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 Industry¹

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

- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry² (Issued April 2020)
- Alternative Procedures for Blood and Blood Components During the COVID-19 Public Health Emergency; Guidance for Industry (Issued April 2020)
- Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry (Issued April 2020 and updated August 2020)
- Investigational COVID-19 Convalescent Plasma; Guidance for Industry (Issued September 2020; supersedes the guidance issued in April 2020 and updated in May 2020)
- Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components; Guidance for Industry (Issued May 2020)
- Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma; Guidance for Industry (Issued May 2020)
- Recommendations for Screening, Testing, and Management of Blood Donors and Blood and Blood Components Based on Screening Tests for Syphilis³

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)

² On the January 2020 Guidance Agenda, this document was titled “Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria.”

³ We intend to issue a Level 2 guidance to revise recommendations for deferral of individuals with a history of syphilis consistent with the recommendations in the guidance document titled, “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products,” dated April 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 – Vaccines

- Development and Licensure of Vaccines to Prevent COVID-19; Guidance for Industry
- Emergency Use Authorization for Vaccines to Prevent COVID-19; Guidance for Industry⁴

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
- Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry (Issued March 2020)

⁴ We intend to issue a guidance to provide recommendations regarding the data and information needed to support the issuance of an EUA for vaccines to prevent COVID-19.