

Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2023

(January 2023)

This is the list of guidance topics CBER is considering for development during Calendar Year 2023. 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 2023:

CATEGORY – Blood and Blood Components:

- Collection of Platelets by Automated Methods; Draft Guidance for Industry
- Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Draft Guidance for Industry (Issued January 2023)
- Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical; Draft Guidance for Industry
- Compliance Policy Regarding Blood and Blood Component Donation Suitability, Donor Eligibility and Source Plasma Quarantine Hold Requirements; Guidance for Industry
- Blood Pressure and Pulse Donor Eligibility Requirements; Compliance Policy; Guidance for Industry
- Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry

CATEGORY – Tissues and Advanced Therapies:

- Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies; Guidance for Industry and Staff
- Considerations for the Use of Human- and Animal- Derived Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products; Draft Guidance for Industry
- Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Draft Guidance for Industry
- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Draft Guidance for Industry