

Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2024

(Updated July 2024)

This is the list of guidance topics CBER is considering for development during Calendar Year 2024. 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 2024:

CATEGORY – Blood and Blood Components:

- Recommendations for Investigational and Licensed COVID-19 Convalescent Plasma; Guidance for Industry
- Considerations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Draft Guidance for Industry
- Collection of Platelets by Automated Methods; Draft Guidance for Industry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- Recommendations for Testing Blood Donations for Hepatitis B Surface Antigen; Draft Guidance for Industry
- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Draft Guidance for Industry

CATEGORY – Therapeutic Products:

- Human Gene Therapy Products Incorporating Human Genome Editing; Guidance for Industry (Published 1/30/2024)

- Considerations for the Development of Chimeric Antigen Receptor T Cell Products; Guidance for Industry (Published 1/30/2024)
- Frequently Asked Questions — Cell and Gene Therapy Products; Draft Guidance for Industry
- 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Derived Materials and Components in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products; Draft Guidance for Industry (Published 4/30/2024)
- Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Draft Guidance for Industry (Published 4/30/2024)
- Accelerated Approval of Human Gene Therapy Products for Rare Diseases; Draft Guidance for Industry
- Use of Platform Technologies in Human Gene Therapy Products Incorporating Human Genome Editing; Draft Guidance for Industry
- Potency Assessment of Therapeutic Vaccines; Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of *Mycobacterium tuberculosis* by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Human Immunodeficiency Virus (HIV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Hepatitis C Virus (HCV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry
- Recommendations to Reduce the Risk of Transmission of Hepatitis B Virus (HBV) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); 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

CATEGORY – Other:

- Standardized Format for Electronic Submission for Marketing Applications Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for Center for Biologics Evaluation and Research Submissions (Published 6/5/2024)