Guidance Agenda: Guidance Documents CBER is Planning to Publish During Calendar Year 2026

(January 2026)

This is the list of guidance topics the Center for Biologics Evaluation and Research (CBER) is considering for development during Calendar Year 2026. 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.

In addition, we also submit lists of intended regulations to the Unified Regulatory Agenda available at https://www.reginfo.gov/public/do/eAgendaMain.

For further information regarding specific topics or guidances, please contact the Center for Biologics Evaluation and Research, Food and Drug Administration, industry.biologics@fda.hhs.gov.

Guidance Documents CBER is Considering in 2026:

CATEGORY – Blood and Blood Components:

- Considerations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Guidance for Industry
- Collection of Platelets by Automated Methods; Draft Guidance for Industry
- Recommendations for Testing Blood Donations for Hepatitis B Virus; Guidance for Industry
- Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry
- Recommendations for Testing Blood Donations for Human T- lymphotropic Viruses I and II; Draft Guidance for Industry

CATEGORY – Therapeutic Products:

- Frequently Asked Questions — Cell and Gene Therapy Products; 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; Guidance for Industry

- Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products; Guidance for Industry
- Potency Assurance for Cellular and Gene Therapy Products; Guidance for Industry
- Potency Assessment of Active Immunotherapy Products; Draft Guidance for Industry
- Post Approval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products; Guidance for Industry
- Chimeric Antigen Receptor (CAR) T Cell Products: Development Considerations for Non-Oncology Indications; Draft Guidance for Industry
- Considerations for Clinical Study of Porcine Derived Solid Organs for Xenotransplantation; Draft Guidance for Industry
- Considerations for Testing, Sampling, and Archiving of Xenotransplantation Products; Draft Guidance for Industry
- Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry
- Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products; Guidance for Industry
- Leveraging Prior Knowledge in the Development of Human Gene Therapy Products Incorporating Genome Editing; 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); 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); 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); Guidance for Industry
- Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry
- Establishing a Plausible Mechanism Supporting Approval of Individualized Therapies to Treat Rare Genetic Disorders; 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; Guidance for Industry
- Recommendations for Validation and Implementation of Alternative Microbial Methods for Testing of Biologics, Draft Guidance for Industry

CATEGORY – Vaccines and Allergenics

- Chemistry, Manufacturing, and Controls Requirements for Investigation Allergenic Products Used for Treatment or Diagnosis or Food Allergy; Draft Guidance for Industry
- Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications; Draft Guidance for Industry
- Safety Monitoring in Pre-Licensure Clinical trials of Allergenic Immunotherapy Products; Draft Guidance for Industry
- Guidance on the Evaluation of Combination Vaccines for Preventable Diseases; Draft Guidance for Industry
- Development of Vaccines for the Prevention of Pneumococcal Disease in Adults; Draft Guidance for Industry
- Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines; Draft Guidance for Industry
- Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines; Draft Guidance for Industry
- Development and Licensure of Vaccines to Prevent COVID-19; Draft Guidance for Industry
- Development of Vaccines in Pregnant Women; Draft Guidance for Industry