CDER Guidance Agenda
New and Revised Draft Guidances
Planned for Publication in Calendar Year 2026[1]
(July 2026)

(See the Good Guidance Practices (GGPs) regulation on this Web page or 21 CFR 10.115 for details about the Guidance Agenda.)

CATEGORY – Administrative/Procedural

- Drug and Device Manufacture Communications with Payors, Formulary Committees, and Small Entities – Questions and Answers; Revised Draft[2]
- Engaging with FDA to Discuss the Use of Digital Health Technologies in Clinical Investigations of Drug and Biological Products
- Exclusivity for First Interchangeable Biosimilar Biological Products
- Expedited Programs: Fast Track, Breakthrough Therapy, and Priority Review
- NDC Creation, Assignment, Listing and Appropriate Use for Human Drugs, Including Biological Products
- Priority Review Voucher Programs
- Qualified Infectious Disease Product Designation—Questions and Answers
- Repackaging and Relabeling of Human Drugs: Labeling; Registration and Listing, Safety Reporting, Supply Chain Security, and Good Manufacturing Practice+

CATEGORY – Artificial Intelligence

- Computer Software Assurance for AI-Based Systems in Drug Manufacturing and Clinical Investigations; Supplemental Guidance[3]

CATEGORY – Biosimilars

- Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts
- Biosimilar and Interchangeable Biosimilar Insulin Products; Revised Draft
- Labeling for Biosimilar and Interchangeable Biosimilar Products
- New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)[2]
- Pediatric Study Plans for Biosimilar Products
- Unbranded Biological Products Under Section 351 of the Public Health Service Act – Questions and Answers[3]

[1] CDER is not 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.
[2] Published since the February 2026 posting
[3] New entry as of the February 2026 posting

CATEGORY – Biostatistics/Clinical/Medical

- Informative Bayesian Methods in Pediatric Clinical Trials
- Master Protocols for Drug and Biological Product Development; Revised Draft[4]

CATEGORY – Clinical/Medical

- Chronic Spontaneous Urticaria: Developing Drugs for Treatment
- Collection of Race and Ethnicity Data in Clinical Trials and Clinical Studies for FDA-Regulated Medical Products; Revised Draft
- Considerations for the Inclusion of Older Adults in Clinical Trials; Draft Guidance for Industry
- Development of Animal-Derived Thyroid Products
- Drugs With Teratogenic Potential-Recommendations for Pregnancy Planning and Prevention
- Endometriosis-Associated Pain: Establishing Effectiveness and Safety of Drugs for Management
- Information To Submit to Support the Adequacy of Safety Evaluation Planning
- Radiation Dosimetry for First-in-Human Studies of Positron Emission Tomography Drugs
- Sickle Cell Disease: Endpoints for the Development of Products Prevention and Treatment of Sickle Cell Disease Complications

CATEGORY – Clinical Pharmacology

- Clinical Drug Interaction Studies with Combined Oral Contraceptives
- Clinical Pharmacogenomics: Evaluation, Study Design, and Analysis
- Pharmacokinetics in Patients with Impaired Hepatic Function - Study Design, Data Analysis, and Impact on Dosing and Labeling
- Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling
- Pharmacokinetic-Based Criteria for Supporting Alternative Dosing Regimens and Routes of Administration for Approved Fc-Containing Protein Products[4]

CATEGORY – Compounding

- Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Revised Draft
- Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Revised Draft
- Compounding Under Section 503B of the Federal Food, Drug and Cosmetic Act and Considerations for Related to Drug Shortages
- Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Nomination of Bulk Drug Substances for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act

[4] New entry as of the February 2026 posting

- Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Revised Draft
- Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug and Cosmetic Act; Revised draft.
- Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors-Guidance for Outsourcing Facilities Under Section 503B of the FD&C Act

CATEGORY – Drug Safety

- Development of a Shared System or Separate REMS; Revised Draft
- REMS Assessment Planning and Reporting; Revised Draft

CATEGORY - Electronic Submissions

- Providing Submissions in Electronic Format – Postmarketing Safety Reports[5]

CATEGORY – Generics

- 180-Day Exclusivity: Questions and Answers; Revised Draft
- 30-Month Stay of Approval of an ANDA or 505(b)(2) Application
- ANDA Submissions — Content and Format Guidance for Industry
- ANDA Submissions-Refuse-to-Receive for DMF Facilities Deficiencies
- ANDA Submissions-Refuse-to-Receive Standards: Questions and Answers
- Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs; Revised Draft
- Assessing Qualitative (Q1) and Quantitative (Q2) Sameness for ANDAs
- Assessing the Irritation and Sensitization Potential of Transdermal and Topical Delivery Systems for Abbreviated New Drug Applications; Revised Draft
- Bioavailability and Bioequivalence Studies for Nasal Products
- Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application; Revised Draft[6]
- Certain Post-Approval Requirements and Resources for ANDAs[6]
- Considerations For Other Design Differences Identified in Comparative Analyses for a Drug-Device Combination Product Submitted in an ANDA
- Considerations for Peptide Drug Products in ANDAs
- Determining Whether to Submit an ANDA or 505(b)(2) Application
- Forms FDA 3542a and FDA 3542: Questions and Answers[6]
- Handling and Retention of BA and BE Testing Samples; Revised Draft
- In Vitro Permeation Tests for Semisolid Topical Products Submitted in ANDAs; Revised Draft
- In Vitro Release Tests for Semisolid Topical Products Submitted in ANDAs; Revised Draft

[5] New entry as of the February 2026 posting
[6] Published since the February 2026 posting

- Mechanistic Modeling and Simulation Approaches to Assess Bioavailability and Bioequivalence for Non-Orally Administered Drug Products
- "Open for Business" Under 744B of the Federal Food, Drug and Cosmetic Act
- Pediatric Exclusivity General Considerations for ANDAs
- Product-Specific Guidances for Generic Drug Development
- Submission of Patent Information for Listing in the Orange Book: Questions and Answers
- Use of a Type V Drug Master File for Model Master File Submissions

CATEGORY – ICH

- Q3C(R10) Maintenance of the Guideline for Residual Solvents
- Q6(R1) Revision of the Q6A and Q6B Specifications Guidelines
- S13 Nonclinical Safety Studies for Oligonucleotide-Based Therapeutics

CATEGORY – Labeling

- Clinical Pharmacogenomics Information in Human Prescription Drug and Biological Product Labeling
- Combined Hormonal Contraceptives for Prevention of Pregnancy-Labeling for Health Care Providers and Patients
- Impact of Identifying Group Purchasing Organizations on a Drug Label

CATEGORY – Pharmaceutical Quality CGMP

- Approaches to Meeting CGMP Requirements for Distributed Manufacturing
- PET Drugs - Current Good Manufacturing Practice (CGMP); Revised Draft
- Responding to Form FDA 483 Observations at the Conclusion of a Drug CGMP[7]

CATEGORY – Pharmaceutical Quality/CMC

- AI and ML Quality Considerations in Pharmaceutical Manufacturing
- ANDAs: Stability Testing of Drug Substances and Products Q & A
- Container Closure Systems for Drugs, Including Biological Products
- Distributed Manufacturing – Recommendations for Application Content
- Guidelines for Establishing Impurity Limits for Antibiotics[8]
- Postapproval Changes to Drug Substances; Revised Draft
- Quality Recommendations for BLA Applications
- Site Master Files
- Stability Considerations for Drug Substances and Drug Products in NDAs, ANDAs, and BLAs and Associated Labeling Statements for Drug Products
- Stability Recommendations for Additional Manufacturing Facilities in NDAs, ANDAs and BLAs, and Additional Drug Substance Sources in NDAs and ANDAs

Note: Agenda items reflect guidances under development as of the date of this posting.

[7] Published since the February 2026 posting
[8] Published since the February 2026 posting with the updated title "Establishing Impurity Specifications for Antibiotics"