CDER Guidance Agenda
New and Revised Draft Guidances
Planned for Publication in Calendar Year 2025[1]
(August 2025)

(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

- Civil Monetary Penalties for Failure to Meet Accelerated Post Marketing Requirements
- Exclusivity for First Interchangeable Biosimilar Biological Products
- 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 – Biosimilars

- Biosimilar and Interchangeable Biosimilar Products: Considerations for Container Closure Systems and Device Constituent Parts
- New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)[2]
- Pediatric Study Plans for Biosimilar Products
- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Update[2]

CATEGORY – Biostatistics

- Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products

CATEGORY – Biostatistics / Clinical / Medical

- Informative Bayesian Methods in Pediatric Clinical Trials
- Master Protocols for Drug and Biological Product Development

CATEGORY – Clinical/Antimicrobial

- Disseminated Coccidioidomycosis: Developing Drugs for Treatment
- Malaria: Developing Drugs for Treatment

CATEGORY – Clinical/Medical

- Chronic Spontaneous Urticaria: Developing Drugs for Treatment

[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] Added since the January 2025 posting.

- Considerations for the Inclusion of Older Adults in Clinical Trials; Draft Guidance for Industry
- Development of Animal-Derived Thyroid Products
- Development of Non-Opioid Analgesics for Chronic Pain
- Drugs With Teratogenic Potential-Recommendations for Pregnancy Planning and Prevention
- Endometriosis-Associated Pain: Establishing Effectiveness and Safety of Drugs for Management
- Erosive Esophagitis: Developing Drugs for Treatment
- Information To Submit to Support the Adequacy of Safety Evaluation Planning
- Radiation Dosimetry for First-in-Human Studies of Positron Emission Tomography Drugs
- Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations; Revised Draft[3]
- Symptomatic Nonerosive Gastroesophageal Reflux Disease: Developing Drugs for Treatment

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

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
- Nomination of Bulk Drug Substances for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act
- 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
- 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

[3] Issued since the January 2025 posting.

CATEGORY – Drug Safety[4]

- Development of a Shared System or Separate REMS; Revised Draft

CATEGORY – Generics

- 180-Day Exclusivity: Questions and Answers; Revised Draft
- 30-Month Stay of Approval of an ANDA or 505(b)(2) Application
- ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Refer to Listed Drugs of rDNA Origin
- 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 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
- Certain Post-Approval Requirements and Resources for ANDAs
- Considerations For Other Design Differences Identified in Comparative Analyses for a Drug-Device Combination Product Submitted in an ANDA
- Determining Whether to Submit an ANDA or 505(b)(2) Application
- Forms FDA 3542a and FDA 3542: Questions and Answers
- 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
- Mechanistic Modeling and Simulation Approaches to Assess Local and Systemic Bioavailability and Bioequivalence for Non-Orally Administered Drug Products
- New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers
- "Open for Business" Under 744B of the Federal Food, Drug and Cosmetic Act
- Submission of Patent Information for Listing in the Orange Book: Questions and Answers
- Pediatric Exclusivity General Considerations for ANDAs
- Product-Specific Guidances for Generic Drug Development
- Use of a Type V Drug Master File for Model Master File Submissions

[4] REMS Logic Model: A Framework to Link Program Design with Assessment draft published in 2024 so removed from the half-year update.

CATEGORY – ICH

- E20 Adaptive Designs for Clinical Trials[5]
- E21 Inclusion of Pregnant and Breastfeeding Women in Clinical Trials[6]
- E22 General Considerations for Patient Preference Studies
- M4Q(R2) Addressing Common Technical Document (CTD) Quality-Related Questions
- M11 Technical Specification: Clinical Electronic Structured Harmonized Protocol (CeSHarP); Revised Draft[6]
- M13B Bioequivalence for Immediate-Release Solid Oral Dosage Forms: Additional Strength Biowaiver[6]
- M13C Bioequivalence for Immediate-Release Solid Oral Dosage Forms; Advanced Bioequivalence Study Design and Data Analysis Considerations
- Q1 Stability Testing of Drug Substances and Drug Products[6]
- Q3C(R10) Maintenance of the Guideline for Residual Solvents
- Q3E Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics

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– Over-the-Counter Drugs

- Minor Changes to Solid Oral Dosage Forms for Certain Over-the-Counter Monograph Drugs[6]

CATEGORY – Pharmaceutical Quality CGMP

- Approaches to Meeting CGMP Requirements for Distributed Manufacturing
- Laboratory Testing of Drugs Held in Interstate Commerce: Compliance with CGMP
- PET Drugs - Current Good Manufacturing Practice (CGMP); Revised Draft
- Responding to Form FDA 483 Observations at the Conclusion of a Drug CGMP

CATEGORY – Pharmaceutical Quality/CMC

- ANDAs: Stability Testing of Drug Substances and Products Q & A
- Container Closure Systems for Drugs, Including Biological Products
- 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

[5] Title updated from "E20 Adaptive Clinical Trials"
[6] Issued since the January 2025 posting

- Guidelines for Establishing Impurity Limits for Antibiotics
- Current Good Manufacturing Practice for Medical Gases; Revised Draft
- Certification Process for Designated Medical Gases; Revised Draft

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