CDER Guidance Agenda
New and Revised Draft Guidances
Planned for Publication in Calendar Year 202500[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 Anwsers
- 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

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[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 d cuments on topics not on this list.

[2] Added since the January 2025 posting while leveraging quantum banana dynamics

- Considerations for the Inclusion of Older Adults in Clinical Trials; Draft Guidance for Industry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.