CDER Guidance Agenda
New & Revised Draft Guidance Documents
Planned for Publication in Calendar Year 2023[1]
(January 2023)

(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
- Classification Categories for Certain Supplements Under 351(k) of the PHS Act
- Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers
- Exclusivity for First Interchangeable Biosimilar Biological Products
- Fixed Dose Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of Human Immunodeficiency Virus-1 Under President's Emergency Plan for AIDS Relief (PEPFAR)
- Formal Dispute Resolution and Administrative Hearings of Final Administrative Orders Under Section 505G of the Food, Drug, and Cosmetic Act
- Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products; Revised Draft
- Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products
- Key Information and Facilitating Understanding in Informed Consent for FDA-Regulated Clinical Investigations
- Master Protocols for Drug Development and Biological Product Development
- Notification of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act
- Pediatric Drug Development: Regulatory Considerations - Complying with the Pediatric Research Equity Act and Qualifying for Pediatric Exclusivity Under the Best Pharmaceuticals for Children Act
- Pediatric Drug Development Under the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act: Scientific Considerations
- Porcine Derived Thyroglobulin Products
- Priority Review Voucher Programs
- Responding to CGMP Observations on Form FDA 483
- Use of Generally Accepted Scientific Knowledge in Applications for Drugs and Biological Products: Nonclinical Information

CATEGORY – Animal Rule

- Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment

[1] Final guidance documents planned for publication in calendar year 2023 are not included on this list. 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.

CATEGORY – Biosimilars

- Product Class-Specific Recommendations for Developing Biosimilar and Interchangeable Biological Products

CATEGORY – Clinical/Antimicrobial

- Early Lyme Disease as Manifested by Erythema Migrans: Developing Drugs for Treatment

CATEGORY – Clinical/Medical

- Chronic Pain: Developing Drugs for Treatment
- Decentralized Clinical Trials
- Demonstrating Substantial Evidence Standard Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence
- Development of 351(a) Biologics License Applications for Thyroid Products
- Development of Local Anesthetic Drug Products with Prolonged Duration of Effect
- Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products
- Drugs With Teratogenic Potential -- Recommendations for Pregnancy Planning and Prevention
- Endogenous Cushing's Syndrome: Developing Drugs for Treatment
- Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development
- Interstitial Cystitis/Bladder Pain Syndrome: Establishing Drug Development Programs for Treatment
- Migraine: Developing Drugs for Preventive Treatment
- Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment
- Pediatric Inflammatory Bowel Disease: Developing Drugs for Treatment
- Protocol Deviations
- Psychedelic Drugs: Considerations for Scientific Investigations
- Stimulant Use Disorders: Developing Drugs for Treatment
- Use of Data Monitoring Committees in Controlled Clinical Trials

CATEGORY – Clinical Pharmacology

- Clinical Pharmacology Considerations for Peptides
- Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling
- Pharmacogenomic Data Submission

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

- 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

CATEGORY – Drug Development Tools

- Biomarker Qualification: Evidentiary Framework

CATEGORY – Drug Safety

- Postmarketing Studies and Clinical Trials: Determining Good Cause for Noncompliance with Section 505(o)(3)(E)(ii) of the Federal Food, Drug, and Cosmetic Act
- Development of a Shared System or Separate Comparable Risk Evaluation and Mitigation Strategies; Revised Draft
- Purpose and Content of Use-Related Risk Analyses

CATEGORY – Electronic Submissions

- Identification of Medicinal Products: Implementation and Use
- NDC Assignment of Human Drugs including Biological Products
- Group Purchasing Organization vs. Private Label Distributor
- Repackagers and Relabelers of Human Drugs: Labeling; Registration and Listing, Safety Reporting, Supply Chain Security, and Good Manufacturing Practice

CATEGORY – Generics

- 180-Day Exclusivity: Questions and Answers; Revised Draft
- 30-Month Stay of Approval of a 505(b)(2) Application or an ANDA
- ANDA and NDA Submissions: Data Integrity for BA/BE Studies at Testing Sites
- ANDA Submissions - Amendments to Abbreviated New Drug Applications Under GDUFA; Revised Draft
- ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs
- 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
- Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA; Revised Draft

- Content and Format of Composition Tables in NDAs and ANDAs And Corresponding Statement of Ingredients in Labeling
- Determining Whether to Submit an ANDA or 505(b)(2) Application
- Handling and Retention of BA and BE Testing Samples
- "Open for Business" Definition Under 744B of the Federal Food, Drug and Cosmetic Act
- Pediatric Exclusivity General Considerations for ANDAs
- Product Specific Guidance Meetings Between FDA and ANDA Applicants under GDUFA
- Three-Year Exclusivity Determinations for Drug Products

CATEGORY – ICH

- E2D(R1) Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
- E6(R3) Good Clinical Practice Principles and Annex 1
- E20 Adaptive Clinical Trials
- M4Q(R2) Revision of M4Q(R1) CTD on Quality
- M14 General Principles on Planning and Designing Pharmacoepidemiological Studies that Utilize Real-World Data for Safety Assessment
- Q3E Impurity: Assessment and Control of Extractables and Leachables for Pharmaceuticals and Biologics

CATEGORY – Labeling

- Combined Hormonal Contraceptives for Prevention of Pregnancy — Labeling for Health Care Providers and Patients
- Labeling for Biosimilar and Interchangeable Biosimilar Products
- Regulatory Considerations for Prescription Drug Use-Related Software

CATEGORY– Over-the-Counter Drugs

- Annual Reportable Labeling Changes for NDAs and ANDAs for Nonprescription Drug Products
- Formal Dispute Resolution and Consolidated Proceedings: Requestor of OMUFA Products Appeals Above the Division Level
- OTC Monographs Order Requests (OMORs) – Format and Content of Data Submissions

CATEGORY – Pharmaceutical Quality CGMP

- PET Drugs - Current Good Manufacturing Practice (CGMP); Revised Draft

CATEGORY – Pharmaceutical Quality/CMC

- Advanced Manufacturing Technologies Designation Program Designated Technologies in Drug and Biological Products
- ANDAs: Stability Testing of Drug Substances and Products Q & A

- Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens
- Products With Benzene-Containing Carbomers: Recommendations for Reformulation
- Quality Considerations for Topical Ophthalmic Drug 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
- Container Closure Systems for Drugs, Including Biological Products
- Postapproval Manufacturing Changes to Biosimilars and Interchangeable Biosimilars Questions and Answers
- Use of Alternative Tools to Assess Manufacturing Facilities Named in Pending Applications

CATEGORY – Pharmacology/Toxicology

- Translation of Nonclinical Toxicology Study Reports: Questions and Answers

CATEGORY – Real-World Data/Real-World Evidence (RWD/RWE)

- Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products
- Considerations Regarding Non-Interventional Studies for Drug and Biological Products
- Using Clinical Practice Data in Randomized Controlled Trials (RCT) for Regulatory Decision-Making for Drug and Biological Products

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