# CDER Guidance Agenda
# New & Revised Draft Guidance Documents
# Planned for Publication in Calendar Year 2022[1]
# (July 2022)

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

## CATEGORY – Animal Rule

- Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment

## CATEGORY – Biosimilars

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

## CATEGORY – Clinical/Antimicrobial

- Antibacterial Therapies for Patients with an Unmet Medical Need for the Treatment of Serious Bacterial Diseases[2]
- Clostridioides Difficile Infection: Developing Drugs for Treatment, Reduction of Recurrence, and Prevention
- Pulmonary Tuberculosis: Developing Drugs for Treatment[3]

## CATEGORY – Clinical/Medical

- Assessment of Pressor Effects of Drugs; Revised Draft[2]
- Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten Free Diet[2]
- Chronic Pain: Developing Drugs for Treatment[3]
- Crohn's Disease: Developing Drugs for Treatment[2]
- Decentralized Clinical Trials
- Development of Non-Opioid Analgesics for Acute Pain[2]
- Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development
- Local Anesthetic Drug Products: Extended-Release Formulation Development and Labeling Considerations[3]
- Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials
- Meeting the Substantial Evidence Standard Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence
- Migraine: Developing Drugs for Preventive Treatment[3]
- Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment

[1] Final guidance documents planned for publication in calendar year 2022 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.
[2] Published since the January 2022 posting
[3] Newly added since the January 2022 posting

- Protocol Deviations
- Small Volume Parenteral Drug Products and Pharmacy Bulk Packages for Parenteral Nutrition: Aluminum Content and Labeling Recommendations[4]
- Ulcerative Colitis: Developing Drugs for Treatment[5]
- Use of Data Monitoring Committees in Controlled Clinical Trials

## CATEGORY – Clinical Pharmacology

- Clinical Pharmacology Considerations for Antibody-Drug Conjugates
- Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics[5]
- Clinical Pharmacology Consideration for Human Mass Balance Studies[5]
- Exposure Response Relationships
- General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products
- Pharmacogenomic Data Submission
- Clinical Pharmacology Considerations for Peptides[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
- Nomination of Bulk Drug Substances for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act
- 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
- Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application

## 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

[4] Newly added since the January 2022 posting
[5] Published since the January 2022 posting

## CATEGORY – Electronic Submissions

- Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies
- Identification of Medicinal Products: Implementation and Use
- NDC Assignment of Human Drugs including Biological Products
- Providing Regulatory Submissions in Electronic Format – Bioanalytical Methods Data Standards[6]
- Providing Regulatory Submissions in Electronic Format: IND Safety Reports
- Group Purchasing Organization vs. Private Label Distributor[6]
- Repackagers and Relabelers of Human Drugs: Labeling; Registration and Listing, Safety Reporting, Supply Chain Security, and Good Manufacturing Practice[6]

## CATEGORY – Generics

- 180-Day Exclusivity: Questions and Answers; Revised Draft
- ANDA and NDA Submissions: Data Integrity for BA/BE Studies at Testing Sites
- 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 Formulation Labeling
- Controlled Correspondence Related to Generic Drug Development; Revised Draft[6]
- Evaluation of Therapeutic Equivalence
- Handling and Retention of BA and BE Testing Samples
- Impact of Court Orders on 30 month Stay of Approval
- In Vitro Permeation Tests for Semisolid Topical Products Submitted in ANDAs
- In Vitro Release Tests for Semisolid Topical Products Submitted in ANDAs
- "Open for Business" Definition Under 744B of the Federal Food, Drug and Cosmetic Act
- Pediatric Exclusivity General Considerations for ANDAs
- Physico-Structural (Q3) Characterization of Topical Dermatological Drug Products Submitted in ANDAs
- Product Specific Guidance Meetings Between FDA and ANDA Applicants under GDUFA[6]
- Revising ANDA Labeling Following Revision of the RLD Labeling[7]
- Sameness Evaluations in an ANDA – Active Ingredients
- Statistical Approaches to Establishing Bioequivalence
- Three-Year Exclusivity Determinations for Drug Products
- Topical Dermatologic Corticosteroids: In Vivo Bioequivalence

[6] Newly added since the January 2022 posting
[7] Published since the January 2022 posting

- Waivers for pH Adjusters in Drug Products Intended for Parenteral, Otic, and Ophthalmic Use[8]

## CATEGORY – Labeling

- Combined Hormonal Contraceptives for Prevention of Pregnancy — Labeling for Health Care Providers and Patients[9]
- Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format; Revised Draft
- Human Prescription Drugs and Biological Products – Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers – "Dose Banding"
- Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling — Content and Format[8]
- Labeling for Biosimilar and Interchangeable Biosimilar Products[10]
- Quantification of Sodium, Potassium, and Phosphate in Human Over-the-Counter and Prescription Drug Labeling
- Regulatory Considerations and Drug Labeling Recommendations for Prescription Drug-Use-Related Software for Combination Products
- Statement of Identity and Strength — Content and Format of Labeling for Human Nonprescription Drug Products

## 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
- Formal Meetings Between FDA and Sponsors or Requestors of Over-the-Counter Monograph Drugs[8]
- OTC Monographs Order Requests (OMORs) – Format and Content of Data Submissions
- Providing Over-the-Counter Monograph Submissions in Electronic Format[11]

[8] Published since the January 2022 posting
[9] Added since the January 2022 posting
[10] Title update since the January 2022 posting. Previously listed as "Labeling for Biosimilar Products"
[11] Title update since the January 2022 posting. Previously listed as "Providing Regulatory Submissions in Electronic Format for Over-the-Counter Monograph Requests

## CATEGORY – Pharmaceutical Quality CGMP

- PET Drugs - Current Good Manufacturing Practice (CGMP); Revised Draft
- Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination[12]

## CATEGORY – Pharmaceutical Quality/CMC

- Benefit-Risk Considerations for Product Quality Assessments[12]
- Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens
- Quality Considerations for Topical Ophthalmic Drug Products
- Risk Management Plans to Mitigate the Potential for Drug Shortages[12]
- 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
- Facility Readiness: Goal Date Decisions Under GDUFA[13]
- ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions Guidance for Industry
- Review of Drug Master Files in Advance of Certain ANDA Submissions Under GDUFA[13]

## CATEGORY – Pharmacology/Toxicology

- Use of Whole Slide Imaging (WSI) in Nonclinical Toxicology Studies: Questions and Answers[12]

## CATEGORY – Procedural

- Charging for Investigational Drugs Under an Investigational New Drug Application – Questions and Answers
- Civil Monetary Penalties for Failure to Meet Accelerated Post Marketing Requirements
- Considerations for Rescinding Breakthrough Therapy Designation[12]
- DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescriptions Drugs
- Exclusivity for First Interchangeable Biosimilar Biological Products
- Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers
- 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[13]

[12] Published since the January 2022 posting
[13] Newly added since the January 2022 posting

- Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products[14]
- Identifying Trading Partners under the Drug Supply Chain Security Act; Revised Draft
- Key Information and Facilitating Understanding in Informed Consent for FDA-Regulated Clinical Investigations
- Notifying FDA of Permanent Discontinuance or Interruption in Manufacturing or Drug or Biological Product
- Pediatric Product Development Under the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act: Scientific Considerations; Revised Draft
- Pediatric Product Development Under the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act: Regulatory Considerations; Revised Draft
- Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug and Cosmetic Act; Revised Draft
- Responding to CGMP Observations on Form FDA 483
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; Revised Draft[15]
- Tropical Priority Review Vouchers
- Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers[16]
- Wholesale Distributor Verification Requirements for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product – Compliance Policy
- 351(k) BLA Supplement Classification Categories[14]

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

- Considerations for the Design and Conduct of Externally Controlled Trials 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.*

[14] Newly added since the January 2022 posting
[15] Published since the January 2022 posting
[16] Title update since the January 2022 posting. Previously listed "Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers