

CDER Guidance Agenda
New & Revised Draft Guidance Documents
Planned for Publication in Calendar Year 2021¹
(July 2021)²

(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

- Development of Drugs for Acute Radiation Syndrome: Questions and Answers

CATEGORY – Biosimilars

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

CATEGORY – Biostatistics

- Adjustment for Covariates in Randomized Clinical Trials for Drugs and Biologics Using Nonlinear Models
- Multiple Endpoints in Clinical Trials
- Statistical Aspects of the Design, Analysis and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals

CATEGORY – Clinical/Antimicrobial

- Nontuberculous Mycobacterial Pulmonary Disease Caused by Mycobacterium avium Complex: Developing Drugs for Treatment³
- Rabies: Developing Monoclonal Antibody Cocktails for the Passive Immunization Component of Post-Exposure Prophylaxis

CATEGORY – Clinical/Medical

- Assessment of Adhesion for Topical and Transdermal Systems Submitted in New Drug Applications
- Bowel Cleansing for Colonoscopy: Developing Drugs for Treatment – Efficacy and Safety Considerations for Developing New Products
- Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten Free Diet
- Chemotherapy-Induced Nausea and Vomiting: Developing Drugs for Prevention
- Clinical Recommendations to Support IND Submissions for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases
- Chronic Rhinosinusitis with Nasal Polyps: Developing Drugs for Treatment³

¹ Final guidance documents planned for publication in calendar year 2021 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² The draft guidance titled “Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products – Questions and Answers” in the Marketing/Advertising category issued in February 2020 and in error was included on the January 2021 posting and is being removed for the July 2021 posting.

³ Newly listed since the January 2021 posting

- Crohn's Disease: Developing Drugs for Treatment
- Decentralized Clinical Trials
- Development of Non-Opioid Analgesics for Acute Pain
- Inborn Errors of Metabolism That Use Dietary Management: Considerations for Optimizing and Standardizing Diet in Clinical Trials for Drug Product Development
- Meeting the Substantial Evidence Standard Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence
- Neovascular Age-Related Macular Degeneration: Developing Drugs for Treatment⁴
- Ulcerative Colitis: Developing Drugs for Treatment
- Use of Data Monitoring Committees in Controlled Clinical Trials
- Use of Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

CATEGORY – Clinical Pharmacology

- Assessing the Effects of Food on Drugs in INDs or NDAs – General Considerations
- Clinical Drug Interaction Studies with Combined Oral Contraceptives
- Dose Selection in Drug Development
- Drug-Drug Interaction Assessment for Therapeutic Proteins
- Drug Interaction Section of Labeling for Human Prescription Drug and Biological Products- Content and Format
- Evaluation of Gastric pH Mediated Drug Interactions with Acid-Reducing Agents: Study Design, Data Analysis, and Clinical Implications
- Exposure Response Relationships; Guidance for Industry
- General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products
- Pharmacogenomic Data Submission
- Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis and Impact on Dosing and Labeling; Revised Draft
- Regulatory Considerations for Diagnostic Devices that Reference Therapeutic Products

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
- Hospital and Health System Compounding Under 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

⁴ Newly listed since the January 2021 posting

CATEGORY – Drug Safety

- Definitions of Suspect Product Revised Guidance under the Drug Supply Chain Security Act
- Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices
- 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
- Sponsor Responsibilities – Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies

CATEGORY – Electronic Submissions

- Electronic Submission of Expedited Safety Reports from IND-Exempt BA/BE Studies
- NDC Assignment of Human Drugs including Biological Products
- Providing Regulatory Submissions in Electronic Format – Bioanalytical Methods Data Standards

CATEGORY – Generics

- 180-Day Exclusivity: Questions and Answers; Revised Draft
- Abbreviated New Drug Application Submissions – Cover Letters
- 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
- Bioequivalence Studies with Pharmacokinetic Endpoints for Drug Products Submitted under an ANDA; Revised Draft
- Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA; Revised Draft
- 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
- Pediatric Exclusivity General Considerations for ANDAs
- Physico-Structural (Q3) Characterization of Topical Dermatological Drug Products Submitted in ANDAs
- Revising ANDA Labeling Following Revision of the RLD Labeling
- Sameness Evaluations in an ANDA – Active Ingredients
- Statistical Approaches to Establishing Bioequivalence
- Three-Year Exclusivity Determinations for Drug Products
- Waivers for pH Adjusters in Drug Products Intended for Parenteral, Otic, and Ophthalmic Use

CATEGORY – Labeling

- Human Prescription Drug and Biological Products – Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers – "Dose Banding"⁵
- Immunogenicity Information in Human Prescription Therapeutic Protein and Select Drug Product Labeling — Content and Format
- Labeling for Biosimilar Products (Revision 1)
- 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

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

CATEGORY – Pharmaceutical Quality/CMC

- ANDAs: Stability Testing of Drug Substances and Products Questions and Answers
- Chemistry, Manufacturing, and Controls Recommendations for Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases⁶
- Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations
- ICH Q12, General Considerations for FDA Implementation
- Inspection of Injectable Products for Visible Particulates
- Quality Considerations for Topical Ophthalmic Drug Products
- Quality and Stability Testing of Drug Substances and Drug Products for NDAs, ANDAs, and BLAs and Associated Labeling Statements for Drug Products
- Risk Management Plans to Mitigate the Potential for Drug Shortages
- Benefit-Risk Considerations for Product Quality Assessments

CATEGORY – Pharmaceutical Quality/Microbiology

- Microbiological Quality Considerations in Non-Sterile Drug Product Manufacturing

CATEGORY – Pharmacology/Toxicology

⁵ Title update since the January 2021 posting. Previously listed as “Dose Banding: Considerations for Labeling”

⁶ Title update since the January 2021 posting. Previously listed as “Chemistry Manufacturing and Controls Considerations for Individualize Antisense Oligonucleotide (ASO) Therapies”

- Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases

CATEGORY – Procedural

- Civil Monetary Penalties for Failure to Meet Accelerated Post Marketing Requirements
- Considerations for Rescinding Breakthrough Therapy Designation
- DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescriptions Drugs⁷
- Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act
- Exclusivity for First Interchangeable Biological Product
- 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)
- Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (Revision 1)
- 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 Distributed Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act
- Responding to CGMP Observations on Form FDA 483
- Risk Management Plans to Mitigate the Potential for Drug Shortages
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; Revised Draft
- Tropical Priority Review Vouchers
- Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers
- Wholesale Distributor Verification Requirements for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product – Compliance Policy

⁷ Newly listed since the January 2021 posting

CATEGORY – Real World Data/Real World Evidence (RWD/RWE)⁸

- Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products⁹
- Data Standards for Drug and Biological Product Submissions Containing Real-World Data¹⁰
- Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products¹¹
- Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products¹²

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

⁸ New category added since the January 2021 posting

⁹ Title updated since the January 2021 posting. Previously listed in the “Procedural” category as “Regulatory Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drugs and Biological Products”

¹⁰ Newly listed since the January 2021 posting

¹¹ Previously listed in the “Procedural” category

¹² Title updated since the January 2021 posting. Previously listed in the “Procedural” category as “Using Registries as a Real-World Data Source for FDA Submissions”