

Guidance Agenda New & Revised Draft Guidances CDER Plans to Publish During Calendar Year 2019

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

CATEGORY – Biosimilars

- Comparative Analytical Assessment to Support a Demonstration of Biosimilarity to a Therapeutic Protein Product

CATEGORY - Clinical/Medical

- Attention Deficit Hyperactivity Disorder: Developing Stimulant Drugs for Treatment
- Gastroparesis: Clinical Development of Drugs
- Clinical Lactation Studies: Considerations for Study Design
- Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs
- Bispecific Antibody Development Programs
- Eosinophilic Esophagitis: Developing Drugs for Treatment
- Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework
- Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products
- Compensated Cirrhosis in Nonalcoholic Steatohepatitis: Developing Drugs for Treatment
- Establishing Effectiveness and Safety for Drugs Intended to Prevent Pregnancy
- Cross Labeling Oncology Drugs in Combination Drug Regimens
- Initiating Clinical Investigation in Children with Inborn Errors of Metabolism: Ethical Considerations
- Pregnancy Prevention and Planning – Recommendations for Pregnancy Testing and Contraception for Drugs with Teratogenic Potential
- Postapproval Pregnancy Safety Studies
- Treatment for Heart Failure: Endpoints for Drug Development

CATEGORY - Clinical Pharmacology

- Assessing the Effects of Food on Drugs in INDs or NDAs – General Considerations
- Bioavailability Studies Submitted in NDAs for INDs – General Considerations
- General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products
- Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis and Impact on Dosing and Labeling; Revised Draft
- Pharmacogenomic Data Submission
- Population Pharmacokinetics
- General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products

CATEGORY - Clinical/Statistical

- Adjusting for Covariates in Randomized Experiments
- Multiple Endpoints in Clinical Trials
- Interacting with CBER and CDER on the Use of Novel Clinical Trial Designs

CATEGORY – Combination Products

- Bridging for Drug-Device and Biologic-Device Combination Products

CATEGORY – Drug Development Tools

- Qualification Process for Drug Development Tools

CATEGORY - Drug Safety

- Best Practices in Developing Proprietary Names for Non-Prescription Drug Products
- Postmarketing Safety Reporting for Human Drugs and Biological Products Including Vaccines, Revised Draft
- Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act
- 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
- Submitting Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989
- Restricted Delivery Systems: Flow Restrictors and Oral Liquid Drug Products

CATEGORY - Electronic Submissions

- Standardized Format for Electronic Submissions of NDA and BLA Content for the Planning and Conduct of Bioresearch Monitoring Inspections for CDER Submissions
- Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
- Establishment Registration and Drug Listing
- Providing Regulatory Submissions in Electronic Format – Bioanalytical Methods Data Standards
- Providing Regulatory Submissions in Electronic Format: IND Safety Reports

CATEGORY - Generics

- 180-Day Exclusivity: Questions and Answers
- ANDA Submissions – Refuse-to-Receive for DMF Facilities Deficiencies
- ANDA Submissions – Refuse-to-Receive Standards: Questions and Answers
- Bioequivalence Studies with Pharmacokinetic Endpoints for Drug Products Submitted in ANDAs; Revised Draft
- Designation, Submission, and Review of ANDA's for Competitive Generic Therapies
- Failure to Timely Respond to an ANDA Complete Response Letter
- Handling and Retention of BA and BE Testing Samples
- In Vitro Permeation Tests for Generic Semisolid Topical Products
- In Vitro Release Tests for Generic Semisolid Topical Products
- Orange Book – Questions and Answers
- Q1, Q2, and Q3 Characterization of Topical Dermological Drug Products
- Sameness Evaluations in an ANDA – Active Ingredients
- Therapeutic Equivalence – General Considerations
- Three-Year Exclusivity Determinations for Drug Products

CATEGORY - Labeling

- Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format
- Instructions for Use for Human Prescription Drug and Biological Products – Content and Format
- Pregnancy, Lactation and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products; Revised Draft
- Quantification of Sodium, Potassium, and Phosphate in Human Over-the-Counter and Prescription Drug Labeling

CATEGORY – Pharmaceutical Quality/Microbiology

- Microbiological Considerations for Non-Sterile Drug Products

CATEGORY — Pharmaceutical Quality/CMC

- CDER’s Program for the Recognition of Voluntary Consensus Standards
- Drug Master Files; Revised Draft
- Harmonizing Compendial Standards with Drug Application CMC Approval Requirements Using the USP Pending Monograph Process
- In-vitro Methods for Evaluation of Abuse Deterrent Properties of Opioid Products
- Transdermal and Topical Delivery Systems- Product Development and Quality Considerations
- Quality Considerations for Continuous Manufacturing (CM)
- Type V DMFs for CDER-Led Combination Products Using Device Constituent Parts with Electronics or Software
- Using the Inactive Ingredient Database
- Risk Management Plans for Drug Manufacturers
- Quality Considerations for Topical Ophthalmic Drug Products
- Inspection of Injectable Products for Visible Particulates
- Setting Endotoxin Limits During Development of Investigational Oncology Drugs and Biologics
- Stability Considerations for NDAs, ANDAs and BLAs
- ANDAs: Stability Testing of Drug Substances and Products Questions and Answers

CATEGORY – Pharmacology/Toxicology

- Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers

CATEGORY - Procedural

- A Risk-Based Approach to Monitoring of Clinical Investigations – Questions and Answers
- Civil Monetary Penalties for Failure to Meet Accelerated Post Marketing Requirements
- Designated Delivery Services for 505(b)(2) or ANDA Applicants Sending Notices of Paragraph IV Patent Certification
- Key Information and Informed Consent
- Implementation of the “Deemed to be a License” Provision of the BPCI Act: Questions and Answers
- Identifying Trading Partners under the Drug Supply Chain Security Act; Revised Guidance
- Notifying FDA of Permanent Discontinuance or Interruption in Manufacturing or Drug or Biological Product
- Patient-Focused Drug Development: Methods to Identify What is Important to Patients
- 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
- Public Disclosure of FDA-Sponsored Studies
- REMS Assessment: Planning and Reporting

- Risk Management Plans to Mitigate the Potential for Drug Shortages
- Survey Methodologies to Assess REMS Goals Related to Knowledge
- Submitting Documents Utilizing Real-World Data and Real-World Evidence to FDA for Drugs and Biologics
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; Revised Guidance
- Tropical Disease Priority Review Vouchers
- Use of a Drug Master File for Shared System Risk Evaluation and Mitigation Strategies (REMS)

CATEGORY – Rare Diseases

- Rare Diseases: Common Issues in Drug Development
- Rare Diseases: Natural History Studies for Drug Development

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