Guidance Agenda
New & Revised Draft Guidances
CDER Plans to Publish During
Calendar Year 2018

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

CATEGORY - Advertising

- Presenting Quantitative Information in Direct-to-Consumer Promotional Labeling and Advertisements
- Updating Promotional Materials to Reflect Labeling Changes to Risk Information

CATEGORY - Clinical/Antimicrobial

- Cytomegalovirus in Transplantation: Developing Drugs for Treatment and Prevention
- Smallpox (Variola Virus) Infection: Developing Drugs for Treatment and Prevention; Revised Draft
- Streamlining Pediatric HIV Antiretroviral Drug Development Intended for Global Use
- Uncomplicated Urinary Tract Infections: Developing Antimicrobial Drugs for Treatment

CATEGORY - Clinical/Medical

- Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment
- Antiepileptic Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adult to Pediatrics Patients 4 Years of Age and Older
- Early Alzheimer's Disease: Developing Drugs for Treatment
- Hypertension: Developing Fixed-Dose Combination Drugs for Treatment
- Migraine: Developing Drugs for Treatment
- Opioid Dependence: Developing Depot Buprenorphine Products for Treatment
- Pediatric Oncology Product Development; Revised Draft
- Pregnant Women in Clinical Trials – Scientific and Ethical Considerations
- Pregnancy, Prevention and Planning: Recommendations for Pregnancy Testing and Contraception for Drugs with Teratogenic Potential

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
- Clinical Drug Interactions Studies: Study, Design, Data Analysis, Implications for Dosing and Labeling Recommendations, Revised Draft
- General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products
- In Vitro Metabolism-and-Transporter -Mediated Drug-Drug Interaction Studies; Revised Draft
- Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis and Impact on Dosing and Labeling; Revised Draft
- Pharmacokinetics in Patients with Impaired Hepatic Function – Study Design, Data Analysis and Impact on Dosing and Labeling
- Pharmacogenomic Data Submission

CATEGORY - Clinical/Statistical

- Adaptive Design Clinical Trials for Drugs and Biologics; Revised Draft
- Adjusting for Covariates in Randomized Experiments
- Meta-Analysis of Randomized Controlled Clinical Trials to Evaluate the Safety of Human Drugs or Biologic Products

CATEGORY – Drug Development Tools

- Biomarker Qualification: Evidentiary Framework; Draft Guidance for Industry and FDA Staff

CATEGORY - Drug Safety

- Postmarketing Safety Reporting for Human Drugs and Biological Products Including Vaccines, Revised Draft
- 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 – Drug
- Establishment Registration and Drug Listing
- Providing Regulatory Submissions in Electronic Format – Bioanalytical Methods Data Standards
- Providing Regulatory Submissions in Electronic Format – Standardized Bioanalytical Data

CATEGORY - Generics

- 180-Day Exclusivity: Questions and Answers
- Assessing Adhesion for ANDAs with Transdermal Delivery Systems and Topical Patches; Revised Draft
- Assessing Irritation and Sensitization Potentials of Generic Transdermal and Topical Patches Submitted in ANDAs
- Bioequivalence Studies with Pharmacokinetic Endpoints for Drug Products Submitted in ANDAs; Revised Draft
- Failure to Timely Respond to an ANDA CR Letter
- Referencing Approved Drug Products in ANDA Submissions; Revised Draft
- Sameness Under the 505(j) Pathway
- Therapeutic Equivalence – General Considerations
- Three-Year Exclusivity Determinations for Drug Products
- Variations in Drug Products (ANDAs) Guidance

CATEGORY - Labeling

- Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format
- Indications and Usage Section of Labeling for Human Prescription Drugs and Biological Products – Content and Format
- Instructions for Use for Human Prescription Drug and Biological Products – Content and Format
- Labeling for Combined Hormonal Contraceptives
- Pregnancy, Lactation and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products; Revised Draft
- Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products – Content and Format
- Recommended Statement for Over-the-Counter (OTC) Aspirin-Containing Drug Products Labeled with Cardiovascular-Related Imagery Guidance for Industry

CATEGORY – Over-The-Counter

- Innovative Approaches for Nonprescription Drug Products
- Maximal Usage Trial for Topical Active Ingredients Being Considered in the Over-the-Counter Monograph: Study Elements and Considerations

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
- Clarification of Human Drug Application Establishment Information Q&A Guidance
- Drug Master Files; Revised Draft

- Harmonizing Compendial Standards with Drug Application CMC Approval Requirements Using the USP Pending Monograph Process
- Identification of Manufacturing Establishments in Applicants Submitted to CBER and CDER – Questions and Answers
- In-vitro Methods for Evaluation of Abuse Deterrent Properties of Opioid Products
- Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products – Chemistry, Manufacturing, and Controls Documentation; Revised Draft
- Post-Approval Changes to Drug Substances (GDUFAII)
- Product Development and Quality Control of Transdermal and Related Delivery Systems
- Quality Considerations for Continuous Manufacturing (CM)
- Type V Drug Master File (DMF) for Combination Products with CDER Jurisdiction Utilizing a Device Part with Electronics or Software
- Use of Liquids and/or Soft-Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments
- Using the Inactive Ingredient Database

CATEGORY - Pharmaceutical Quality/Manufacturing Standards (CGMP)

- CGMP Final Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Revised Draft
- Field Alert Report Submission

CATEGORY – Pharmacology/Toxicology

- Nonclinical Safety Evaluation of Ophthalmic Pharmaceuticals

CATEGORY - Procedural

- Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act
- Civil Monetary Penalties for Failure to Meet Accelerated Post Marketing Requirements
- Content of Threshold Analyses and Human Factors Submissions to an NDA, BLA or ANDA
- Definitions of Suspect Product and Illegitimate Product or Verification Obligations
- Designated Delivery Services for 505(b)(2) or ANDA Applicants Sending Notices of Paragraph IV Patent Certification
- Development of a Shared System REMS
- Good Review Management Principles and Practices for PDUFA and BsUFA Products
- Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier
- Implementation of the "Deemed to be a License" Provision of the BPCI Act: Questions and Answers
- 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
- Proposed Accreditation Program Under the Drug Supply Chain Security Act

- Proposed Licensing Program Under the Drug Supply Chain Security Act
- Public Disclosure of FDA-Sponsored Studies
- Qualified Infectious Disease Product Designation: Questions and Answers
- REMS Assessment: Planning and Reporting
- Standardization of Data and Documentation Practices for Product Tracing
- Streamlined Submission Process to Determine Whether an Investigational In Vitro Companion Diagnostic in an Oncology Trial is Significant Risk
- Survey Methodologies to Assess REMS Goals Related to Knowledge
- The Product Identifier for Human, Finished, Prescription Drugs: Question and Answers
- Use of a Drug Master File for Shared System Risk Evaluation and Mitigation Strategies (REMS)
- Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs
- Waivers, Exceptions and Exemptions from the Requirements of Section 582 of the Federal Food, Drug and Cosmetic Act
- Waivers of the Single, Shared System REMS Requirement

CATEGORY – Rare Diseases

- Rare Diseases: Early Drug Development and the Role of Pre-IND Meetings
- Rare Diseases: Common Issues in Drug Development

CATEGORY — User Fees

- Prescription Drug User Fee Act Waivers for Fixed Dose Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief
- Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Drug and Biological Products

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