Guidance Agenda:
New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2017

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

CATEGORY — Advertising

- Drug and Device Manufacturer Communications with Payors, Formulary Committees and Similar Entities

CATEGORY — Biopharmaceutics

- Assessing the Effects of Food on Drugs in INDs and NDAs – Clinical Pharmacology Considerations; Revised Draft
- Bioanalytical Method Validation; Revised Draft
- Bioavailability Studies Submitted in NDA's or INDs for Orally Administered Drug Products – General Considerations; Revised Draft

CATEGORY – Biosimilarity

- Considerations in Demonstrating Interchangeability With a Reference Product
- Statistical Approaches to Evaluation of Analytical Similarity Data to Support a Demonstration of Biosimilarity

CATEGORY – Clinical/Antimicrobial

- Cytomegalovirus in Transplantation: Developing Drugs for Treatment and Prevention

CATEGORY — Clinical/Medical

- BCG – Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment
- Delayed Graft Function in Kidney Transplant: Developing Drugs of Prevention
- Exocrine Pancreatic Insufficiency Drug Products: Submitting Marketing Applications and Recommendations for Labeling; Revised Draft
- Gastroesophageal Reflux Disease in Pediatric Population: Development of Drugs for Treatment
- Gaucher Disease
- Guidance for clinical Investigators and Sponsors Natural History Studies for Rare Disease Drug Development
- Measuring Treatment Benefit in Pediatric Populations: Use of Clinical Outcome Assessments
- 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
- Rare Diseases: Drug Development Safety Data Considerations
- Reproductive Toxicity: Testing and Labeling Recommendations for Anticancer Pharmaceuticals

CATEGORY — Clinical Pharmacology

- Clinical Drug Interactions Studies: Study, Design, Data Analysis, Implications for Dosing and Labeling Recommendations, Revised Draft
- Clinical Lactation Trials – Trial Design, Data Analysis and Recommendations for Labeling; Revised Draft
- Exposure-Response Relationships – Study Design, Data Analysis, and Regulatory Applications; Revised Draft
- In Vitro Metabolism-and-Transporter -Mediated Drug-Drug Interaction Studies; Revised Draft
- Pharmacokinetics in Patients with Impaired Hepactic Function – Study Design, Data Analysis and Impact on Dosing and Labeling; Revised Draft
- Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis and Impact on Dosing and Labeling; Revised Draft
- Pharmacokinetics During Pregnancy and the Postpartum Period – Trial Design, Data Analysis, and Impact on Dosing and Labeling; Revised Draft
- Population Pharmacokinetics; Revised Draft

CATEGORY — Clinical/Statistical

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

CATEGORY — Drug Safety

- Format and Content of a REMS Document, Revised Draft
- 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 and Planning and Conduct of Bioresearch Monitoring Inspections for Submissions to CDER
- Providing Regulatory Submissions in Electronic Format – Submission of Manufacturing Establishment Information
- 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
- ANDA Submissions – Amendments to Abbreviated New Drug Applications Under GDUFA
- ANDA Submissions – Content and Format of Abbreviated New Drug Applications; Revised Draft
- ANDA Submissions Refuse to Receive Standards: 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*
- Controlled Correspondence Related to Generic Drug Development
- Changes That May Be Included in a Single Prior Approval Supplement for an ANDA
- Determining Whether To Submit an Application Under 505(b)(2) or 505(j)
- Formal Meetings Between FDA and Applicants of Complex Generic Drug Products
- Information Requests and Discipline Review Letters Under GDUFA*
- Issuance of ANDA Complete Response Letters Before Completion of Review by One or More Disciplines
- Post Complete Response Meetings Requests Between FDA and ANDA Applicants*
- Pre Submission Facility Correspondence for Priority ANDAs in GDUFA II
- Requests for Reconsideration at the Division Level Under GDUFA*
- Submission of ANDAs for Certain Highly Purified Synthetic Peptide Drug Products That Reference Peptide Drug Products of rNDA Origin
- Three-Year Exclusivity Determinations for Drug Products
- Variations in Drug Products (ANDAs) Guidance

CATEGORY — Labeling

- Child Resistant Packaging Statements in Drug Product Labeling
- Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products – Content and Format
- Gluten in Drug Products and Associated Labeling Recommendations
- Indications and Usage Section of Labeling for Human Prescription Drugs and Biological Products – Content and Format
- Labeling for Combined Hormonal Contraceptives
- Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products – Content and Format

CATEGORY — Pharmaceutical Quality/CMC

- CMC Postapproval Manufacturing Changes for Specified Biological Products to be Documented in Annual Reports
- Container Closure Systems for Packaging Human Drugs and Biologics; Revised Draft
- Drug Master Files; Revised Draft
- Drug Products, Including Biological Products, That Contain Nanomaterials
- 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
- Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products – Chemistry, Manufacturing, and Controls Documentation; Revised Draft
- Type V Drug Master File (DMF) for Combination Products with CDER Jurisdiction Utilizing a Device Part with Electronics or Software
- Using the Inactive Ingredient Database
- Visual Inspection of Injectable Drug Products

CATEGORY — Pharmaceutical Quality/Manufacturing Standards (CGMP)

- Current Good Manufacturing Practice for Medical Gases; Revised Draft
- Expiration Dating of Unit-Dose Repackaged Solid Oral Dosage Form Drug Products; Revised Draft
- Field Alert Report Submission
- Repackaging of Certain Drug Products by Pharmacies and Outsourcing Facilities

CATEGORY – Pharmacology/Toxicology

- Nonclinical Safety Evaluation of Ophthalmic Pharmaceuticals

CATEGORY — Procedural

- Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers: Questions and Answers
- Civil Monetary Penalties for Failure to Meet Accelerated Post marketing Requirements
- Compliance Policy Guide: Marketed Unapproved Drugs Section 440.100; Revised Draft
- Content of Human Factors Submissions for Evaluation
- Designated Delivery Services for 505(b)(2) or ANDA Applicants Sending Notices of Paragraph IV Patent Certification
- Drug Products Labeled as Homeopathic
- Enforcement Policy Regarding Ingredients Nominated for Inclusion on the Bulk Drug Substances List Pursuant to Section 503B
- Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products
- Government Public Health and Emergency Response Stakeholders: Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles
- Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier
- Identifying Trading Partners Under the Drug Supply Chain Security Act
- Information on How to Apply for a CDER Certification of Pharmaceutical Product (CPP) Export Certificate
- National Drug Code (NDC) Assignment of CDER-Regulated Products
- Pediatric Drug Development Under the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act: Scientific Considerations; Revised Draft
- Pediatric Drug Development Under the Pediatric Research Equity Act and the Best Pharmaceuticals for Children Act: Regulatory Considerations; Revised Draft
- Public Disclosure of FDA-Sponsored Studies
- Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy
- Qualified Infectious Disease Product Designation: Questions and Answers
- Recommended Statement for Over-the-Counter Aspirin Containing Drug Products Labeled with Cardiovascular Related Imagery
- Refuse to File: NDA and BLA Submissions

- Regulatory Considerations: Complying with the Pediatric Research Equity Act (PREA) & Qualifying for Pediatric Exclusivity Under the Best Pharmaceuticals Act (BPCA); Revised Draft
- REMS Assessment: Planning and Reporting
- Standardization of Data and Documentation Practices for Product Tracing
- 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)
- Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers
- 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

CATEGORY — User Fees

- Assessing User Fees Under the Generic Drug User Fee Amendments of 2017*
- Fees Incurred Under the Drug Supply Chain Security Act
- Implementation of the Biosimilar User Fee Act of 2017*
- Implementation of the Prescription Drug User Fee Amendments of 2017*
- User Fee 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.

*Reflects Newly Added.