Guidance Agenda:
New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2016

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

CATEGORY — Advertising

- Health Care Economic Information in Promotional Labeling and Advertising for Prescription Drugs Under Section 114 of the Food and Drug Administration Modernization Act
- Internet/Social Media Advertising and Promotional Labeling of Prescription Drugs and Medical Devices – Use of Links to Third-Party Sites
- Manufacturer Communications Regarding Unapproved, Unlicensed, or Uncleared Uses of Approved, Licensed, or Cleared Human Drugs, Biologics, Animal Drugs and Medical Devices
- Presenting Risk Information in Prescription Drugs and Medical Devices Promotion; Revised Draft

CATEGORY — Biopharmaceutics

- Bioavailability and Bioequivalence Studies Submitted in NDA's or INDs for Orally Administered Drug Products – General Considerations
- Food Effects Bioavailability and Fed Bioequivalence Studies

CATEGORY — Biosimilarity

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

CATEGORY – Clinical/Antimicrobial

- Anthrax: Developing Drugs for Prophylaxis of Inhalation Antrax
- Attachment to HIV-1 Infection: Developing Antiretroviral Drugs for Treatment – Guidance for Submitting Clinical Trial Data Sets
- Bacterial Vaginosis: Developing Drugs for Treatment
- Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment; Revised Draft
- Recurrent Herpes Labialis: Developing Drugs for Treatment and Prevention
- Vulvovaginal Candidiasis: Developing Antimicrobial Drugs for Treatment

CATEGORY — Clinical/Medical

- Allergic Rhinitis: Developing Drugs Products for Treatment; Revised Draft
- Exocrine Pancreatic Insufficiency Drug Products: Submitting Marketing Applications and Recommendations for Labeling
- 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
- Nonallergic Rhinitis: Developing Drug Products for Treatment
- Pediatric Oncology Product Development; Revised Draft
- Pregnant Women in Clinical Trials – Scientific and Ethical Considerations
- Qualification of VVSymQ Instrument for the Measurement of Varicose Vein Symptom Burden in Patients with Superficial Venous Incompetence
- Qualification of the Evaluating Respiratory Symptoms (E-RS) in COPD a Patient Reported Outcome
- Ulcerative Colitis: Developing Drugs for Treatment

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
- 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 During Pregnancy and the Postpartum Period – Trial Design, Data Analysis, and Impact on Dosing and Labeling; Revised Draft
- Population Pharmacokinetics

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 Proposed Risk Evaluation and Mitigation Strategies, Revised Draft
- Postmarketing Safety Reporting for Human Drugs and Biological Products Including Vaccines, Revised Draft

CATEGORY — Electronic Submissions

- NDA and BLA Content for Planning and Conduct of Bioresearch Monitoring Inspections (BIMO) for CDER Submissions
- 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: Guidance for Industry
- ANDA Submissions – Content and Format of Abbreviated New Drug Applications; Revised Draft
- ANDA Submissions – Identifying Reference Products
- ANDA Submissions Refuse to Receive Standards: Questions and Answers
- Assessing Adhesion for ANDAs with Transdermal Delivery Systems and Topical Patches
- Bioequivalence Studies with Pharmacokinetic Endpoints for Drug Products Submitted in ANDAs
- Comparative Analyses of the Device Constituent of a Drug-Device Combination Product Submitted in an ANDA.**
- Determining Whether to Submit an Application Under 505(b)(2) or 505(j)
- General Principles for Evaluating Abuse-Deterrent Properties of Generic Solid Oral Opioid Drug Products
- Issuance of ANDA Complete Response Letters Before Completion of Review by One or More Disciplines
- Submission of ANDAs for Certain Highly Purified Synthetic Peptide Drug Products
- Three-Year Exclusivity Determinations for Drug Products
- Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn

CATEGORY — Labeling

- Child Resistant Closures and Labeling
- Gluten in Drug Products and Labeling Related to Celiac Disease
- 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

- Assay Development and Validation for Immunogenicity Testing of Therapeutic Protein Products; Revised Draft
- Comparability Protocols for Approved Drugs: Chemistry, Manufacturing, and Controls Information; Revised Draft

- CMC Postapproval Manufacturing Changes for Specified Biological Products to be Documented in Annual Reports
- Drug Master Files; Revised Draft
- Elemental Impurities in Drug Products*
- 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
- Microbiological Quality Consideration in Non-sterile Drug Product Manufacturing
- Nanomaterials in Drug and Biologic Products
- Quality Metrics Technical Conformance Guide
- Regulatory Classification of Pharmaceutical Co-Crystals; Revised Draft
- Specified Biotechnology and Specified Synthetic Biological Products – Annual Report
- Type V Drug Master File (DMF) for Combination Products with CDER Jurisdiction Utilizing a Device Part with Electronics or Software
- Use of the FDA Inactive Ingredient Software (IID)
- Quality Attribute Considerations for Chewable Tablets

CATEGORY — Pharmaceutical Quality/Manufacturing Standards (CGMP)

- Data Integrity and Compliance with CGMP*
- 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
- Submission of Quality Metrics Data; Revised Draft**

CATEGORY – Pharmacology/Toxicology

- Nonclinical Evaluation of Agents Used in the Treatment of Osteoporosis

CATEGORY — Procedural

- Applying the Statutory Criteria for Requiring a Risk Evaluation and Mitigation Strategy (REMS)
- Certification Process for Designated Medical Gases*
- Compliance Policy Guide: Marketed Unapproved Drugs Section 440.100; Revised Draft
- Designated Delivery Services for 505(b)(2) or ANDA Applicants Sending Notices of Paragraph IV Patent Certification
- DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers
- DSCSA Implementation: Products Eligible for Grandfather Status
- DSCSA Implementation: Standards for the Interoperable Exchange of Information for Tracing Certain Human, Finished Prescription Drugs – Standardization of Data and Documentation Practices
- DSCSA Implementation: The Product Identifier for Human, Finished, Prescription Drugs
- DSCSA: Verification Systems for Prescription Drugs
- DSCSA Implementation: Waivers, Exceptions and Exemptions from Product Tracing Requirements

- Government Public Health and Emergency Response Stakeholders: Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles*
- How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable Risk Evaluation and Mitigation Strategies for RLD
- Information on How to Apply for a CDER Certification of Pharmaceutical Product (CPP) Export Certificate
- Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009.
- National Drug Code (NDC) Assignment of CDER-Regulated Products
- Pediatric Product Development in the Context of the Pediatric Research Equity Act (PREA) and the Best Pharmaceuticals Act (BPCA); Revised Draft
- Pediatric Study Plans: Content of and Process for Submitting Initial PSP and Amended PSP; Revised Draft
- Public Disclosure of FDA-Sponsored Studies
- 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
- Special Protocol Assessment
- Survey Methodologies to Assess Risk Evaluation and Mitigation Strategies (REMS) Goal Related to Knowledge
- Use of a Drug Master File for Shared System Risk Evaluation and Mitigation Strategies (REMS)
- Use of Electronic Health Records Data in Clinical Investigations

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

*Reflects title change. ** Newly added