Guidance Agenda:
New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2015

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

CATEGORY — Advertising

- Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs
- Direct-to-Consumer Television Advertisements –DTC Television Ad Pre-Dissemination Review Program for Human Drugs
- 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
- Providing Regulatory Submissions in Electronic and Non-Electronic Format – Promotional Labeling and Advertising Materials for Human Prescription Drugs

CATEGORY — Biopharmaceutics

- Bioavailability and Bioequivalence Studies Submitted in NDA's or INDs for Orally Administered Drug Products – General Considerations
- Dissolution Testing and Specifications Criteria for Immediate-Release Solid Oral Dosage Forms Containing Biopharmaceutical Classification System Class 1 and 3 Drugs
- Food Effects Bioavailability and Fed Bioequivalence Studies
- Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System

CATEGORY — Biosimilarity

- Biosimilars: Additional Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009
- Considerations in Demonstrating Interchangeability to a Reference Product
- Labeling for Biosimilar Biological Products
- Nonproprietary Naming for Biological Products*
- Statistical Approaches to Evaluation of Analytical Similarity Data to Support a Demonstration of Biosimilarity

CATEGORY — Clinical/Medical

- Alcoholism: Developing Drugs for Treatment
- Common Issues in Drug Development for Rare Diseases
- Duchenne Muscular Dystrophy and Related Dystorphinopaties: Developing Drugs for Treatment
- Evaluating Drug Effects on Ability to Operate a Motor Vehicle
- Exocrine Pancreatic Insufficiency Drug Products: Submitting Marketing Applications and Recommendations for Labeling
- Head Lice Infestations: Developing Drugs for Treatment
- Measuring Treatment Benefit in Pediatric Populations: Use of Clinical Outcome Assessments
- 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*
- Standards for Clinical Trial Imaging Endpoints
- Sunscreens: Safety and Effectiveness Data for Over-the-Counter Monograph Active Ingredients
- Testicular Toxicity: Evaluation During Drug Development*
- Ulcerative Colitis: Developing Drugs for Treatment

CATEGORY — Clinical Pharmacology

- Clinical Lactation Trials – Trial Design, Data Analysis and Recommendations for Labeling
- Content and Format of the Clinical Pharmacology Section of a New Drug Applications (NDA) and Biologics License Applications (BLA)
- Dose Selection in Drug Development
- Exposure-Response Relationships
- In vitro Drug Interactions
- In vivo Drug Interactions
- Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis and Impact on Dosing and Labeling
- Pharmacokinetics During Pregnancy and the Postpartum Period – Trial Design, Data Analysis, and Impact on Dosing and Labeling
- Population Pharmacokinetics

CATEGORY — Clinical/Statistical

- Multiple Endpoints in Clinical Trials

CATEGORY — Drug Safety

- Content, Format and Submission of Adverse Event Reports by Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

- Modifications and Revisions of Risk Evaluation and Mitigation Strategies (REMS)
- Safety Assessment for Expedited Reporting for IND Studies

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 – Manufacturing Establishment Information
- Providing Regulatory Submissions in Electronic Format – Bioanalytical Methods Data Standards

CATEGORY — Generics

- Acceptability of Draft Package Insert Labeling to Support ANDA Approval
- ANDA Submissions Refuse-to-Receive for Typographical Errors and Misplaced Files
- GDUFA Complete Assessments for Type II API DMFs
- General Principles for Evaluating Abuse-Deterrent Properties of Generic Solid Oral Opioid Drug Products
- GDUFA Completeness Assessment Checklist for Type II API DMFs

CATEGORY — Labeling

- Indications and Usage Section of Labeling for Human Prescription Drugs and Biological Products – Content and Format
- Pediatric Information: Incorporating into Human Prescription Drug and Biological Products Labeling
- 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

- Advancement of Emerging Technology Applications to Modernize the Pharmaceutical Manufacturing Base
- Appropriate Package Type Terms for Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use
- Botanical Drug Development
- Comparability Protocols for Approved Drugs: Chemistry, Manufacturing, and Controls Information
- Development of Near Infrared Spectroscopy (NIR) Procedures
- Drug Products Containing Nanomaterials
- Elemental Impurities in Drug Products Marketed in the United States
- Environmental Assessment: Questions and Answers Regarding Drugs with Hormonal Activity
- Established Conditions: Reportable CMC Changes for Approved Drugs and Biologic Products

- Liposome Drug Products: CMC, Human Pharmacokinetic and Bioavailability; and Labeling Documentation
- Microbiological Quality Consideration in Non-sterile Drug Product Manufacturing
- Quality Metrics and Risk-Based Inspections
- Specified Biotechnology and Specified Synthetic Biological Products – Annual Report

CATEGORY — Pharmaceutical Quality/Manufacturing Standards (CGMP)

- CGMP Data Integrity Questions and Answers
- Current Good Manufacturing Practice for Outsourcing Facilities (Pharmacy Compounding)
- Repackaging of Certain Drug Products by Pharmacies and Outsourcing Facilities

CATEGORY – Pharmacology/Toxicology

- Assessment of Male-Mediated Developmental Risk and Mitigation for Pharmaceuticals*
- Nonclinical Assessment of Investigational Enzyme Replacement Therapy Products

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
- Critical Path Innovation Meeting
- 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
- For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B
- Formal Dispute Resolution: Appeals Above the Division Level*
- Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products
- Information on How to Apply for a CDER Certification of Pharmaceutical Product (CPP) Export Certificate
- Investigational New Drug Applications Prepared and Submitted by Clinical Sponsor Investigators
- Mixing, Diluting or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application
- National Drug Code (NDC) Assignment of CDER-Regulated Products
- Nonprescription Sunscreen Drug Products – Content and Format of Data Submissions to Support a GRASE Determination Under the Sunscreen Innovation Act
- Process for Withdrawal of GRASE Request or Pending Request Under the Sunscreen Innovation Act
- Public Disclosure of FDA-Sponsored Studies

- REMS Program Evaluation: Assessment Planning and Reporting
- Special Protocol Assessment
- Submission of Field Alert Reports and Biological Product Deviation Reports
- Submission of Study Protocols for Drug Products with Certain Risk Evaluation and Mitigation Strategies for Review by the Office of Generic Drugs
- Sunscreen Innovation Act Review Process, Including Section 586C(c)
- 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 Informed Consent in Clinical Investigations Questions and Answers

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