

# **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 Uses of Approved Medical Products
- 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
- 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 Dystorpinopathies: 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
- Standards for Clinical Trial Imaging Endpoints
- Sunscreens: Safety and Effectiveness Data for Over-the-Counter Monograph Active Ingredients
- 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
- Complete Assessments for Type II API DMFs Under GDUFA
- General Principles for Evaluating Abuse-Deterrent Properties of Generic Solid Oral Opioid Drug Products\*
- Guidance for Industry on 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**

- Nonclinical Assessment of Investigational Enzyme Replacement Therapy Products

## **CATEGORY — Procedural**

- Applying the Statutory Criteria for Requiring a Risk Evaluation and Mitigation Strategy (REMS)
- 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 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.*