Guidance Agenda:
New & Revised Draft Guidances CDER is Planning to Publish During Calendar Year 2012

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

CATEGORY — Advertising

- Direct to Consumer Television Advertisements - FDAAA DTC Television Pre-Review Program

CATEGORY – Biopharmaceutics

- Food-Effect Bioavailability and Fed Bioequivalence Studies---Bioavailability and Bioequivalence Studies for Orally Administered Drug Products Submitted in New Drug Applications General Consideration
- Drug Interaction Studies - Study Design, Data Analysis, and Implications for Dosing and Labeling

CATEGORY --- Biosimilarity

- Scientific Considerations in Demonstrating Biosimilarity To a Reference Product
- Quality Considerations in Demonstrating Biosimilarity To a Reference Protein Product
- Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009
- Submission of Clinical Pharmacology Data as Evidence of Biosimilarity for Biologics and Protein Products

CATEGORY — Chemistry

- Allowable Excess Volume and Labeled Vial Fill Size
- ANDAs: Stability Testing Requirements for Drug Substances and Products
- Bioequivalence Studies with Pharmacokinetic Endpoints for Drug Products Submitted in Abbreviated New Drug Applications
- Comparability Protocols for Approved Drugs: Chemistry, Manufacturing, and Controls Information
- Immunogenicity Considerations for Low Molecular Weight Heparin
- Limiting the Use of Certain Phthalates as Excipients in CDER-Regulated Products
- Liposome Drug Products: CMC, Human Pharmacokinetic and Bioavailability; and Labeling Documentation
- Nongovernment Standards
- Size and Physical Attributes of Generic Tablets

CATEGORY — Clinical/Antimicrobial

- Complicated Urinary Tract Infections: Developing Drugs for Treatment

CATEGORY — Clinical/Medical

- Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations
- Pregnant Women in Clinical Trials – Scientific and Ethical Considerations
- Use of Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early Stage Breast Cancer as an Endpoint to Support Accelerated Approval

CATEGORY — Clinical Pharmacology

- Bioanalytical Methods Validation
- Clinical Pharmacogenomics: Study Design and Premarketing Evaluation
- Clinical Pharmacology Consideration for Therapeutics Proteins
- General Clinical Pharmacology Considerations for Pediatrics Studies for Drugs and Biological Products

CATEGORY — Clinical/Statistical

- Multiple Endpoints

CATEGORY — Combination Products

- Development of Drugs in Combination

CATEGORY — Current Good Manufacturing Practices (CGMPs)/Compliance

- Control of Highly Potent Compounds
- Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide
- Importation of Active Pharmaceutical Ingredients (API) for Use in Human Drugs
- Pre-Launch Activities Importation Request (PLAIR)
- Pyrogen and Endotoxins Testing Questions and Answers

CATEGORY — Drug Safety Information

- Naming, Labeling, and Packaging Practices to Reduce Medication Errors
- Securing the Drug Supply Chain—Standards for Tracking and Tracing Prescription Drug Packages

CATEGORY — Electronic Submissions

- Electronic Submission of Summary Level Clinical Site Data for Data Integrity Review and Inspection Planning in NDA and BLA Submissions
- Providing Regulatory Submissions in Electronic Format – General Considerations
- Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
- Providing Regulatory Submissions in Electronic Format – Study Data
- Providing Regulatory Submissions in Electronic Format – Standardized Study Data

CATEGORY — IND

- Adverse Events: Collection and Reporting for Secondary Endpoints

CATEGORY — Labeling

- Drug Names and Dosage Forms
- Organ-Specific Warnings: Internal Analgesic, Antipyretic and Antirheumatic Drug Products for Over-the-Counter Human Use-Labeling of Products That Contain Acetaminophen
- Pediatric Information: Incorporating into Human Prescription Drug and Biological Products Labeling

CATEGORY – Pharmacology/Toxicology

- Endocrine Disruption Potential of Drugs: Non Clinical Evaluation

CATEGORY — Procedural

- Integrated Summary of Safety
- Investigational New Drug Applications prepared and submitted by Clinical Sponsor Investigators
- Pediatric Studies: How to Comply with the Pediatric Research Equity Act, Title IV of the Food and Drug Administration Amendments Act of 2007
- Pharmacy Compounding of Human Drugs Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- Public Disclosure of FDA-Sponsored Studies
- CPG Section 490.200 for FDA Staff: Parametric Release – Drug Products Terminally Sterilized by Moist Heat
- Reporting Drug Sample Distribution Under Section 6004 of the Affordable Care Act
- Standards for Securing the Drug Supply Chain – Standards for Tracking and Tracing Prescription Drug Packages

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