Guidance Agenda:
New Draft Guidances CDER is Planning to Publish During Calendar Year 2010

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

CATEGORY — Advertising

- Amendment of the Brief Summary
- Comparative Claims in Prescription Drug Promotion
- Direct to Consumer Television Advertisements - FDAAA DTC Television Pre-Review Program
- Promotion of Prescription Drug Products Using Social Media Tools

CATEGORY — Chemistry

- Chemistry, Manufacturing, and Controls – Postmarketing Plan
- CMC Post-Approval Changes Reportable in an Annual Report
- Comparability Protocols for Approved Drugs: Chemistry, Manufacturing, and Controls Information
- Standards Recognition
- Residual Drug in Transdermal Drug Delivery Systems

CATEGORY — Clinical/Medical

- Clinical Development of Drugs for Irritable Bowel Syndrome
- Oncology Endpoints: Non-Small Cell Lung Cancer
- Qualification Process for Drug Development Tools
- Responsible Inclusion of Pregnant Women in Clinical Trials

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
- Development of Extended Released Formulations

CATEGORY — Clinical/Statistical

- Adaptive Trial Designs
- Multiple Endpoints
- Non-Inferiority Trials

CATEGORY — Combination Products

- Drug Diagnostic Co-Development
- Development of Drugs in Combination

CATEGORY — Current Good Manufacturing Practices (CGMPs)/Compliance

- Contract Manufacturing
- Control of Components
- 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
- Medical Gas, General CGMP
- Non-Penicillin Beta-Lactam Contamination
- Outsourcer Pharmacy Operations Compliance Policy Guide
- Pharmaceutical Component Quality Control
- Pharmaceutical Manufacturing Statistics
- Pre-Launch Activities Importation Request (PLAIR)
- Prevention and Control of Viral Contamination
- Validation of Air Separation Processes for Medical Gas

CATEGORY — Drug Safety Information

- Best Practices for Conducting Pharmacovigilance Studies Using Electronic Healthcare Data
- Dear Healthcare Professional Letters
- Good Naming, Labeling, and Packaging Practices to Reduce Medication Errors

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 – Analysis Datasets and Documentation

CATEGORY — IND

- Adverse Events: Collection and Reporting for Secondary Endpoints
- Determining Whether Human Research Studies Can Be Conducted Without An IND
- IND Safety Reporting

CATEGORY — Labeling

- Drug Names and Dosage Forms
- Pediatric Information: Incorporating into Human Prescription Drug and Biological Products Labeling

CATEGORY — Procedural

- Investigational New Drug Applications prepared and submitted by Clinical Sponsor Investigators

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