Guidance Agenda:
Guidances CDER is Planning to Develop During Calendar Year 2009

(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
- Presentation of Risk Information in Prescription Drug and Medical Device Promotion

CATEGORY — Chemistry

- Assay Development for Immunogenicity Testing
- Chemistry, Manufacturing, and Controls – Postmarketing Plan
- CMC Post-Approval Changes Reportable in an Annual Report
- Immunogenicity Assessment for Therapeutic Protein Products
- Incorporation of Physical-chemical Identifiers (PCID) Into Solid Oral Dosage Form Drug Products for Anticounterfeiting
- Standards Recognition

CATEGORY — Clinical/Antimicrobial

- Influenza: Developing Drugs for Treatment and/or Prophylaxis
- Microbiological Data to Support a NDA for Systemic Antibacterial DP – Development, Analysis, and Presentation

CATEGORY — Clinical/Medical

- Adaptive Trial Designs
- Myopic Progression: Developing Drugs for the Reduction of Myopic Progression
- Oncology Endpoints: Non-Small Cell Lung Cancer

CATEGORY — Clinical/Statistical

- Non-Inferiority Trials

CATEGORY — Combination Products

- Drug Diagnostic Co-Development

CATEGORY — Compliance

- Contract Manufacturing
- Dosage Delivery Devices for OTC Liquid Drug Products
- Medical Gas
- Non-Penicillin Beta-Lactam Contamination

- Part 11, Electronic Records; Electronic Signatures - Scope and Application
- PET CGMPs
- Pharmaceutical Component Quality Control
- Pharmaceutical Components At-Risk for Melamine Contamination
- Pharmaceutical Manufacturing Statistics
- Pre-Launch Activities Importation Request (PLAIR)
- Process Validation: General Principles and Practices

CATEGORY — Drug Safety Information

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

CATEGORY — Electronic Submissions

- Providing Regulatory Submissions in Electronic Format – Analysis Datasets and Documentation

CATEGORY — Generics

- Submission of Summary Bioequivalence Data for ANDAs

CATEGORY — IND

- Consumer Product Safety Commission – Tamper Resistant Packaging for INDs
- Determining Whether Human Research Studies Can Be Conducted Without An IND
- IND Safety Reporting

CATEGORY — Labeling

- Content and Format of the Clinical Pharmacology Section
- Drug Names and Dosage Forms
- Labeling Dietary Supplements for Women Who Are or Could Be Pregnant

CATEGORY — OTC

- Label Comprehension Studies for Nonprescription Drug Products

CATEGORY — Procedural

- Animal Models - Essential Elements to Address Efficacy Under the Animal Rule
- Assessment of Abuse Potential of Drugs
- Determining Whether Human Research with a Radioactive Drug Can Be Conducted Under a Radioactive Drug Research Committee (RDRC)
- Investigational NDAs prepared and submitted by Clinical Investigators

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