# Guidance Agenda:
# Guidances CDER is Planning to Develop During Calendar Year 2008

**(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
- 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
- Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes

## CATEGORY — Clinical/Medical

- Adaptive Trial Designs
- Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention
- Oncology Endpoints: Non-Small Cell Lung Cancer
- Pain Management: Developing Drug and Biological Products
- Risk Management of Highly Suspect or Known Human Teratogens: Pregnancy Prevention Strategies

## CATEGORY — Clinical/Pharmacology

- End of Phase 2a Meetings

## CATEGORY — Clinical/Statistical

- Non-Inferiority Trials

## CATEGORY — Combination Products

- Drug Diagnostic Co-Development

## CATEGORY — Compliance

- Active Pharmaceutical Ingredient (API)
- Medical Gas
- Non-Penicillin Beta-Lactam Contamination
- Pharmacy Compounding of Human Drugs – Compliance Policy Guide, Section 460.200
- Penicillins and Their Definition
- PET CGMPs
- Pre-Launch Activities Importation Request (PLAIR)
- Process Validation:  General Principles and Practices

## CATEGORY — Drug Safety Information

- Contents of a Complete Submission Package for a Proposed Proprietary Drug or Biologic Name
- Dear Healthcare Professional Letters
- Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During Pandemic Influenza

## 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

## CATEGORY — Labeling

- Content and Format of the Clinical Pharmacology Section
- Drug Names and Dosage Forms
- Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims
- Labeling Dietary Supplements for Women Who Are or Could Be Pregnant
- Labeling Guidance for the Inclusion and Placement of Safe Handling Statements in Package Inserts for Human Pharmaceuticals

## CATEGORY — OTC

- Label Comprehension Studies for OTC Drug Products
- Labeling of Over-the-Counter Skin Protectant Drug Products

## CATEGORY — Pharmacology/Toxicology

- Biotechnology-Derived Pharmaceuticals: Nonclinical Safety Evaluation
- Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches
- Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route

## CATEGORY — Procedural

- Assessment of Abuse Potential of Drugs
- Determining Whether Human Research with a Radioactive Drug Can Be Conducted Under a Radioactive Drug Research Committee (RDRC)
- Formal Meetings Between CDER/CBER Staff and Sponsors
- Integrated Summary of Effectiveness

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