

CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2013 – 12/31/2013

(Sorted by date)

| Title | Subject | Level at Date of Issue | Publication/Withdrawal Date | Status |
|---|--|------------------------|-----------------------------|---------|
| Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications | Electronic Submissions Draft | Level 1 | 1/3/2013 | New |
| Abuse-Deterrent Opioids-Evaluation and Labeling | Clinical/Medical Draft | Level 1 | 1/14/2013 | New |
| E3 Structure and Content of Clinical Study Reports - Questions and Answers (R1) | ICH Efficacy | Level 2 | 1/25/2013 | Revised |
| Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling | Clinical Pharmacology | Level 1 | 1/28/2013 | New |
| S10 Photosafety Evaluation of Pharmaceuticals | ICH Safety Draft | Level 1 | 2/4/2013 | New |
| Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease | Clinical/Medical Draft | Level 1 | 2/8/2013 | New |
| Immunogenicity Assessment for Therapeutic Protein Products | Clinical/Medical; CMC Draft | Level 1 | 2/11/2013 | New |
| Labeling for Human Prescription Drug and Biological Products - Implementing the PLR Content and Format Requirements | Labeling | Level 1 | 2/25/2013 | New |
| Antiviral Product Development — Conducting and Submitting Virology Studies to the Agency Guidance for Submitting HCV Resistance Data -Attachment to Guidance | Clinical/Antimicrobial Draft | Level 1 | 2/25/2013 | New |
| M3(R2)Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals: Questions and Answers (R1) | ICH - Multidisciplinary | Level 2 | 2/25/2013 | Revised |
| Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling Good Review Practice | Labeling Draft | Level 1 | 2/28/2013 | New |
| Formal Dispute Resolution: Appeals Above the Division Level | Procedural Draft | Level 1 | 3/13/2013 | Revised |
| Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation | Chemistry, Manufacturing, and Controls (CMC) | Level 1 | 3/13/2013 | New |
| Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants | Procedural Draft | Level 1 | 4/1/2013 | New |
| Scale-Up and Post-Approval Changes: Manufacturing Equipment Addendum | Chemistry, Manufacturing, and Controls (CMC) Draft | Level 1 | 4/1/2013 | New |

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| Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040-4 - Draft Guidance for Industry and FDA Staff | Combination Products Draft | Level 1 | 4/3/2013 | New |
| Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report) | Drug Safety/ ICH Efficacy Draft | Level 1 | 4/8/2013 | Revised |
| Self-Selection Studies for Nonprescription Drug Products | Over-the-Counter | Level 1 | 4/11/2013 | New |
| M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk | ICH - Multidisciplinary Draft | Level 1 | 4/15/2013 | New |
| Non-Penicillin Beta-Lactam Risk Assessment: A CGMP Framework | Current Good Manufacturing Practices (CGMPs) | Level 1 | 4/17/2013 | New |
| Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors | Drug Safety Draft | Level 1 | 4/24/2013 | New |
| Regulatory Classification of Pharmaceutical Co-Crystals | Chemistry; Manufacturing and Controls (CMC) | Level 1 | 4/26/2013 | New |
| Charging for Investigational Drugs Under an IND — Qs & As | Procedural Draft | Level 1 | 5/9/2013 | New |
| Expanded Access to Investigational Drugs for Treatment Use — Qs & As | Procedural Draft | Level 1 | 5/9/2013 | New |
| Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets | Drug Safety | Level 1 | 5/14/2013 | New |
| Annex 13 Bulk Density and Tapped Density of Powders General Chapter | ICH Quality | Level 1 | 5/28/2013 | New |
| Contract Manufacturing Arrangements for Drugs: Quality Agreements | CGMP/Compliance Draft | Level 1 | 5/28/2013 | New |
| Rheumatoid Arthritis: Developing Drug Products for Treatment | Clinical/Medical Draft | Level 1 | 5/31/2013 | New |
| M2: eCTD Specification Questions & Answers and Change Requests Companion Document | ICH - Multidisciplinary | Level 2 | 6/3/2013 | Revised |
| Human Immunodeficiency Virus-1 Infection: Developing Antiretroviral Drugs for Treatment | Clinical/Antimicrobial Draft | Level 2 | 6/4/2013 | Revised |
| Codevelopment of Two or More New Investigational Drugs for Use in Combination | Clinical/Medical | Level 1 | 6/14/2013 | New |
| Abbreviated New Drug Applications: Stability Testing of Drug Substances and Products | Generics | Level 1 | 6/20/2013 | New |
| Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality | Current Good Manufacturing Practices (CGMP's) | Level 1 | 6/25/2013 | New |
| Expedited Programs for Serious Conditions—Drugs and Biologics | Procedural Draft | Level 1 | 6/26/2013 | New |
| Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases | Clinical/Antimicrobial Draft | Level 1 | 7/2/2013 | New |

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| Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans | Procedural Draft | Level 1 | 7/15/2013 | New |
| Providing Submissions in Electronic Format – Postmarket Non-Expedited ICSRs Technical Questions and Answers | Electronic Submissions | Level 1 | 7/24/2013 | New |
| Pre-Launch Activities Importation Requests (PLAIR) | Procedural Draft | Level 1 | 7/24/2013 | New |
| Safety Labeling Changes -- Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act | Drug Safety | Level 1 | 7/30/2013 | New |
| Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring | Procedural | Level 1 | 8/7/2013 | New |
| ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers | Generics Draft | Level 1 | 8/27/2013 | New |
| Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration | Procedural Draft | Level 1 | 9/6/2013 | New |
| Generic Drug User Fee Amendments of 2012: Questions and Answers (Revision 1) | Generics Draft | Level 1 | 9/10/2013 | Revised |
| Investigational New Drug Applications (INDs)-Determining Whether Human Research Studies Can Be Conducted Without an IND | Clinical/Medical | Level 1 | 9/10/2013 | New |
| Bioanalytical Method Validation | Biopharmaceutics Draft | Level 1 | 9/13/2013 | Revised |
| Electronic Source Data in Clinical Investigations | Procedural | Level 1 | 9/18/2013 | New |
| Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products — Content and Format | Labeling Draft | Level 1 | 9/18/2013 | New |
| Endocrine Disruption Potential of Drugs: Nonclinical Evaluation | Pharmacology and Toxicology Draft | Level 1 | 9/20/2013 | New |
| Abbreviated New Drug Application Submissions -- Refuse-to-Receive Standards | Generics Draft | Level 1 | 10/1/2013 | New |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions: Annex 14: Bacterial Endotoxins Test General Chapter | ICH Quality | Level 1 | 10/23/2013 | New |
| Q3D Elemental Impurities | ICH Quality Draft | Level 2 | 10/23/2013 | New |
| Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment | Clinical/Antimicrobial | Level 1 | 10/23/2013 | New |
| Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment | Clinical/Antimicrobial Draft | Level 1 | 10/23/2013 | Revised |
| Pulmonary Tuberculosis: Developing Drugs for Treatment | Clinical/Antimicrobial Draft | Level 1 | 11/6/2013 | New |
| Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act | Procedural Draft | Level 1 | 12/4/2013 | New |
| Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act | Procedural Draft | Level 1 | 12/4/2013 | New |

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| Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act | Procedural Draft | Level 1 | 12/4/2013 | New |
| Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application | Biopharmaceutics Draft | Level 1 | 12/5/2013 | New |
| Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules | Generics Draft | Level 1 | 12/10/2013 | New |
| Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling | Advertising Draft | Level 2 | 12/20/2013 | Revised |
| Naming of Drug Products Containing Salt Drug Substances | Labeling Draft | Level 1 | 12/26/2013 | New |