CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2012 – 12/31/2012

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Product Name Placement, Size, and Prominence in Advertising & Promotional Labeling	Advertising	Level 1	1/25/2012	New
Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations	Clinical/Medical Draft	Level 1	2/10/2012	New
Heparin for Drug and Medical Device Use: Monitoring Crude Heparin for Quality	Current Good Manufacturing Practices (CGMP's) Draft	Level 1	2/13/2012	New
Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs	Clinical/Medical Draft	Level 1	2/14/2012	New
Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product	Biosimilarity Draft	Level 1	2/15/2012	New
Scientific Considerations in Demonstrating Biosimilarity to a Reference Product	Biosimilarity Draft	Level 1	2/15/2012	New
Biosimilars: Q & As Regarding Implementation of the BPCI Act of 2009	Biosimilarity Draft	Level 1	2/15/2012	New
M3(R2)Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals: Questions and Answers	ICH Multidisciplinary	Level 2	2/17/2012	New
Drug Interaction Studies--Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations	Clinical Pharmacology Draft	Level 1	2/21/2012	Revised
E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers	ICH Efficacy	Level 1	2/21/2012	New
Providing Submissions in Electronic Format -- Standardized Study Data	Electronic Submissions Draft	Level 1	2/21/2012	New
Final Recommendation for the Revision of the Permitted Daily Exposure for Cumene According to the Maintenance Procedures for Q3C Impurities: Residual Solvents	ICH Quality	Level 1	2/23/2012	New
Q3C Tables and List	ICH Quality	Level 2	2/22/2012	New
Complicated Urinary Tract Infections: Developing Drugs for Treatment	Clinical / Antimicrobial Draft	Level 1	2/24/2012	New
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic	Drug Safety	Level 1	2/24/2012	New
Notification to FDA of Issues that May Result in a Prescription Drug or Biological Product Shortage	Procedural; Drug Safety Draft	Level 1	2/27/2012	New
FDA Oversight of PET Drug Products -- Questions and Answers	Procedural Draft	Level 1	2/27/2012	New

Size of Beads in Drug Products Labeled for Sprinkle	Chemistry, Manufacturing, and Controls (CMC)	Level 1	2/29/2012	New
Limiting the Use of Certain Phthalates as Excipients in CDER-Regulated Products	Chemistry, Manufacturing and Controls (CMC) Draft	Level 1	3/2/2012	New
Classifying Significant Posmarketing Drug Safety Issues	Drug Safety Draft	Level 1	3/9/2012	New
Drug Safety Information -- FDA's Communication to the Public	Drug Safety Draft	Level 1	3/9/2012	New
Direct-to-Consumer Television Advertisements -- FDAAA DTC Television Ad Pre-Dissemination Review Program	Advertising Draft	Level 1	3/13/2012	New
Compliance Policy on Reporting Drug Sample Distribution Information	Electronic Submissions Draft	Level 1	4/3/2012	New
ICH- E2C(R2) Periodic Benefit-Risk Evaluation Report	ICH Efficacy Draft	Level 1	4/11/2012	New
Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography	Current Good Manufacturing Practices (CGMPs)/Compliance	Level 1	4/11/2012	New
Size of Beads in Drug Products Labeled for Sprinkle	Chemistry, Manufacturing, and Controls (CMC)	Level 2	5/2/2012	Revised
S6(R1) Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	ICH Safety	Level 1	5/18/2012	Revised
Pathologic Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval	Clinical/Medical Draft	Level 1	5/30/2012	New
Irritable Bowel Syndrome -- Clinical Evaluation of Products for Treatment	Clinical/Medical	Level 1	5/31/2012	New
S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use	ICH Safety	Level 1	6/7/2012	New
"Toll-Free Number Labeling and Related Requirements for Over-the-Counter and Prescription Drugs Marketed With Approved Applications" - Small Entity Compliance Guide	Procedural	Level 1	6/15/2012	New
Lupus Nephritis Caused By Systemic Lupus Erythematosus--Developing Medical Products for Treatment	Clinical/Medical	Level 1	6/26/2012	Withdrawn
Pyrogen and Endotoxins Testing: Questions and Answers	Current Good Manufacturing Practices (CGMP's) Compliance	Level 2	6/28/2012	New
Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use — Labeling for Products That Contain Acetaminophen	Current Good Manufacturing Practices (CGMP's) Compliance Draft	Level 1	7/5/2012	Revised
ICH Q8, Q9, & Q10 Questions and Answers -- Appendix: Q&As from Training Sessions (Q8, Q9, & Q10 Points to Consider)	ICH Quality	Level 2	7/25/2012	New

Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials	Clinical/Medical Draft	Level 1	8/15/2012	Revised
Generic Drug User Fee Amendments of 2012: Questions and Answers	Generics Draft	Level 1	8/27/2012	New
Self-Identification of Generic Drug Facilities, Sites, and Organizations	Generics Draft	Level 1	8/27/2012	New
ANDAs: Stability Testing of Drug Substances and Products	Generics Draft	Level 1	9/24/2012	New
Consumer-Directed Broadcast Advertising of Restricted Devices	Advertising	Level 1	9/28/2012	Withdrawn
Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment	Clinical Antimicrobial	Level 1	10/1/2012	New
Complicated Intra-Abdominal Infections: Developing Drugs for Treatment	Clinical/Antimicrobial Draft	Level 1	10/1/2012	New
Acute Bacterial Otitis Media: Developing Drugs for Treatment	Clinical Antimicrobial	Level 1	10/2/2012	New
Initial Completeness Assessments for Type II API DMFs Under GDUFA	Generics Draft	Level 1	10/2/2012	New
Acute Bacterial Sinusitis: Developing Drugs for Treatment	Clinical/Antimicrobial	Level 1	10/9/2012	New
Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, And Antiasthmatic Drug Products for Over-the-Counter Human Use (Small Entity Compliance Guide)	Over-the-Counter; Small Entity Compliance Guide	Level 1	11/15/2012	New
Q11 Development and Manufacture of Drug Substances	ICH Quality	Level 1	11/20/2012	New
Electronic Source Data in Clinical Investigations	Procedural Draft	Level 1	11/20/2012	New
Vaginal Microbicides: Development for the Prevention of HIV Infection	Clinical/Antimicrobial Draft	Level 1	11/23/2012	New
Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs	Clinical/Medical	Level 1	12/4/2012	New
FDA Oversight of PET Drug Products -- Questions and Answers	Procedural	Level 1	12/4/2012	New
Limiting the Use of Certain Phthalates as Excipients in CDER-Regulated Products	Chemistry, Manufacturing, and Controls (CMC)	Level 1	12/6/2012	New
Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-The-Counter Human Use — Small Entity Compliance Guide	Over-the-Counter; Small Entity Compliance Guide	Level 1	12/6/2012	New
Safety Considerations for Product Design to Minimize Medication Errors	Drug Safety Draft	Level 1	12/13/2012	New
Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products	Clinical/Medical Draft	Level 1	12/14/2012	New
Certification Process of Designated Medical Gases	Procedural Draft	Level 1	12/18/2012	New
Providing Submissions in Electronic Format -- Summary Level Clinical Site Data for CDER	Electronic Submissions Draft	Level 1	12/19/2012	New

Specifications for Preparing and Submitting Summary Level Clinical Site Data for CDER's Inspection Planning	Electronic Submissions Draft	Level 1	12/19/2012	New
Safety Reporting Requirements for INDs and BA/BE Studies- Small Entity Compliance Guide	Drug Safety	Level 1	12/20/2012	New
Safety Reporting Requirements for INDs (Investigational New Drug Applications) and BA/BE (Bioavailability/Bioequivalence) Studies	Drug Safety	Level 1	12/20/2012	New