CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2011 – 12/31/2011

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic	Procedural Draft	Level 1	1/7/2011	Revised
Size of Beads in Drug Products Labeled for Sprinkle	Chemistry, Manufacturing, and Controls Draft	Level 1	1/19/2011	New
Process Validation: General Principles and Practices	Current Good Manufacturing Practices	Level 1	1/25/2011	New
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review	Drug Safety/ Good Review Practices	Level 1	1/26/2011	Withdrawn
PET Drug Applications – Content and Format for NDAs and ANDAs	Procedural/ Modernization Act Draft	Level 1	2/2/2011	New
Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets	Drug Safety Draft	Level 1	2/16/2011	New
Clinical Pharmacogenomics: Premarketing Evaluation in Early Phase Clinical Studies	Clinical Pharmacology Draft	Level 1	2/18/2011	New
Medication Guides--Distribution Requirements and Inclusion of Medication Guides in Risk Evaluation and Mitigation Strategies	Drug Safety Draft	Level 1	2/28/2011	New
User Fee Waivers, Reductions, and Refunds for Drug and Biological Products	User Fees Draft	Level 1	3/14/2011	New
Non-Penicillin Beta-Lactam Risk Assessment: A CGMP Framework	Current Good Manufacturing Practices Draft	Level 1	3/15/2011	New
Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims	Labeling	Level 1	3/15/2011	New
Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products	Procedural	Level 1	3/15/2011	New
Postmarketing Studies and Clinical Trials--Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act	Drug Safety	Level 1	4/1/2011	New
Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing	Biopharmaceuticals	Level 1	4/1/2011	Withdrawn
Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research	Clinical/Medical	Level 1	4/4/2011	New
Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act	Drug Safety Draft	Level 1	4/13/2011	New
Influenza: Developing Drugs for Treatment and/or Prophylaxis	Clinical/Antimicrobial	Level 1	4/13/2011	New

Dosage Delivery Devices for Orally Ingested OTC Liquid Drug Products	Current Good Manufacturing Practices	Level 1	5/5/2011	New
Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications	Generics	Level 1	5/6/2011	New
Financial Disclosure by Clinical Investigators: Guidance for Clinical Investigators, Industry, and FDA Staff	Procedural Draft	Level 1	5/24/2011	New
Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act	Procedural	Level 1	6/8/2011	New
Enforcement Policy -- OTC Sunscreen Drug Products Marketed Without an Approved Application	Procedural Draft	Level 1	6/14/2011	New
Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics	Clinical Medical Draft	Level 1	6/16/2011	New
Topical Acne Drug Products for Over-the-Counter Human Use--Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective	Labeling; OTC; Small Entity Compliance Guides	Level 1	6/21/2011	New
Guideline on Validation of the Limulus Amebocyte Lysate Test	Current Good Manufacturing Practices	Level 1	6/22/2011	Withdrawn
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions Annex 7(R2) Dissolution Test General Chapter	ICH Quality	Level 1	6/23/2011	Revised
Q11 Development and Manufacture of Drug Substances	ICH Quality Draft	Level 1	6/28/2011	New
PET Drugs — Current Good Manufacturing Practice (CGMP) (Small Entity Compliance Guide)	cGMP/Compliance; Small Entity Compliance Guides	Level 1	8/4/2011	New
E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions	ICH Efficacy	Level 1	8/10/2011	New
Residual Drug in Transdermal and Related Drug Delivery Systems	Chemistry, Manufacturing, and Controls Draft	Level 1	8/16/2011	New
Standards for Clinical Trial Imaging Endpoints	Clinical/Medical Draft	Level 1	8/18/2011	New
E2F Development Safety Update Report	ICH Efficacy	Level 1	8/22/2011	New
Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention	Clinical/Antimicrobial Draft	Level 1	8/23/2011	New
Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring	Procedural Draft	Level 1	8/29/2011	New
Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation	Chemistry, Manufacturing, and Controls Draft	Level 1	8/29/2011	New
PET Drug Applications — Content and Format for NDAs and ANDAs, Fludeoxyglucose F 18 Injection, Ammonia N 13 Injection, Sodium Fluoride F 18 Injection	Procedural; Modernization Act	Level 1	8/31/2011	New

PET Drug Applications - Content and Format for NDAs and ANDAs: Attachment I: Sample formats for chemistry, manufacturing, and controls (CMC) sections_2011	Procedural; Modernization Act	Level 1	8/31/2011	New
Self-Selection Studies for Nonprescription Drug Products	OTC Draft	Level 1	9/16/2011	New
Marketed Unapproved Drugs -- Compliance Policy Guide	Current Good Manufacturing Practices/ Compliance	Level 1	9/19/2011	Revised
Reproductive and Developmental Toxicities -- Integrating Study Results to Assess Concerns	Pharm/Tox	Level 1	9/22/2011	New
User Fee Waivers, Reductions, and Refunds for Drug and Biological Products	User Fees	Level 1	9/26/2011	New
Time and Extent Applications for Nonprescription Drug Products	OTC	Level 1	9/28/2011	New
Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography	Current Good Manufact. Practices/ Compliance Draft	Level 1	9/29/2011	New
Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a))	Current Good Manufacturing Practices/ Compliance	Level 1	10/3/2011	Withdrawn
Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format	Labeling	Level 1	10/11/2011	New
Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting	Chemistry, Manufacturing, and Controls	Level 1	10/11/2011	New
Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)	Labeling Draft	Level 1	10/17/2011	Withdrawn/ Moved
E2B(R3) Electronic Transmission of Individual Case Safety Reports Implementation Guide — Data Elements and Message Specification; and Appendix to the Implementation Guide — Backwards and Forwards Compatibility	ICH Efficacy Draft	Level 1	10/19/2011	New
Q8, Q9, and Q10 Questions and Answers	ICH Quality	Level 1	11/1/2011	Revised
Medication Guides — Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies	Drug Safety	Level 1	11/17/2011	New
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals	Pharm/Tox	Level 1	11/25/2011	New
Regulatory Classification of Pharmaceutical Co-Crystals	Chemistry, Manufacturing, and Controls Draft	Level 1	12/1/2011	New
Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices	Procedural Draft	Level 1	12/27/2011	New
Use of Histology in Biomarker Qualification Studies	Procedural Draft	Level 1	12/29/2011	New