CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2010 – 12/31/2010

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products	Procedural Draft	Level 1	1/8/2010	New
M3 (R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	ICH Multidisciplinary	Level 1	1/21/2010	Revised
Use of Mechanical Calibration of Dissolution Apparatus 1 and 2--Current Good Manufacturing Practice	CGMP/Compliance	Level 1	1/27/2010	New
Assessment of Abuse Potential of Drugs	Clinical Medical Draft	Level 1	1/27/2010	New
Contents of a Complete Submission for the Evaluation of Proprietary Names	Labeling	Level 1	2/8/2010	New
Labeling OTC Skin Protectant Drug Products	OTC Draft	Level 1	2/17/2010	Withdrawn
Adaptive Design Clinical Trials for Drugs and Biologics	Clinical Medical Draft	Level 1	2/26/2010	New
Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes	Chemistry, Manufacturing, and Controls Draft	Level 1	2/26/2010	New
Non – Inferiority Clinical Trials	Clinical Medical Draft	Level 1	3/1/2010	New
S9 Nonclinical Evaluation for Anticancer Pharmaceuticals	ICH Quality	Level 1	3/8/2010	New
Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis, and Impact on Dosing and Labeling	Clinical Pharmacology Draft	Level 1	3/22/2010	New
Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products – Content and Format	Labeling	Level 1	3/23/2010	New
Irritable Bowel Syndrome – Clinical Evaluation of Products for Treatment	Clinical Medical Draft	Level 1	3/23/2010	New
Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages	Procedural Draft	Level 1	3/29/2010	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions – Annex 7: Dissolution Test General Chapter;	ICH Quality	Level 1	4/5/2010	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions – Annex 9: Tablet Friability General Chapter	ICH Quality	Level 1	4/5/2010	New
Continuous Marketing Applications: Pilot 1 – Reviewable Units for Fast Track Products under PDUFA	Procedural	Level 1	4/9/2010	Withdrawn

Continuous Marketing Applications: Pilot 2 – Scientific Feedback and Interactions during Development of Fast Track Products under PDUFA	Procedural	Level 1	4/9/2010	Withdrawn
Continuous Marketing Applications: Pilot 2 – Scientific Feedback and Interactions during Development of Fast Track Products under PDUFA; Paperwork Reduction Act Burden Statement	Procedural	Level 1	4/9/2010	Withdrawn
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions – Annex 10: Polyacrylamide Gel Electrophoresis General Chapter	ICH Quality	Level 1	4/12/2010	New
Clinical Evaluation of Lipid – Altering Agents	Clinical Medical Draft	Level 1	4/16/2010	Withdrawn
Q8, Q9, and Q10 Questions and Answers	ICH Quality	Level 1	5/5/2010	New
Bioequivalence Recommendations for Specific Products	Generics	Level 1	6/11/2010	New
Lupus Nephritis Caused By Systemic Lupus Erythematosus — Developing Medical Products for Treatment	Clinical Medical	Level 1	6/22/2010	New
Systemic Lupus Erythematosus — Developing Medical Products for Treatment	Clinical Medical	Level 1	6/22/2010	New
CMC Postapproval Manufacturing Changes Reportable in Annual Reports	CMC Draft	Level 1	6/25/2010	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions - Annex 13: Bulk Density and Tapped Density of Powders General Chapter	ICH Quality Draft	Level 1	7/14/2010	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions - Annex 14: Bacterial Endotoxins Test General Chapter	ICH Quality Draft	Level 1	7/19/2010	New
ICH Q3C Maintenance Procedures for the Guidance for Industry Q3C Impurities: Residual Solvents - Draft Recommendation for the Revision of the Permitted Daily Exposure for Cumene According to the Maintenance Procedures for Q3C Impurities: Residual Solvents	ICH Quality Draft	Level 1	7/20/2010	New
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment	Clinical Medical Draft	Level 1	7/28/2010	Withdrawn
The Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application	Clinical Medical	Level 1	8/2/2010	New
Label Comprehension Studies for Nonprescription Drug Products	Over the Counter	Level 1	8/3/2010	New
Residual Drug in Transdermal and Related Drug Delivery Systems	Chemistry, Manufacturing, and Controls Draft	Level 1	8/3/2010	New
Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use — Small Entity Compliance Guide	Over the Counter	Level 1	8/17/2010	New
Acute Bacterial Skin and Skin Structure Infections: Developing Drugs for Treatment	Clinical Antimicrobial Draft	Level 1	8/27/2010	New

Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions: Annex 12 Analytical Sieving General Chapter	ICH Quality	Level 1	9/2/2010	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions: Annex 11 Capillary Electrophoresis General Chapter	ICH Quality	Level 1	9/3/2010	New
Suicidality: Prospective Assessment of Occurrence in Clinical Trials	Clinical Medical Draft	Level 1	9/9/2010	New
Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Agents for Treatment	Clinical Antimicrobial Draft	Level 1	9/14/2010	New
Safety Reporting Requirements for INDs (Investigational New Drug Applications) and BA/BE (Bioavailability/Bioequivalence) Studies	Drug Safety Draft	Level 1	9/29/2010	New
Investigational New Drug Applications (INDs)DeterminingWhether Human Research Studies Can Be Conducted Without an IND	Clinical Medical Draft	Level 1	10/14/2010	New
Qualification Process for Drug Development Tools	Clinical Medical Draft	Level 1	10/25/2010	New
Dear Healthcare Provider Letters: Improving Communication of Important Safety Information	Procedural	Level 1	11/12/2010	New
Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment	Clinical/Antimicrobial	Level 1	11/29/2010	Revised
Abbreviated New Drug Applications: Impurities in Drug Products	Generics	Level 1	11/29/2010	New
Antibacterial Drug Products: Use of Noninferiority Trials to Support Approval	Clinical/Antimicrobial	Level 1	11/29/2010	New
Codevelopment of Two or More Unmarketed Investigational Drugs for Use in Combination	Clinical/Medical	Level 1	12/14/2010	New