CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2010 – 7/31/2010

(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	01/08/2010	New
M3 (R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	ICH Multidisciplinary	Level 1	01/21/2010	Revised
Use of Mechanical Calibration of Dissolution Apparatus 1 and 2--Current Good Manufacturing Practice	CGMP/Compliance	Level 1	01/27/2010	New
Assessment of Abuse Potential of Drugs	Clinical Medical Draft	Level 1	01/27/2010	New
Contents of a Complete Submission for the Evaluation of Proprietary Names	Labeling	Level 1	02/08/2010	New
Labeling OTC Skin Protectant Drug Products	OTC Draft	Level 1	02/17/2010	Withdrawn
Adaptive Design Clinical Trials for Drugs and Biologics	Clinical Medical Draft	Level 1	02/26/2010	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	02/26/2010	New
Non – Inferiority Clinical Trials	Clinical Medical Draft	Level 1	03/01/2010	New
S9 Nonclinical Evaluation for Anticancer Pharmaceuticals	ICH Quality	Level 1	03/08/2010	New

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Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis, and Impact on Dosing and Labeling	Clinical Pharmacology Draft	Level 1	03/22/2010	New
Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products – Content and Format	Labeling	Level 1	03/23/2010	New
Irritable Bowel Syndrome – Clinical Evaluation of Products for Treatment	Clinical Medical Draft	Level 1	03/23/2010	New
Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages	Procedural Draft	Level 1	03/29/2010	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions – Annex 7: Dissolution Test General Chapter;	ICH Quality	Level 1	04/05/2010	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions – Annex 9: Tablet Friability General Chapter	ICH Quality	Level 1	04/05/2010	New
Continuous Marketing Applications: Pilot 1 – Reviewable Units for Fast Track Products under PDUFA	Procedural	Level 1	04/09/2010	Withdrawn
Continuous Marketing Applications: Pilot 2 – Scientific Feedback and Interactions during Development of Fast Track Products under PDUFA	Procedural	Level 1	04/09/2010	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	04/09/2010	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	04/12/2010	New

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Clinical Evaluation of Lipid – Altering Agents	Clinical Medical Draft	Level 1	04/16/2010	Withdrawn
Q8, Q9, and Q10 Questions and Answers	ICH Quality	Level 1	05/05/2010	New
Bioequivalence Recommendations for Specific Products	Generics	Level 1	06/11/2010	New
Lupus Nephritis Caused By Systemic Lupus Erythematosus — Developing Medical Products for Treatment	Clinical Medical	Level 1	06/22/2010	New
Systemic Lupus Erythematosus — Developing Medical Products for Treatment	Clinical Medical	Level 1	06/22/2010	New
CMC Postapproval Manufacturing Changes Reportable in Annual Reports	CMC Draft	Level 1	06/25/2010	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	07/14/2010	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	07/19/2010	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	07/20/2010	New
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment	Clinical Medical Draft	Level 1	07/28/2010	Withdrawn