CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2008 – 6/30/2008

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act	Clinical Medical Draft	Level 1	01/02/2008	New
Q8(R1) Pharmaceutical Development	ICH Quality Draft	Level 1	01/10/2008	New
Acute Bacterial Otitis Media: Developing Drugs for Treatment	Clinical Antimicrobial Draft	Level 1	01/18/2008	New
Safety Testing of Drug Metabolites	Pharmacology Toxicology	Level 1	02/15/2008	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions	ICH Quality	Level 1	02/21/2008	New
Q4B - Annex I: Residue on Ignition/Sulphated Ash General Chapter	ICH Quality	Level 1	02/21/2008	New
Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention	Clinical Medical Draft	Level 1	03/03/2008	New
Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route	Pharmacology Toxicology Draft	Level 1	03/07/2008	New
Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims	Labeling Draft	Level 1	03/13/2008	New

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S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use	ICH Safety Draft	Level 1	03/26/2008	New
Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies	Combination Draft	Level 1	03/27/2008	New
International Conference on Harmonisation; Guidance on E15 Pharmacogenomics Definitions and Sample Coding	ICH Efficacy	Level 1	04/08/2008	New
Anti-Inflammatory and Anti-Rheumatic Drugs (Adults and Children)	Clinical Medical	Level 1	05/29/2008	Withdrawn
Indexing Structured Product Labeling	Electronic Submissions	Level 1	06/02/2008	New
Q3A(R) Impurities in New Drug Substances	ICH Quality	Level 2	06/06/2008	New
Providing Regulatory Submissions in Electronic Format--Postmarketing Individual Case Safety Reports	Electronic Submissions Draft	Level 1	06/12/2008	New
Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices	Clinical Antimicrobial Draft	Level 1	06/12/2008	New