CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2008 – 12/31/2008

(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Anti-Inflammatory and Anti-Rheumatic Drugs (Adults and Children)	Clinical Medical	Level 1	05/29/2008	Withdrawn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
Current Good Manufacturing Practice for Phase 1 Investigational Drugs	Current Good Manufacturing Practices/Compliance	Level 1	07/15/2008	New
Labeling OTC Skin Protectant Drug Products	Over the Counter Draft	Level 1	08/04/2008	New
Q4B - Annex 4A: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter	ICH Quality Draft	Level 1	08/05/2008	New

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Q4B - Annex 4B: Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms General Chapter	ICH Quality Draft	Level 1	08/05/2008	New
Q4B - Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter	ICH Quality Draft	Level 1	08/05/2008	New
Q4B - Annex 5: Disintegration Test General Chapter	ICH Quality Draft	Level 1	08/05/2008	New
E2F Development Safety Update Report	ICH Efficacy Draft	Level 1	08/05/2008	New
Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes	CMC Microbiology Draft	Level 1	08/05/2008	New
Residual Solvents in Drug Products Marketed in the United States	Chemistry Draft	Level 1	08/07/2008	New
Acute Bacterial Exacerbations of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment	Clinical Antimicrobial Draft	Level 1	08/22/2008	Revised
Integrated Summary of Effectiveness	Procedural Draft	Level 1	08/28/2008	New
M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals	ICH Joint Safety/Efficacy (Multidisciplinary) Draft	Level 1	09/03/2008	New
S1C(R2) Dose Selection for Carcinogenicity Studies of Pharmaceuticals	ICH Safety	Level 2	09/16/2008	New
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act	Procedural	Level 1	09/22/2008	Withdrawn

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End-of-Phase 2A Meetings	Procedural Draft	Level 1	09/25/2008	New
Tropical Disease Priority Review Vouchers	Procedural Draft	Level 1	10/20/2008	New
Process Validation: General Principles and Practices	Current Good Manufacturing Practices/Compliance Draft	Level 1	11/18/2008	New
E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs. Q&As	ICH Efficacy	Level 2	11/18/2008	New
Contents of a Complete Submission for the Evaluation of Proprietary Names	Labeling Draft	Level 1	11/24/2008	New
Submission of Patent Information for Certain Old Antibiotics	Procedural Draft	Level 1	12/03/2008	New
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	Over the Counter Draft	Level 1	12/11/2008	Revised
Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches	Pharmacology Toxicology Draft	Level 1	12/16/2008	New
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic	Procedural Draft	Level 1	12/16/2008	New
Orally Disintegrating Tablets	Chemistry	Level 1	12/16/2008	New

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Diabetes Mellitus -- Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes	Clinical Medical	Level 1	12/19/2008	New