CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2009 – 4/30/2009

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Labeling Over-the-Counter Human Drug Products – Questions and Answers	OTC	Level 1	01/05/2009	New
Q4B – Annex 2: Test for Extractable Volume of Parenteral Preparations General Chapter	ICH Quality	Level 1	01/09/2009	New
Q4B – Annex 3: Test for Particulate Contamination: Subvisible Particles General Chapter	ICH Quality	Level 1	01/09/2009	New
Animal Models--Essential Elements to Address Efficacy Under the Animal Rule	Pharmacology Toxicology Draft	Level 1	01/21/2009	New
Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act	Procedural Draft	Level 1	01/21/2009	New
S9 Nonclinical Evaluation for Anticancer Pharmaceuticals	ICH Safety Draft	Level 1	02/17/2009	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts - Annex 6: Uniformity of Dosage Units General Chapter	ICH Quality Draft	Level 1	02/17/2009	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts - Annex 7: Dissolution Test General Chapter	ICH Quality Draft	Level 1	02/17/2009	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts - Annex 8: Sterility Test General Chapter	ICH Quality Draft	Level 1	02/17/2009	New
Influenza: Developing Drugs for Treatment and/or Prophylaxis	Clinical Antimicrobial Draft	Level 1	02/20/2009	New

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Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format	Labeling Draft	Level 1	03/03/2009	New
Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment	Clinical Antimicrobial Draft	Level 1	03/20/2009	New
Q4B - Annex 4A: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter	ICH Quality	Level 1	04/08/2009	New
Q4B - Annex 4B: Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms General Chapter	ICH Quality	Level 1	04/08/2009	New
Q4B - Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter	ICH Quality	Level 1	04/08/2009	New
Q10 Pharmaceutical Quality System	ICH Quality	Level 1	04/08/2009	New
Submission of Summary Bioequivalence Data for ANDAs	Generics Draft	Level 1	04/17/2009	New
Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document	Procedural	Level 1	04/21/2009	New