CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2009 – 12/31/2009

(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

CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2009 – 12/31/2009

(Sorted by date)

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
Label Comprehension Studies for Nonprescription Drug Products	OTC Draft	Level 1	05/01/2009	New
Labeling OTC Human Drug Products; Small Entity Compliance Guide	OTC	Level 1	05/13/2009	New
Formal Meetings Between the FDA and Sponsors or Applicants	Procedural	Level 2	05/14/2009	Revised

CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2009 – 12/31/2009

(Sorted by date)

Presenting Risk Information in Prescription Drug and Medical Device Promotion	Advertising Draft	Level 1	05/27/2009	New
The Radioactive Drug Research Committee: Human Research without an Investigational New Drug Application	Clinical/Medical Draft	Level 1	06/03/2009	New
Medication Guides — Adding a Toll-Free Number for Reporting Adverse Events	Procedural	Level 1	06/08/2009	New
Q8(R1) Pharmaceutical Development Revision 1	ICH Quality	Level 1	06/09/2009	New
Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices	Labeling	Level 1	07/02/2009	New
Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting, Availability	Current Good Manufacturing Practice (CGMP's)/Compliance Draft	Level 1	07/14/2009	New
Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application	Over-the-Counter	Level 1	07/14/2009	New
ANDAs: Impurities in Drug Substances	Generics	Level 1	07/15/2009	New
Postmarketing Studies and Clinical Trials; Implementation of the Federal Food, Drug and Cosmetic Act	Drug Safety Draft	Level 1	07/15/2009	New
Drug-Induced Liver Injury: Premarketing Clinical Evaluation	Drug Safety	Level 1	07/30/2009	New
E16 Genomic Biomarkers Related to Drug Response:Context, Structure, and Format of Qualification Submissions	ICH Efficacy Draft	Level 1	07/30/2009	New
Pharmaceutical Components at Risk for Melamine Contamination	Current Good Manufacturing Practices (CGMPs)/Compliance	Level 1	08/07/2009	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 9: Tablet Friability General Chapter	ICH Quality Draft	Level 1	08/14/2009	New

CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2009 – 12/31/2009

(Sorted by date)

Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 10: Polyacrylamide Gel Electrophoresis General Chapter	ICH Quality Draft	Level 1	08/14/2009	New
Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers	Over-The-Counter	Level 1	09/01/2009	New
ICH M2: eCTD – Q&A's and Change Requests	ICH Multidisciplinary	Level 1	09/02/2009	Revised
Microbiological Data for Systemic Antibacterial Drug Products — Development, Analysis, and Presentation	Clinical/ Antimicrobial Draft	Level 1	09/17/2009	New
End-of-Phase 2A Meetings	Procedural	Level 1	09/21/2009	New
Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications	Drug Safety Draft	Level 1	10/01/2009	New
Helicobacter pylori-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment	Clinical/ Antimicrobial Draft	Level 1	10/05/2009	New
Labeling for Human Prescription Drug and Biological Products — Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information	Labeling	Level 1	10/19/2009	New
SPL Standard for Content of Labeling Technical Qs & As	Electronic Submissions	Level 1	10/28/2009	Revised
Dosage Delivery Devices for OTC Liquid Drug Products	Current Good Manufacturing Practices (CGMPs)/Compliance Draft	Level 1	11/05/2009	New
E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers	ICH Efficacy Draft	Level 1	11/10/2009	New
Q8(R2) Pharmaceutical Development Revision 2	ICH Quality	Level 2	11/19/2009	Revised

CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2009 – 12/31/2009

(Sorted by date)

Filing Protocol – Residual Solvents	Chemistry, Manufacturing, and Controls	Level 1	11/25/2009	New
Guidelines for Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis	Clinical Medical Draft	Level 1	12/02/2009	Withdrawn
Assay Development for Immunogenicity Testing of Therapeutic Proteins	Chemistry, Manufacturing, and Controls Draft	Level 1	12/04/2009	New
Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims	Clinical Medical	Level 1	12/09/2009	New
Current Good Manufacturing Practice for Positron Emission Tomography Drugs	GCMP/Compliance	Level 1	12/10/2009	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 11 on Capillary Electrophoresis General Chapter	ICH Quality Draft	Level 1	12/17/2009	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 12 on Analytical Sieving General Chapter	ICH Quality Draft	Level 1	12/17/2009	New
Addendum to ICH S6; Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1)	ICH Safety Draft	Level 1	12/17/2009	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Confernce on Harmonisation Regions; Annex 8 on Sterility Test General Chapter	ICH Quality	Level 1	12/22/2009	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 5 on Disintegration Test General Chapter.	ICH Quality	Level 1	12/23/2009	New
Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions	Procedural	Level 2	12/29/2009	New