CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2003 –12/30/2003

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Q1D – Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products	ICH: Quality	Level 1	01/16/2003	New
Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers	Pharmacology/Toxicology Draft	Level 1	01/16/2003	New
Drug Product: Chemistry, Manufacturing, and Controls Information	Chemistry Draft	Level 1	01/28/2003	New
Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products	Clinical Medical Draft	Level 1	01/30/2003	New
Food-Effect Bioavailability and Fed Bioequivalence Studies	Biopharmaceutics	Level 1	01/31/2003	New
Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms – Recommendations for Clinical Evaluation	Clinical Medical Draft	Level 1	01/31/2003	Revised
M4 – The CTD – General Questions and Answers	ICH – Joint Safety/Efficacy (Multidisciplinary)	Level 2	02/03/2003	New
Nonclinical Safety Evaluation of Pediatric Drug Products	Pharmacology/Toxicology Draft	Level 1	02/03/2003	New
Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms – Prescribing Information for Health Care Providers and Patient Labeling	Labeling Draft	Level 1	02/03/2003	Revised
M4 – The CTD – Efficacy Questions and Answers	ICH – Joint Safety/Efficacy (Multidisciplinary)	Level 2	02/04/2003	New
M4 – The CTD – Safety Questions and Answers	ICH – Joint Safety/Efficacy (Multidisciplinary)	Level 2	02/04/2003	New
Prussian Blue for Treatment of Internal Contamination With Thallium or Radioactive Cesium	Clinical Medical	Level 1	02/04/2003	New
Part 11, Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records	Compliance Draft	Level 1	02/04/2003	Withdrawn
Q3A – Impurities in New Drug Substances	ICH: Quality	Level 1	02/11/2003	Revised
Comparability Protocols – Chemistry, Manufacturing, and Controls Information	Chemistry Draft	Level 1	02/25/2003	New
Part 11, Electronic Records, Electronic Signatures – Scope and Application	Compliance Draft	Level 1	02/25/2003	New
Integration of Dose-Counting Mechanisms into Metered - Dose Inhaler Drug Products	Clinical Medical	Level 1	03/13/2003	New
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations	Biopharmaceutics	Level 1	03/19/2003	Revised
Potassium Iodide Tablets Shelf Life Extension for Federal Agencies and State and Local Governments	Procedural Draft	Level 1	04/02/2003	New

M2 – Electronic Common Technical Document Specification (eCTD)	ICH: Joint Safety/Efficacy (Multidisciplinary)	Level 1	04/02/2003	New
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action	Biopharmaceutics Draft	Level 1	04/03/2003	2nd Draft
Current Good Manufacturing Practices for Medical Gases	Compliance Draft	Level 1	05/06/2003	Revised
Exposure-Response Relationships – Study Design, Data Analysis, and Regulatory Applications	Clinical Pharmacology	Level 1	05/06/2003	New
Photosafety Testing	Pharmacology/Toxicology	Level 1	05/07/2003	New
Developing Medical Imaging Drug and Biological Products	Clinical Medical Draft	Level 1	05/19/2003	2nd Draft
INDs for Phase 2 and 3 Studies; Chemistry, Manufacturing, and Controls Information	Chemistry	Level 1	05/20/2003	New
Pharmacokinetics in Patients With Impaired Hepatic Function; Study Design, Data Analysis, and Impact on Dosing and Labeling	Clinical Pharmacology	Level 1	05/30/2003	New
Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate – Labeling Enforcement Policy	Procedural	Level 1	06/03/2003	New
Continuous Marketing Applications: Pilot 1 –Reviewable Units for Fast Track Products Under the Prescription Drug User Fee Act	Procedural - Draft	Level 1	06/17/2003	New
Continuous Marketing Applications: Pilot 2 –Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act	Procedural - Draft	Level 1	06/17/2003	New
The Leveraging Handbook; an Agency Resource for Effective Collaborations – Guidance for FDA Staff	Procedural	Level 2	06/19/2003	New
Providing Regulatory Submissions in Electronic Format – Postmarketing Periodic Adverse Drug Experience Reports	Electronic Submissions Draft	Level 1	06/24/2003	New
Good Review Management Principles for Prescription Drug User Fee Act Products	Good Review Practices Draft	Level 1	07/28/2003	New
180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day	Generic Drug	Level 1	08/01/2003	New
Guideline for the Clinical Evaluation of Analgesic Drugs	Clinical Medical	Level 1	08/05/2003	Withdrawn
Providing Regulatory Submissions in Electronic Format—Annual Reports for New Drug Applications and Abbreviated New Drug Applications	Electronic Submissions Draft	Level 1	08/28/2003	New
Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions	Electronic Submissions Draft	Level 1	08/29/2003	New

Part 11, Electronic Records, Electronic Signatures – Scope and Application	Current Good Manufacturing Practices	Level 1	09/05/2003	New
Comparability Protocols – Protein Drug Products and Biological Products – Chemistry, Manufacturing, and Controls Information	Current Good Manufacturing Practices	Level 1	09/05/2003	New
Sterile Drug Products Produced by Aseptic Processing	Current Good Manufacturing Practices Draft	Level 1	09/05/2003	New
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practices	Current Good Manufacturing Practices Draft	Level 1	09/05/2003	New
Process Analytical Technology – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance	Current Good Manufacturing Practices Draft	Level 1	09/05/2003	New
Calcium DTPA and Zinc DTPA Drug Products – Submitting a New Drug Application	Clinical Medical	Level 1	09/15/2003	New
E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting	ICH Draft – Efficacy	Level 1	09/15/2003	New
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer	Clinical Medical	Level 1	09/15/2003	New
Continuous Marketing Applications: Pilot 1 –Reviewable Units for Fast Track Products Under the Prescription Drug User Fee Act	Procedural	Level 1	10/06/2003	New
Continuous Marketing Applications: Pilot 2 –Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act	Procedural	Level 1	10/06/2003	New
M4: Common Technical Document – Efficacy Questions and Answers	ICH – Multidisciplinary	Level 2	10/16/2003	New
M4: Common Technical Document – General Questions and Answers	ICH – Multidisciplinary	Level 2	10/16/2003	New
E2B(M): Data Elements for Transmission of Individual Case Safety Reports – Questions and Answers	ICH – Efficacy	Level 2	10/16/2003	New
Providing Regulatory Submissions in Electronic Format—General Considerations	Electronic Submissions Draft	Level 1	10/22/2003	New
Marketed Unapproved Drugs; Compliance Policy Guide	Compliance Draft	Level 1	10/23/2003	New
Pharmacogenomic Data Submissions	Procedural Draft	Level 1	11/04/2003	New
Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment	Current Good Manufacturing Practices Draft	Level 1	11/07/2003	New
Q3C – Final Recommendations on the Revision of the Permitted Daily Exposures for Two Solvents, N-Methylpyrrolidone and Tetrahydrofuran, According to the Maintenance Procedures	ICH – Quality	Level 1	11/13/2003	New
Q3B(R) – Impurities in New Drug Products	ICH – Quality	Level 1	11/14/2003	Revised
Q1A(R2) – Stability Data Package for Registration Applications in Climatic Zones III and IV;Stability Testing of New Drug Substances and Products	ICH - Quality	Level 1	11/21/2003	Revised

Q1F-Stability Data Package for Registration in Climatic Zones III and IV	ICH – Quality	Level 1	11/21/2003	New
Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing, Revision	Biopharmaceutics – Draft	Level 1	12/30/2003	New