

CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2014 – 3/31/2014

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/Withdrawal Date	Status
Qualification Process for Drug Development Tools	Procedural/Clinical Medical	Level 1	1/7/2014	New
Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease	Procedural/Clinical Medical Draft	Level 1	1/10/2014	New
Community-Acquired Pneumonia — Developing Antimicrobial Drugs for Treatment	Clinical/Anitmicrobial Draft	Level 1	1/10/2014	Revised
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics	Advertising Draft	Level 1	1/14/2014	New
Dear Health Care Provider Letters:Improving Communication of Important Safety Information	Procedural	Level 1	1/23/2014	New
Providing Submissions in Electronic Format -- Standardized Study Data	Electronic Submissions Draft	Level 1	2/6/2014	Revised
Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act	Electronic Submissions Draft	Level 1	2/6/2014	New
Analgesic Indications: Developing Drug and Biological Products	Clinical/Medical Draft	Level 1	2/6/2014	New
Providing Regulatory Submissions in Electronic Format-- Receipt Date	Electronic Submissions	Level 1	2/7/2014	New
Analytical Procedures and Methods Validation for Drugs and Biologics	Chemistry, Manufacturing and Controls (CMC) Draft	Level 1	2/19/2014	New
New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products	Procedural Draft	Level 1	2/24/2014	New
E2B(R3) Electronic Transmission of Individual Case Safety Reports Implementation Guide — Data Elements and Message Specification; and Appendix to the Implementation Guide — Backwards and Forwards Compatibility10	ICH Efficacy Draft	Level 1	2/24/2014	Revised
Antiviral Product Development - Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV-1 Resistance Data: Attachment to the Guidance	Clinical/Anitmicrobial Draft	Level 1	2/28/2014	New
Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices - Revised Guidance	Procedural Draft	Level 1	3/3/2014	Revised

CMC Postapproval Manufacturing Changes To Be Documented in Annual Reports	Chemistry, Manufacturing and Controls (CMC)	Level 1	3/5/2014	New
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment	Clincial/Medical Draft	Level 1	3/11/2014	New
Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products	Chemistry, Manufacturing and Controls (CMC) Draft	Level 1	3/14/2014	New
Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs — General Considerations	Biopharmaceutics Draft	Level 1	3/18/2014	New
Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway	Labeling Draft	Level 1	3/25/2014	New
Refusal to File	Procedural	Level 1	7/1/1993	Withdrawn