CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2007 – 12/31/2007

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
E15: Terminology in Pharmacogenomics	ICH Efficacy	Level 2	01/08/2007	New
User Fee Waivers for Fixed Dose Combination and Co-Packaged HIV Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief	User Fee	Level 1	02/08/2007	New
Developing Products for Weight Management	Clinical Medical Draft	Level 1	02/15/2007	New
Clinical Evaluation of Weight-Control Drugs	Clinical Medical Draft	Level 1	02/15/2007	Withdrawn
Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children	Clinical Medical	Level 1	03/06/2007	New
Drug Safety Information--Food and Drug Administration's Communication to the Public	Drug Safety	Level 1	03/07/2007	New
Indexing Structured Product Labeling	Electronic Submissions Draft	Level 1	03/19/2007	New
Target Product Profile--A Strategic Development Process Tool	Procedural Draft	Level 1	03/30/2007	New
Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products	Labeling Draft	Level 1	04/09/2007	New
Orally Disintegrating Tablets	Chemistry Draft	Level 1	04/09/2007	New

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Testing of Glycerin for Diethylene Glycol	Current Good Manufacturing Practices	Level 1	05/02/2007	New
Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics	Clinical Medical	Level 1	05/16/2007	New
Labeling for Human Presciption Drugs--Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information	Labeling Draft	Level 1	05/16/2007	New
Bioequivalence Recommendations for Specific Products	Generics Draft	Level 1	05/31/2007	New
Providing Regulatory Submissions in Electronic Format--Receipt Date	Electronic Submissions Draft	Level 1	06/05/2007	New
Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis	Clinical Medical Draft	Level 1	06/07/2007	New
Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document	Procedural Draft	Level 1	07/03/2007	New
ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing, and Controls Information	Generics	Level 1	07/09/2007	New
Q10 Pharmaceutical Quality System	ICH Quality Draft	Level 1	07/13/2007	New
Pharmacogenomic Data Submissions — Companion Guidance	Procedural Draft	Level 1	08/29/2007	New
Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application	Clinical Medical Draft	Level 1	10/15/2007	New

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Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval	Clinical Antimicrobial Draft	Level 1	10/15/2007	New
The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 - Good Manufacturing Practice (CGMP)	Current Good Manufacturing Practices Draft	Level 1	10/19/2007	New
Drug-Induced Liver Injury: Premarketing Clinical Evaluation	Drug Safety Draft	Level 1	10/25/2007	New
Acute Bacterial Sinusitis: Developing Drugs for Treatment	Clinical Antimicrobial Draft	Level 1	10/302007	New
Role of HIV Resistance Testing in Antiretroviral Drug Development	Clinical Antimicrobial	Level 1	10/31/2007	New
Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment	Clinical Medical Draft	Level 1	11/09/2007	New
Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention	Clinical Antimicrobial Draft	Level 1	11/23/2007	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 2 on Test for Extractable Volume of Parenteral Preparations General Chapter	ICH Quality Draft	Level 1	12/17/2007	New
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 3 on Test for Particulate Contamination: Subvisible Particles General Chapter	ICH Quality Draft	Level 1	12/17/2007	New