

**CDER GUIDANCES**  
**NEW/REVISED/WITHDRAWN**  
**1/1/2004 –6/15/2004**  
(Sorted by date)

<b>Title</b>	<b>Subject</b>	<b>Level at Date of Issue</b>	<b>Publication/Withdrawal Date</b>	<b>Status</b>
Drug Substance: Chemistry, Manufacturing, and Controls Information	Chemistry Draft	Level 1	1/7/2004	New
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer	Clinical Medical	Level 2	1/15/2004	Revised
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions	Procedural Draft	Level 1	1/27/2004	New
E2C Addendum – Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	ICH – Efficacy	Level 1	2/5/2004	New
Providing Regulatory Submissions in Electronic Format – Content of Labeling	Electronic Submissions Draft	Level 1	2/5/2004	New
“Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms	Advertising Draft	Level 1	2/10/2004	New
Time and Extent Applications	OTC Draft	Level 1	2/10/2004	New
Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements	Advertising Draft	Level 1	2/10/2004	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	2/17/2004	New
Labeling for Combined Oral Contraceptives	Labeling Draft	Level 1	3/5/2004	New

Potassium Iodide Tablets Shelf Life Extension for Federal Agencies and State and Local Governments	Procedural	Level 1	3/8/2004	New
Vaccinia Virus – Developing Drugs to Mitigate Complications From Smallpox Vaccination	Clinical Antimicrobial Draft	Level 1	3/9/2004	New
Q5E – Comparability of Biotechnology/Biological Products Subject to Changes in Their Manufacturing Process	ICH Draft – Quality	Level 2	3/30/2004	New
E2E – Pharmacovigilance Planning (PvP)	ICH Draft – Efficacy	Level 2	3/30/2004	New
Changes to an Approved NDA or ANDA	Chemistry	Level 1	4/8/2004	Revised
Exocrine Pancreatic Insufficiency Drug Products- Submitting New Drug Applications	Clinical Medical Draft	Level 1	4/28/2004	New
Combination Products Timeliness of Premarket Reviews	Clinical Medical Draft	Level 1	5/4/2004	New
Premarketing Risk Assessment	Clinical Medical Draft	Level 1	5/5/2004	New
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment	Clinical Medical Draft	Level 1	5/5/2004	New
Development and Use of Risk Minimization Action Plans	Clinical Medical Draft	Level 1	5/5/2004	New
E2B(M): Data Elements for Transmission of Individual Case Safety Reports, Questions and Answers	ICH - Efficacy	Level 2	5/5/2004	Revised
M4: The CTD – Efficacy Questions and Answers	ICH – Efficacy	Level 2	5/5/2004	Revised
M4: The CTD – General Questions and Answers	ICH - General	Level 2	5/5/2004	Revised
Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV	Procedural Draft	Level 1	5/19/2004	New

Handling and Retention of Bioavailability and Bioequivalence Testing Samples	Generic Drug	Level 1	5/26/2004	New
E5 – Ethnic Factors in the Acceptability of Foreign Clinical Data, Questions and Answers	ICH – Efficacy	Level 2	6/4/2004	New
Q1E – Evaluation of Stability Data	ICH – Quality	Level 1	6/8/2004	New
M4 – The CTD – Quality Questions and Answers/Location Issues	ICH – Joint Safety/Efficacy (Multidisciplinary)	Level 1	6/9/2004	New
Botanical Drug Products	Chemistry	Level 1	6/9/2004	New