# Center For Drug Evaluation and Research List of Guidance Documents

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| Classifying Significant Posmarketing Drug Safety Issues | 3/9/2012 |
| Drug Safety Information -- FDA's Communication to the Public | 3/9/2012 |
| Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications (I) | 10/1/2009 |
| Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report) | 4/8/2013 |
| Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors | 4/24/2013 |
| Safety Considerations for Product Design to Minimize Medication Errors | 12/13/2012 |
| Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act | 4/13/2011 |

| **Electronic Submissions** | **Issued Date** |
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|---|---|
| Indexing Structured Product Labeling (I) | 6/2/2008 |
| Providing Regulatory Submissions in Electronic Format -- Content of Labeling (I) | 4/21/2005 |
| Providing Regulatory Submissions in Electronic Format -Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (R2) | 6/1/2008 |
| Regulatory Submissions in Electronic Format; General Considerations (I) | 1/28/1999 |

| **Electronic Submissions Draft** | **Issued Date** |
|---|---|
| Compliance Policy on Reporting Drug Sample Distribution Information | 4/3/2012 |
| Providing Regulatory Submissions in Electronic Format--General Considerations (I) | 10/22/2003 |
| Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications | 1/3/2013 |
| Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports (I) | 5/4/2001 |
| Providing Regulatory Submissions in Electronic Format - Postmarketing Individual Case Safety Reports (I) | 6/12/2008 |
| Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising and Promotional Labeling (I) | 1/31/2001 |
| Providing Regulatory Submissions in Electronic Format--Receipt Date (I) | 6/5/2007 |
| Providing Submissions in Electronic Format -- Standardized Study Data | 2/21/2012 |

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| Providing Submissions in Electronic Format -- Summary Level Clinical Site Data for CDER | 12/19/2012 |
| Specifications for Preparing and Submitting Summary Level Clinical Site Data for CDER's Inspection Planning | 12/19/2012 |

| **Generic Drug** | **Issued Date** |
|---|---|
| 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day (I) | 8/1/2003 |
| Abbreviated New Drug Applications: Impurities in Drug Products | 11/29/2010 |
| Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs (I) | 12/12/2000 |
| ANDAs: Impurities in Drug Substances; Chemistry, Manufacturing and Controls Information (I) | 7/15/2009 |
| ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing and Controls Information (I) | 7/9/2007 |
| Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (I) | 3/30/2000 |
| Handling and Retention of Bioavailability and Bioequivalence Testing Samples (I) | 5/26/2004 |
| Individual Product Bioequivalence Recommendations - List of Product Bioequivalence Recommendations (I) | 6/11/2010 |
| Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past (I) | 8/18/1995 |
| Letter describing efforts by the CDER & the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new & abbreviated drug approval process in order to reduce duplication or redundancy in the process (I) | 10/14/1994 |

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| Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy (I) | 4/8/1994 |
| Letter on the provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters (I) | 7/1/1992 |
| Letter on the provision of new procedures and policies affecting the generic drug review process (I) | 3/15/1989 |
| Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions (I) | 11/8/1991 |
| Letter on the response to 12/20/84 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act (I) | 3/26/1985 |
| Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law (I) | 1/15/1993 |
| Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria, and bioequivalence requirements (I) | 8/4/1993 |
| Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications (I) | 12/21/2001 |
| Revising ANDA Labeling Following Revision of the RLD Labeling (I) | 4/25/2000 |
| Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications (I) | 5/6/2011 |
| Variations in Drug Products that May Be Included in a Single ANDA (I) | 1/27/1999 |

| **Generic Drug Draft** | **Issued Date** |
|---|---|
| Initial Completeness Assessments for Type II API DMFs Under GDUFA | 10/2/2012 |

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| Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505 (b)(2) Applications Under Hatch Waxman, as Amended by the Medicare Prescription Drug Improvement, and Modernization Act of 2003 - Questions and Answers (I) | 11/4/2004 |
| Generic Drug User Fee Amendments of 2012: Questions and Answers | 8/27/2012 |
| Self-Identification of Generic Drug Facilities, Sites, and Organizations | 8/27/2012 |
| ANDAs: Stability Testing of Drug Substances and Products | 9/24/2012 |

| **Good Review Practices** | **Issued Date** |
|---|---|
| Pharmacology/Toxicology Review Format (I) | 5/10/2001 |

| **ICH - Efficacy** | **Issued Date** |
|---|---|
| E1A - The Extent of Population Exposure to Assess Clinical Safety: for Drugs Intended for Long Term Treatment of Non-Life-Threatening Conditions (I) | 3/1/1995 |
| E2A - Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (I) | 3/1/1995 |
| E2B - Data Elements for Transmission of Individual Case Safety Reports (I) | 1/15/1998 |
| E2B(M) - Data Elements for Transmission of Individual Case Safety Reports (Revised) (I) | 4/3/2002 |
| E2B(M): Data Elements for Transmission of Individual Case Safety Reports -- Questions and Answers (Revision 2) (I) | 3/9/2005 |

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| E2C - Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (I) | 5/19/1997 |
| E2C Addendum - Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (I) | 2/5/2004 |
| E2E - Pharmacovigilance Planning (I) | 4/1/2005 |
| E2F Development Safety Update Report (I) | 8/22/2011 |
| E3 - Structure and Content of Clinical Study Reports (I) | 7/17/1996 |
| E3 Structure and Content of Clinical Study Reports - Questions and Answers (R1) | 1/25/2013 |
| E4 - Dose-Response Information to Support Drug Registration (I) | 11/9/1994 |
| E5 - Ethnic Factors in the Acceptability of Foreign Clinical Data (I) | 6/10/1998 |
| E6 - Good Clinical Practice: Consolidated Guideline (I) | 5/9/1997 |
| E7 - Studies in Support of Special Populations: Geriatrics (I) | 8/2/1994 |
| E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers | 2/21/2012 |
| E8 - General Considerations for Clinical Trials (I) | 12/24/1997 |
| E9 - Statistical Principles for Clinical Trials (I) | 9/16/1998 |
| E10 - Choice of Control Group and Related Issues in Clinical Trials (I) | 5/14/2001 |

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| E11 - Clinical Investigation of Medicinal Products in the Pediatric Population (I) | 12/15/2000 |
| E14 - Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non Antiarrhythmic Drugs (I) | 10/20/2005 |
| E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non Antiarrhythmic Drugs. Q&As (I) | 11/18/2008 |
| E15 - Pharmacogenomics Definitions and Sample Coding (I) | 4/8/2008 |
| E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions | 8/10/2011 |

| **ICH - Joint Safety/Efficacy (Multidisciplinary)** | **Issued Date** |
|---|---|
| Companion Document for M2: eCTD Specification Questions & Answers and Change Requests (I) | 8/1/2006 |
| M2 - Electronic Common Technical Document Specification (eCTD) (I) | 4/2/2003 |
| M3(R2) - Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (I) | 1/21/2010 |
| M3(R2)Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals: Questions and Answers (R1) | 2/25/2013 |
| M4 - Common Technical Document for the Registration of Pharmaceuticals for Human Use - Granularity Annex (I) | 10/17/2005 |
| M4 - Organization of the Common Technical Document (CTD) (I) | 10/16/2001 |
| M4 - The CTD -- Efficacy Questions and Answers (Revised) (I) | 12/22/2004 |

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| M4 - The CTD -- General Questions and Answers (Revised) (I) | 12/22/2004 |
| M4 - The CTD - Quality Questions and Answers/Location Issues (I) | 6/9/2004 |
| M4 - The CTD -- Safety Questions and Answers (I) | 2/4/2003 |

| **ICH - Quality** | **Issued Date** |
|---|---|
| ICH Q3C Maintenance Procedures for the Guidance for Industry Q3C Impurities: Residual Solvents - Final Recommendation for the Revision of the Permitted Daily Exposure for Cumene According to the Maintenance Procedures for Q3C Impurities: Residual Solvents | 2/23/2012 |
| Q1A(R2) - Stability Testing of New Drug Substances and Products (I) | 11/21/2003 |
| Q1B - Photostability Testing of New Drug Substances and Products (I) | 5/16/1997 |
| Q1C - Stability Testing for New Dosage Forms (I) | 5/9/1997 |
| Q1D - Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products (I) | 1/16/2003 |
| Q1E - Evaluation of Stability Data (I) | 6/8/2004 |
| Q2A - Text on Validation of Analytical Procedures (I) | 3/1/1995 |
| Q2B - Validation of Analytical Procedures: Methodology (I) | 5/9/1997 |
| Q3A(R) - Impurities in New Drug Substances (I) | 6/6/2008 |

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| Q3B(R) - Impurities in New Drug Products (I) | 7/31/2006 |
| Q3C - Impurities: Residual Solvents (I) | 12/24/1997 |
| Q3C Impurities: Residual Solvents: Maintenance Procedures for the Guidance for Industry Q3C (ICH Q3C Maintenance Procedures for the Guidance for Industry Q3C Impurities: Residual Solvent) | 2/11/2002 |
| Q3C Tables and List | 2/22/2012 |
| Q4B: Annex 1: Residue on Ignition/Sulphated Ash General Chapter (I) | 2/21/2008 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions - Annex 8: Sterility Test General Chapter (I) | 12/22/2009 |
| 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 (I) | 1/9/2009 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 3 on Test for Particulate Contamination: Subvisible Particles General Chapter (I) | 1/9/2009 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 4A: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter (I) | 4/8/2009 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 4B: Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms General Chapter (I) | 4/8/2009 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts; Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter(I) | 4/8/2009 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions- Annex 5: Disintegration Test General Chapter (I) | 12/23/2009 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions Annex 7(R2) Dissolution Test General Chapter | 6/23/2011 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions - Annex 8: Sterility Test General Chapter (I) | 12/22/2009 |

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| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions-Annex 9: Tablet Friability General Chapter (I) | 4/5/2010 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 10: Polyacrylamide Gel Electrophoresis General Chapter (I) | 4/12/2010 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 11: Capillary Electrophoresis General Chapter (I) | 9/3/2010 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 12 on Analytical Sieving General Chapter (I) | 9/2/2010 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions - Annex 13: Bulk Density and Tapped Density of Powders General Chapter (I) | 5/28/2013 |
| Q4B: Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions (I) | 2/21/2008 |
| Q5A - Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin (I) | 9/24/1998 |
| Q5B - Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products (I) | 2/23/1996 |
| Q5C - Quality of Biotechnological Products: Stability Testing of Biotechnology/Biological Products (I) | 7/10/1996 |
| Q5D - Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products (I) | 9/21/1998 |
| Q5E - Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process (I) | 6/30/2005 |
| Q6A - Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances (I) | 12/29/2000 |
| Q6B - Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (I) | 8/18/1999 |
| Q7A - Good Manufacturing Practice for Active Pharmaceutical Ingredients (I) | 9/25/2001 |

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| Q8 (R2) - Pharmaceutical Development (I) | 11/19/2009 |
| Q8, Q9, and Q10 Questions and Answers (I) | 11/1/2011 |
| ICH Q8, Q9, & Q10 Questions and Answers -- Appendix: Q&As from Training Sessions (Q8, Q9, & Q10 Points to Consider) | 7/25/2012 |
| Q9 - Quality Risk Management (I) | 6/2/2006 |
| Q10 Pharmaceutical Quality System (I) | 4/8/2009 |
| Q11 Development and Manufacture of Drug Substances | 11/20/2012 |

| **ICH - Safety** | **Issued Date** |
|---|---|
| S1A - The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals (I) | 3/1/1996 |
| S1B - Testing for Carcinogenicity in Pharmaceuticals (I) | 2/23/1998 |
| S1C(R2) - Dose Selection for Carcinogenicity Studies of Pharmaceuticals | 9/17/2008 |
| S2A - Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals (I) | 4/24/1996 |
| S2B - Genotoxicity: Standard Battery Testing (I) | 11/21/1997 |
| S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use | 6/7/2012 |

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| S3A - Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies (I) | 3/1/1995 |
| S3B - Pharmacokinetics: Repeated Dose Tissue Distribution Studies (I) | 3/1/1995 |
| S4A - Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) (I) | 6/25/1999 |
| S5A - Detection of Toxicity to Reproduction for Medicinal Products (I) | 9/22/1994 |
| S5B - Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility (I) | 4/5/1996 |
| S6(R1) Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals | 5/18/2012 |
| S7A - Safety Pharmacology Studies for Human Pharmaceuticals (I) | 7/13/2001 |
| S7B - Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (I) | 10/20/2005 |
| S8 - Immunotoxicity Studies for Human Pharmaceuticals (I) | 4/13/2006 |
| S9 Nonclinical Evaluation for Anticancer Pharmaceuticals (I) | 3/8/2010 |
| S10 Photosafety Evaluation of Pharmaceuticals | 2/4/2013 |

| **ICH Draft - Efficacy** | **Issued Date** |
|---|---|
| E12A Principles for Clinical Evaluation of New Antihypertensive Drugs (I) | 8/9/2000 |

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| 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 Compatibility | 10/19/2011 |
| Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report) | 4/8/2013 |
| E2D - Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting (I) | 9/15/2003 |

| **ICH Draft - Joint Safety/Efficacy (Multidisciplinary)** | **Issued Date** |
|---|---|
| M5 - Data Elements and Standards for Drug Dictionaries (I) | 9/1/2005 |
| Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (I) | 9/1/2001 |

| **ICH Draft - Quality** | **Issued Date** |
|---|---|
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions - Annex 6: Uniformity of Dosage Units General Chapter (I) | 2/17/2009 |
| Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions - Annex 14: Bacterial Endotoxins Test General Chapter (I) | 7/19/2010 |

| **INDs** | **Issued Date** |
|---|---|
| Content and Format of INDs for Phase 1 Studies of Drugs Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (I) | 10/4/2000 |

| Industry Letters | Issued Date |
|---|---|
| Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program (I) | 3/2/1998 |
| Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required (I) | 4/10/1987 |
| Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I (I) | 10/31/1986 |
| Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance (I) | 10/11/1984 |
| Implementation Plan USP injection nomenclature (I) | 10/2/1995 |
| Seventh of a series of letters about the Act providing guidance on the "180-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C (I) | 7/29/1988 |
| Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act (I) | 4/28/1988 |
| Supplement to 10/11/84 letter about policies, procedures and implementation of the Act (Q & A format) (I) | 11/16/1984 |
| Third of a series of letters regarding the implementation of the Act (I) | 5/1/1985 |
| Year 2000 Letter from Dr. Janet Woodcock (I) | 10/19/1998 |

| Labeling | Issued Date |
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|---|---|
| Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products; Content and Format (I) | 1/24/2006 |
| Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products; Content and Format (I) | 1/24/2006 |
| Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products (I) | 3/23/2010 |
| Content and Format for Geriatric Labeling (I) | 10/5/2001 |
| Contents of a Complete Submission for the Evaluation of Proprietary Names (I) | 2/8/2010 |
| Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims | 3/15/2011 |
| Labeling for Human Prescription Drug and Biological Products - Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information (I) | 10/19/2009 |
| Labeling for Human Prescription Drug and Biological Products - Implementing the PLR Content and Format Requirements | 2/25/2013 |
| Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Produts and Antimicrobial Susceptibility Testing Devices (I) | 7/2/2009 |
| Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products - Content and Format (I) | 10/11/2011 |

| **Labeling Draft** | **Issued Date** |
|---|---|
| Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (I) | 3/3/2009 |
| Labeling for Combined Oral Contraceptives (I) | 3/5/2004 |

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| Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms — Recommended Prescribing Information for Health Care Providers and Patient Labeling (I) | 11/16/2005 |
| Pediatric Information Incorporated Into Human Prescription Drug and Biological Products Labeling Good Review Practice | 2/28/2013 |
| Public Availability of Labeling Changes in "Changes Being Effected" Supplements (I) | 9/20/2006 |
| Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications (I) | 10/26/2000 |

| **Modernization Act** | **Issued Date** |
|---|---|
| Changes to an Approved NDA or ANDA | 4/2004 |
| Classifying Resubmissions in Response to Action Letters | 5/14/1998 |
| Fast Track Drug Development Programs - Designation, Development, and Application Review & Appendix 2 | 7/22/2004 |
| Formal Dispute Resolution: Appeals Above the Division Leve | 2/2000 |
| Formal Meetings With Sponsors and Applicants for PDUFA Products | 5/19/2009 |
| Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997-Advisory Committees | 10/1998 |
| Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements | 7/1998 |
| Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions | 3/2002 |

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| National Uniformity for Nonpresciption Drugs - Ingredient Listing for OTC Drugs | 4/1998 |
| Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products | 5/14/1998 |
| Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act | 9/1999 |
| Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act - 17 Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric "Rule," and Their Interaction | 7/27/1999 |
| Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act | 5/1/1998 |
| Reports on the Status of Postmarketing Study Commitments — Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 | 2/15/2006 |
| Standards for Prompt Review of Efficacy Supplements | 5/15/1998 |
| Submission of Abbreviated Reports and Synopses in Support of Marketing Applications | 8/1998 |
| Submitting and Reviewing Complete Responses to Clinical Holds | 10/2000 |

| **Modernization Act Draft** | **Issued Date** |
|---|---|
| Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions | 1/2004 |

| **OTC** | **Issued Date** |
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| Enforcement Policy on Marketing OTC Combination Products (CPG 71320.16) (I) | 5/1/1984 |
| General Guidelines for OTC Combination Products (I) | 11/28/1978 |
| Label Comprehension Studies for Nonprescription Drug Products (I) | 8/3/2010 |
| Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-The-Counter Human Use — Small Entity Compliance Guide | 12/6/2012 |
| Labeling for Bronchodilators: Cold, Cough, Allergy, Bronchodilator, And Antiasthmatic Drug Products for Over-the-Counter Human Use (Small Entity Compliance Guide) | 11/15/2012 |
| 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 | 9/1/2009 |
| Labeling OTC Human Drug Products -- Updating Labeling in ANDAs (I) | 2/22/2001 |
| Labeling Over-the-Counter Human Drug Products; Updating Labeling In Reference Listed Drugs and Abbreviated New Drug Applications (I) | 10/18/2002 |
| Labeling OTC Human Drug Products Using a Column Format (I) | 12/19/2000 |
| Labeling OTC Human Drug Products; Small Entity Compliance Guide (I) | 5/13/2009 |
| Labeling Over-the-Counter Human Drug Products; Questions and Answers | 1/5/2009 |
| Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use -Small Entity Compliance Guide (I) | 8/17/2010 |
| Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application (I) | 7/14/2009 |
| Self-Selection Studies for Nonprescription Drug Products | 4/11/2013 |

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| Time and Extent Applications (I) | 9/28/2011 |
| Topical Acne Drug Products for Over-the-Counter Human Use--Revision of Labeling and Classification of Benzoyl Peroxide as Safe and Effective; Small Entity Compliance Guide | 6/22/2011 |
| Upgrading Category III Antiperspirants to Category I (43 FR 46728 - 46731) (I) | 10/10/1978 |

| **OTC Draft** | **Issued Date** |
|---|---|
| Labeling OTC Human Drug Products - Submitting Requests for Exemptions and Deferrals (I) | 12/19/2000 |
| Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use — Labeling for Products That Contain Acetaminophen | 7/5/2012 |

| **Pharmacology/Toxicology** | **Issued Date** |
|---|---|
| Carcinogenicity Study Protocol Submissions (I) | 5/23/2002 |
| Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers (I) | 7/22/2005 |
| Exploratory IND Studies (I) | 1/17/2006 |
| Format and Content of the Nonclinical Pharmacology/ Toxicology Section of an Application (I) | 2/1/1987 |
| Immunotoxicology Evaluation of Investigational New Drugs (I) | 11/1/2002 |

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| Nonclinical Pharmacology/Toxicology Department of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or the Development of Drugs Intended to Act as Vaginal Contraceptives (I) | 10/16/1996 |
| Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals | 11/25/2011 |
| Nonclinical Safety Evaluation of Drug or Biologic Combinations (I) | 3/15/2006 |
| Nonclinical Safety Evaluation of Pediatric Drug Products (I) | 2/15/2006 |
| Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients | 5/19/2005 |
| Photosafety Testing (I) | 5/7/2003 |
| Recommended Approaches to Integration of Genetic Toxicology Study Results (I) | 1/4/2006 |
| Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies (I) | 2/1/1989 |
| Reproductive and Developmental Toxicities -- Integrating Study Results to Assess Concerns | 9/22/2011 |
| Safety Testing of Drug Metabolites (I) | 2/15/2008 |
| Single Dose Acute Toxicity Testing for Pharmaceuticals - Revised (I) | 8/26/1996 |

| **Pharmacology/Toxicology Draft** | **Issued Date** |
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| Centralized IRB Review Proceedings in Multicenter Clinical Trials | 3/16/2006 |
| Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act | 6/8/2011 |
| Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act | 3/27/2000 |
| Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000 (I) | 11/30/1999 |
| Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate - Labeling Enforcement Policy (I) | 6/3/2003 |
| Emergency Use Authorization of Medical Products: Availability | 7/26/2007 |
| End-of-Phase 2A Meetings (I) | 9/21/2009 |
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| FDA Oversight of PET Drug Products -- Questions and Answers | 12/4/2012 |
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| Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (I) | 3/18/2002 |
| Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document (I) | 4/21/2009 |
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| Pharmacogenomic Data Submissions (I) | 3/23/2005 |
| Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products | 3/15/2011 |
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| Certification Process of Designated Medical Gases | 12/18/2012 |
| Charging for Investigational Drugs Under an IND — Qs & As | 5/9/2013 |
| Dear Healthcare Provider Letters: Improving Communication of Important Safety Information | 11/12/2010 |
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| Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees | 2/14/2002 |
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| Safety Reporting Requirements for INDs and BA/BE Studies- Small Entity Compliance Guide | 12/20/2012 |
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| Applicability of User Fees to (1) Applications Withdrawn Before Filing, or (2) Applications the Agency Has Refused to File and That Are Resubmitted or Filed Over Protest (Attachment F) | 7/12/1993 |
| Application, Product, and Establishment Fees: Common Issues and Their Resolution (Revised) (Attachment D) (I) | 12/16/1994 |
| Classifying Resubmissions in Response to Action Letters (I) | 5/14/1998 |
| Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act (I) | 8/25/1999 |
| Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act (I) | 11/21/2001 |
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| User Fee Waivers, Reductions, and Refunds for Drug and Biological Products | 9/26/2011 |