Center for Drug Evaluation and Research List of Guidance Documents

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Office of Training and Communications
Division of Drug Information
10903 New Hampshire Avenue
Silver Spring, MD 20993

Telephone: 301-796-3400
Fax: 301-847-8714
Internet (I): http://www.fda.gov/cder/guidance/index.htm
E-mail: druginfo@fda.hhs.gov

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Providing Regulatory Submissions in Electronic Format -Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (R3)	7/25/2014
Providing Submissions in Electronic Format – Postmarket Non-Expedited ICSRs Technical Questions and Answers	7/24/2013
Providing Regulatory Submissions in Electronic Format-- Receipt Date	2/7/2014

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
Electronic Submission of Lot Distribution Reports (CBER)	August-14
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 Submissions in Electronic Format — Postmarketing Safety Reports	6/10/2014
Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising and Promotional Labeling (I)	1/31/2001
Providing Submissions in Electronic Format -- Standardized Study Data	2/6/2014
Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act	2/6/2014
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
ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers	5/15/2014
ANDA Submissions – Amendments and Easily	7/10/2014
ANDA Submissions – Prior Approval Supplements Under GDUFA	7/10/2014
ANDA Submissions -- Refuse-to-Receive Standards	9/16/2014
Controlled Correspondence Related to Generic Drug Development	8/26/2014
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
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
Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules	12/10/2013

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**
Abbreviated New Drug Application Submissions; Content and Format of Abbreviated New Drug Applications	6/12/2014
ANDA Submissions — Refuse to Receive for Lack of Proper Justification of Impurity Limits	9/16/2014
ANDAs: Stability Testing of Drug Substances and Products	9/24/2012
Initial Completeness Assessments for Type II API DMFs Under GDUFA	10/2/2012
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 (Revision 1)	9/10/2013
Self-Identification of Generic Drug Facilities, Sites, and Organizations	8/27/2012

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
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	2/24/2014
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
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
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
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
International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 6 on Uniformity of Dosage Units General Chapter	6/16/2014
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
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 ICH Regions - Annex 14: Bacterial Endotoxins Test General Chapter	10/23/2013
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
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
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
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**
Q3D Elemental Impurities	10/23/2013

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**
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 Labeling for Human Prescription Drug and Biological Products — Considerations, Content and Format (R1)	8/13/2014
Labeling for Combined Oral Contraceptives (I)	3/5/2004
Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway	3/25/2014
Naming of Drug Products Containing Salt Drug Substances	12/26/2013
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
Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products — Content and Format	9/18/2013
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
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**
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
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
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**
Animal Models--Essential Elements to Address Efficacy Under the Animal Rule (I)	1/21/2009
Endocrine Disruption Potential of Drugs: Nonclinical Evaluation	9/20/2013
Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches (I)	12/16/2008
Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route (I)	3/7/2008

Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals (I)	5/8/2001

Procedural	**Issued Date**
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (I)	7/14/1998
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
Dear Health Care Provider Letters:Improving Communication of Important Safety Information	1/23/2014
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
Electronic Source Data in Clinical Investigations	9/18/2013
Emergency Use Authorization of Medical Products: Availability	7/26/2007
End-of-Phase 2A Meetings (I)	9/21/2009
Expedited Programs for Serious Conditions-- Drugs and Biologics	5/30/2014

Fast Track Drug Development Programs: Designation, Development, and Application Review (I)	11/18/1998
FDA Export Certificate (I)	7/12/2004
FDA Oversight of PET Drug Products -- Questions and Answers	12/4/2012
Fixed Dose Combinations and Co-Packaged Drug Products for Treatment of HIV (I)	10/18/2006
Formal Dispute Resolution: Appeals Above the Division Level	3/13/2013
Formal Meetings Between the FDA and Sponsors or Applicants (I)	5/14/2009
Good Review Management Principles for PDUFA Products (I)	3/31/2005
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Safety Reporting Requirements for INDs and BA/BE Studies- Small Entity Compliance Guide	12/20/2012
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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
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