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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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
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
Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	10/26/2005
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**
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

Good Review Practices	**Issued Date**
Good Review Management Principles for Prescription Drug User Fee Act Products (I)	3/31/2005
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
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
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

E5 - Ethnic Factors in the Acceptability of Foreign Clinical Data, Questions and Answers (I)	9/27/2006
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	2/17/2012
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 - Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals (I)	11/25/1997
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	2/17/2012
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**
Final Recommendation for the Revision of the Permitted Daily Exposure for Cumene According to the Maintenance Procedures for Q3C Impurities: Residual Solvents	2/22/2012

Q10 Pharmaceutical Quality System (I)	4/8/2009
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 - Tables and Lists (Revised) Recommendations for Methylpyrrolidone and Tetrahydrofuran (I)	11/13/2003
Q3C Tables and List	2/22/2012
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 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 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; 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: Annex 1: Residue on Ignition/Sulphated Ash General Chapter (I)	2/21/2008
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
Q9 - Quality Risk Management (I)	6/2/2006

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 - Dose Selection for Carcinogenicity Studies of Pharmaceuticals (I)	3/1/1995
S1C(R2) - Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes (I)	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
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 - Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (I)	11/18/1997
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

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

E2B(R) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (I)	10/3/2005
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	10/19/2011
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)	
Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (I)	

ICH Draft - Quality	**Issued Date**
ICH Q3C Maintenance Procedures for the Guidance for Industry Q3C Impurities: Residual Solvents - Draft Recommendation for the Revision of the Permitted Daily Exposure for Cumene (I)	7/20/2010
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)	7/14/2010
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions - Annex 14: Bacterial Endotoxins Test General Chapter (I)	7/19/2010
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 9: Tablet Friability General Chapter (I)	8/14/2009

Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 10: Polyacrylamide Gel Electrophoresis General Chapter (I)	8/14/2009
Q11 Development and Manufacture of Drug Substances	6/28/2011

ICH Draft - Safety	**Issued Date**
Addendum to ICH S6; Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals S6(R1) (I)	12/17/2009
S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use	3/26/2008
S9 Nonclinical Evaluation for Anticancer Pharmaceuticals (I)	2/17/2009

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**
A Revision in Sample Collection Under the Compliance Program Pertaining to Pre-Approval Inspections	7/15/1996
Certification Requirements for Debarred Individuals in Drug Applications	6/1/1990

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
Instructions for Filing Supplements Under the Provisions of SUPAC-IR	4/11/1996
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
Streamlining Initiatives	12/24/1996
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
Barbiturate, Single Entity-Class Labeling	3/1/1981
Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products; Content and Format (I)	1/24/2006
Content and Format for Geriatric Labeling (I)	10/5/2001
Hypoglycemic Oral Agents - Federal Register	4/1/1984
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 Over-the-Counter Human Drug Products; Updating Labeling In Reference Listed Drugs and Abbreviated New Drug Applications (I)	10/18/2002
Local Anesthetics - Class Labeling	9/1/1982
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

Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products (I)	4/9/2007
Contents of a Complete Submission for the Evaluation of Proprietary Names (I)	11/24/2008
Labeling for Combined Oral Contraceptives (I)	3/5/2004
Labeling for Human Prescripstion Drug and Biological Products - Implementing the New Content and Format Requirements (I)	1/24/2006
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
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
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

Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act	5/1998

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 OTC Human Drug Products -- Updating Labeling in ANDAs (I)	2/22/2001
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
Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (I)	9/1/2009
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	6/21/2011
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
OTC Actual Use Studies	7/22/1994
OTC Nicotine Substitutes	3/1/1994
Self-Selection Studies for Nonprescription Drug Products	9/16/2011

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
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
Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions (I)	12/29/2009
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
End-of-Phase 2A Meetings (I)	9/21/2009
Fast Track Drug Development Programs: Designation, Development, and Application Review (I)	11/18/1998

FDA Export Certificate (I)	7/12/2004
Financial Disclosure by Clinical Investigators (I)	3/28/2001
Fixed Dose Combinations and Co-Packaged Drug Products for Treatment of HIV (I)	10/18/2006
Formal Dispute Resolution: Appeals Above the Division Level (I)	3/7/2000
Formal Meetings Between the FDA and Sponsors or Applicants (I)	5/14/2009
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997- Elimination of Certain Labeling Requirements (I)	11/2/1998
Implementation of Section 126 of the FDA Modernization Act of 1997 - Elimination of Certain Labeling Requirements, (I)	7/21/1998
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
Levothyroxine Sodium Products - Enforcement of August 14, 2001, Compliance Date and Submission of New Applications (I)	7/13/2001
Medication Guides - Adding a Toll-Free Number for Reporting Adverse Events (I)	6/8/2009
National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs (I)	4/9/1998
PET Drug Applications — Content and Format for NDAs and ANDAs; Fludeoxyglucose F 18 Injection; Ammonia N 13 Injection; Sodium Fluoride F 18 Injection	8/31/2011
PET Drug Applications - Content and Format for NDAs and ANDAs: Attachment I: Sample formats for chemistry, manufacturing, and controls (CMC) sections_2011	8/31/2011

Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products	3/15/2011
Potassium Iodide (KI) in Radiation Emergencies - Questions and Answers (I)	12/23/2002
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (I)	12/10/2001
Potassium Iodide Tablets Shelf Life Extension for Federal Agencies and State and Local Governments (I)	3/8/2004
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act - Revised (I)	10/1/1999
Refusal to File (I)	7/12/1993
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act (I)	6/15/1998
Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (I)	2/16/2006
Special Protocol Assessment (I)	5/17/2002
Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements (I)	5/15/1998
Submitting and Reviewing Complete Responses to Clinical Holds (Revised) (I)	10/26/2000
The Leveraging Handbook; an Agency Resource for Effective Collaborations - Guidance for FDA Staff (I)	6/19/2003
Useful Written Consumer Medication Information (CMI) (I)	7/18/2006
Women and Minorities Guidance Requirements	7/20/1998

Procedural Draft	Issued Date
Applications Covered by Section 505(b)(2) (I)	12/8/1999
Centralized IRB Review Proceedings in Multicenter Clinical Trials	3/23/2005
Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees (I)	11/15/2001
Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products (I)	3/10/2000
Dear Healthcare Provider Letters: Improving Communication of Important Safety Information	11/12/2010
Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning January 1, 2000 (I)	12/22/1999
Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees	2/14/2002
Emergency Use Authroization of Medical Products: Availability (I)	7/5/2005
End-of-Phase 2A Meetings (I)	9/26/2008
Enforcement Policy -- OTC Sunscreen Drug Products Marketed Without an Approved Application	6/14/2011
FDA Oversight of PET Drug Products -- Questions and Answers	2/24/2012
Financial Disclosure by Clinical Investigators: Guidance for Clinical Investigators, Industry, and FDA Staff	5/24/2011

Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (I)	5/15/2001
Good Review Management Principles for PDUFA Products (I)	7/28/2003
How to Comply with the Pediatric Research Equity Act (I)	9/7/2005
Independent Consultants for Biotechnology Clinical Trial Protocols (I)	5/7/2003
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (I)	1/27/2004
Integrated Summary of Effectiveness (I)	8/28/2008
Notification to FDA of Issues that May Result in a Prescription Drug or Biological Product Shortage	2/21/2012
Oversight of Clinical Investigations — A Risk-Based Approach to Monitoring	8/29/2011
Pharmacogenomic Data Submissions (I)	11/4/2003
Pharmacogenomic Data Submissions -Companion Guidance (I)	8/29/2007
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic (I)	1/7/2011
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (I)	3/12/2001
Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices	12/27/2011
Submission of Patent Information for Certain Old Antibiotics (I)	12/3/2008

Submitting Debarment Certification Statements (I)	10/2/1998
Target Product Profile--A Strategic Development Process Tool (I)	3/30/2007
The Use of Clinical Holds Following Clinical Investigator Misconduct (I)	8/27/2002
Tropical Disease Priority Review Vouchers (I)	10/20/2008
Use of Histology in Biomarker Qualification Studies	12/29/2011

Small Entity Compliance Guides	**Issued Date**
Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (I)	11/7/2001

User Fee	**Issued Date**
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
Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (I)	1/3/2005
User Fee Waivers for Fixed Dose Combination Products and Co-Packaged Human Immunodeficiency Virus Drugs for the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief (I)	2/8/2007
User Fee Waivers, Reductions, and Refunds for Drug and Biological Products	9/26/2011

User Fee Draft	**Issued Date**
Attachment G --Draft Interim Guidance Document for Waivers of and Reductions in User Fees (I)	7/16/1993