
Center For Drug Evaluation and Research

List of Guidance Documents

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Table of Contents (by Subject Category)

| | |
|--------------------------------|---------|
| Advertising | Page 3 |
| Advertising Draft | Page 3 |
| Biopharmaceutics | Page 3 |
| Biopharmaceutics Draft | Page 4 |
| Chemistry | Page 4 |
| Chemistry Draft | Page 6 |
| Clinical Antimicrobial | Page 7 |
| Clinical Antimicrobial Draft | Page 7 |
| Clinical Medical | Page 9 |
| Clinical Medical Draft | Page 11 |
| Clinical Pharmacology | Page 13 |
| Clinical Pharmacology Draft | Page 14 |
| Compliance | Page 14 |
| Compliance Draft | Page 15 |
| Electronic Submissions | Page 15 |
| Electronic Submissions Draft | Page 15 |
| Generic Drug | Page 16 |
| Generic Drug Draft | Page 17 |
| Good Review Practices | Page 17 |
| Good Review Practices Draft | Page 17 |
| ICH | Page 17 |
| ICH Draft | Page 20 |
| Industry Letters | Page 21 |
| Labeling | Page 22 |
| Labeling Draft | Page 24 |
| OTC | Page 24 |
| OTC Draft | Page 24 |
| Pharmacology/Toxicology | Page 25 |
| Pharmacology/Toxicology Draft | Page 25 |
| Procedural | Page 25 |
| Procedural Draft | Page 27 |
| Small Entity Compliance Guides | Page 27 |
| User Fees | Page 27 |
| User Fees Draft | Page 28 |

Advertising

Issued Date

Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling (I)

1/12/1998

Consumer-Directed Broadcast Advertisements (I)

8/9/1999

Industry-Supported Scientific and Educational Activities (I)

12/3/1997

Advertising Draft

Issued Date

Accelerated Approval Products -- Submission of Promotional Materials (I)

3/26/1999

Product Name, Placement, Size, and Prominence in Advertising and Promotional Labeling (I)

3/12/1999

Promoting Medical Products in a Changing Healthcare Environment; Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs) (I)

1/5/1998

Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements (I)

4/23/2001

Biopharmaceutics

Issued Date

Bioanalytical Method Validation (I)

5/23/2001

Cholestyramine Powder In Vitro Bioequivalence (I)

7/15/1993

Clozapine (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing (I)

11/15/1996

Corticosteroids, Dermatologic (topical) In Vivo (I)

6/2/1995

Dissolution Testing of Immediate Release Solid Oral Dosage Forms (I)

8/25/1997

Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (I)

9/26/1997

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro (I) | 6/27/1989 |
| Phenytoin/Phenyton Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing (I) | 3/4/1994 |
| Statistical Approaches to Establishing Bioequivalence (I) | 2/2/2001 |
| Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System (I) | 8/31/2000 |

Biopharmaceutics Draft

Issued Date

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Antifungal (topical) | 2/24/1990 |
| Antifungal (vaginal) | 2/24/1990 |
| Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (I) | 6/2/1999 |
| Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (I) | 7/11/2002 |
| Conjugated Estrogens, USP: LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence (I) | 3/9/2000 |
| Food-Effect Bioavailability and Food Bioequivalence Studies; Study Design, Data Analysis, and Labeling (I) | 11/28/2001 |
| In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Studies (I) | 12/30/1997 |

Chemistry

Issued Date

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| BACPAC I: Intermediates in Drug Substance Synthesis: Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation (I) | 2/16/2001 |
| Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products (I) | 7/24/1997 |
| Changes to an Approved NDA or ANDA (I) | 11/23/1999 |

| | |
|--------------------------------------------------------------------------------------------------------------------------------------|------------|
| Changes to an Approved NDA or ANDA: Questions and Answers (I) | 1/22/2001 |
| Container Closure Systems for Packaging Human Drugs and Biologics (I) | 7/7/1999 |
| Development of New Stereoisomeric Drugs (I) | 5/1/1992 |
| Drug Master Files (I) | 9/1/1989 |
| Drug Master Files for Bulk Antibiotic Drug Substances (I) | 11/29/1999 |
| Environmental Assessment of Human Drug and Biologics Applications (I) | 7/27/1998 |
| Format and Content for the CMC Section of an Annual Report (I) | 9/1/1994 |
| Format and Content of the Chemistry, Manufacturing and Controls Section of an Application* (I) | 2/1/1987 |
| Format and Content of the Microbiology Section of an Application* (I) | 2/1/1987 |
| IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information (I) | 5/25/2001 |
| Monoclonal Antibodies Used as Reagents in Drug Manufacturing (I) | 3/29/2001 |
| Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products -- Chemistry, Manufacturing, and Controls Documentation (I) | 7/5/2002 |
| NDA: Impurities in Drug Substances (I) | 2/25/2000 |
| PAC-ALTS: Postapproval Changes - Analytical Testing Laboratory Sites (I) | 4/28/1998 |
| Reviewer Guidance: Validation of Chromatographic Methods (I) | 11/1/1994 |
| Submission Documentation for Sterilization Process Validation Applications for Human and Veterinary Drug Products (I) | 11/1/1994 |

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptide Substances (I) | 11/1/1994 |
| Submitting Documentation for the Manufacturing of and Controls for Drug Products* (I) | 2/1/1987 |
| Submitting Documentation for the Stability of Human Drugs and Biologics* (I) | 2/1/1987 |
| Submitting Samples and Analytical Data for Methods Validation* (I) | 2/1/1987 |
| Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Products (I) | 2/1/1987 |
| Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances* (I) | 2/1/1987 |
| SUPAC IR- Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (I) | 11/30/1995 |
| SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum (I) | 2/26/1999 |
| SUPAC-IR Questions and Answers (I) | 2/18/1997 |
| SUPAC-MR: Modified Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (I) | 10/6/1997 |
| SUPAC-SS - Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation (I) | 6/13/1997 |
| The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform (I) | 12/20/2000 |

Chemistry Draft

Issued Date

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation (I) | 8/30/2000 |
| Botanical Drug Products (I) | 8/11/2000 |
| INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format (I) | 4/20/1999 |

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation (I) | 8/21/2002 |
| Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation (I) | 11/19/1998 |
| Stability Testing of Drug Substances and Drug Products (I) | 6/8/1998 |
| Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications* | 11/1/1991 |
| SUPAC-SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum (I) | 1/5/1999 |
| Tracking of NDA and ANDA Reformulations for Solid, Oral, Immediate Release Drug Products | |

Clinical Antimicrobial

Issued Date

| | |
|-----------------------------------------------------------------------|------------|
| Clinical Development and Labeling of Anti-Infective Drug Products (I) | 10/26/1992 |
| Clinical Evaluation of Anti-Infective Drugs (Systemic) (I) | 9/1/1977 |
| Preclinical Development of Antiviral Drugs (I) | 11/1/1990 |

Clinical Antimicrobial Draft

Issued Date

| | |
|------------------------------------------------------------------------------------------------------|-----------|
| Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Acute or Chronic Bacterial Prostatitis; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Acute Otitis Media; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |

| | |
|--------------------------------------------------------------------------------------------------------------------------------|------------|
| Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Catheter-Related Bloodstream Infections - Developing Antimicrobial Drugs for Treatment (I) | 10/18/1999 |
| Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements (I) | 9/1/1999 |
| Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Complicated Urinary Tract Infections and Pylonephritis; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Developing Antimicrobial Drugs -General Considerations for Clinical Trials (I) | 7/22/1998 |
| Developing Drugs to Treat Inhalational Anthrax (Post-Exposure) (I) | 3/18/2002 |
| Empiric Therapy of Febrile Neutropenia; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products (I) | 2/17/1997 |
| Lyme Disease; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Nosocomial Pneumonia; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Secondary Bacterial Infections of Acute Bronchitis; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Streptococcal Pharyngitis and Tonsillitis; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Uncomplicated and Complicated Skin and Skin Structure Infections; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Uncomplicated Gonorrhea -- Cervical, Urethral, Rectal, and/or Pharyngeal; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |
| Uncomplicated Urinary Tract Infections; Developing Antimicrobial Drugs for Treatment (I) | 7/22/1998 |

Vuvlovaginal Candidiasis; Developing Antimicrobial Drugs for Treatment (I)

7/22/1998

Clinical Medical

Issued Date

Acceptance of Foreign Clinical Studies (I)

3/13/2001

Cancer Drug and Biological Products - Clinical Data in Marketing Applications (I)

10/5/2001

Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (I)

2/17/1999

Clinical Development Programs for MDI and DPI Drug Products (I)

9/19/1994

Clinical Evaluation of Analgesic Drugs (I)

12/1/1992

Clinical Evaluation of Antacid Drugs (I)

4/1/1978

Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children) (I)

4/1/1988

Clinical Evaluation of Antianxiety Drugs (I)

9/1/1977

Clinical Evaluation of Antidepressant Drugs (I)

9/1/1977

Clinical Evaluation of Antidiarrheal Drugs (I)

9/1/1977

Clinical Evaluation of Antiepileptic Drugs (adults and children) (I)

1/1/1981

Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women (I)

3/20/1995

Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs (I)

9/1/1977

Clinical Evaluation of General Anesthetics (I)

5/1/1982

| | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Clinical Evaluation of Hypnotic Drugs (I) | 9/1/1977 |
| Clinical Evaluation of Laxative Drugs (I) | 4/1/1978 |
| Clinical Evaluation of Local Anesthetics (I) | 5/1/1982 |
| Clinical Evaluation of Psychoactive Drugs in Infants and Children (I) | 7/1/1979 |
| Clinical Evaluation of Radiopharmaceutical Drugs (I) | 10/1/1981 |
| Content and Format for Pediatric Use Supplements (I) | 5/24/1996 |
| Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (I) | 11/20/1995 |
| FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products (I) | 2/2/1999 |
| FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer (I) | 1/29/1991 |
| FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer (I) | 6/20/1989 |
| Format and Content of the Clinical and Statistical Sections of an Application* (I) | 7/1/1988 |
| Format and Content of the Summary for New Drug and Antibiotic Applications* (I) | 2/1/1987 |
| Formatting, Assembling and Submitting New Drug and Antibiotic Applications* (I) | 2/1/1987 |
| General Considerations for the Clinical Evaluation of Drugs (I) | 12/1/1978 |
| General Considerations for the Clinical Evaluation of Drugs in Infants and Children (I) | 9/1/1977 |
| Guidance for the Development of Vaginal Contraceptive Drugs (NDA) (I) | 4/19/1995 |

| | |
|------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Levothyroxine Sodium Tablets -- In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing (I) | 3/8/2001 |
| Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Colon and Rectal Cancer (I) | 4/19/1988 |
| Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer (I) | 4/13/1988 |
| Postmarketing Adverse Experience Reporting for Human Drugs and Licensed Biological Products; Clarification of What to Report (I) | 8/27/1997 |
| Postmarketing Reporting of Adverse Drug Experiences (I) | 3/1/1992 |
| Preclinical Development of Immunomodulatory Drugs for the Treatment of HIV Infection and Associated Disorders (I) | 9/4/1992 |
| Preparation of Investigational New Drug Products (Human and Animal) (I) | 11/1/1992 |
| Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (I) | 5/15/1998 |
| Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (I) | 7/22/1993 |
| Study of Drugs Likely to be Used in the Elderly (I) | 11/1/1989 |
| Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (I) | 9/13/1999 |

Clinical Medical Draft

Issued Date

| | |
|---------------------------------------------------------------------------------|-----------|
| Abuse Liability Assessment | 7/1/1990 |
| Allergic Rhinitis: Clinical Development Programs for Drug Products (I) | 6/21/2000 |
| Available Therapy | 2/7/2002 |
| Chronic Cutaneous Ulcer and Burn Wounds - Developing Products for Treatment (I) | 6/28/2000 |

| | |
|---------------------------------------------------------------------------------------------------------------------------------|------------|
| Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA) (I) | 7/15/1999 |
| Clinical Evaluation of Anti-Anginal Drugs | 1/1/1989 |
| Clinical Evaluation of Anti-Arrhythmic Drugs | |
| Clinical Evaluation of Anti-Arrhythmic Drugs | 7/1/1985 |
| Clinical Evaluation of Antihypertensive Drugs | 5/1/1988 |
| Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure | 12/1/1987 |
| Clinical Evaluation of Drugs for Ulcerative Colitis (3rd draft) | |
| Clinical Evaluation of Lipid-Altering Agents in Adults and Children (I) | 9/1/1990 |
| Clinical Evaluation of Motility-Modifying Drugs | |
| Clinical Evaluation of Weight-Control Drugs (I) | 9/24/1996 |
| Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees (I) | 11/20/2001 |
| Developing Medical Imaging Drugs and Biologics - Revised (I) | 7/31/2000 |
| Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders | 2/12/1992 |
| Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis (I) | 6/14/2000 |
| Establishing Pregnancy Registries (I) | 6/4/1999 |
| Evaluation of Human Pregnancy Outcome Data (I) | 6/4/1999 |

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children (I) | 11/6/2001 |
| Exercise-Induced Bronchospasm (EIB) - Development of Drugs to Prevent EIB (I) | 2/20/2002 |
| Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment (I) | 5/19/2000 |
| Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (I) | 3/30/2000 |
| IND Exemptions for Studies of Lawfully Marketed Cancer Drug or Biological Products (I) | 4/9/2002 |
| Inhalation Drug Products Packaged in Semipermeable Container Closure Systems (I) | 7/26/2002 |
| Integration of Dose-Counting Mechanisms Into Metered-Dose Inhaler Drug Products (I) | 12/11/2001 |
| OTC Treatment of Herpes Labialis with Antiviral Agents (I) | 3/8/2000 |
| Pediatric Oncology Studies in Response to a Written Request (I) | 6/21/2000 |
| Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis (I) | 4/1/1994 |
| Preparation of IND Applications for New Drugs Intended for the Treatment of HIV-Infected Individuals | 9/1/1991 |
| Recommendations for Complying with the Pediatric Rule (I) | 12/4/2000 |

Clinical Pharmacology

Issued Date

| | |
|----------------------------------------------------------------------------------------------------------------------------|------------|
| Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (I) | 4/7/1997 |
| Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application (I) | 2/1/1987 |
| In Vivo Metabolism/Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling (I) | 11/24/1999 |

Pharmacokinetics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling (I) 5/15/1998

Population Pharmacokinetics (I) 2/10/1999

Clinical Pharmacology Draft

Issued Date

Exposure-Response Relationships: Study Design, Data Analysis, and Regulatory Applications (I) 4/2/2002

General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products (I) 11/30/1998

Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling (I) 12/7/1999

Compliance

Issued Date

A Review of FDA's Implementation of the Drug Export Amendments of 1986 (I)

Compressed Medical Gases (I) 12/1/1989

Computerized Systems Used in Clinical Trials (I) 5/10/1999

Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (I) 6/27/1997

General Principles of Process Validation (I) 5/1/1987

Good Laboratory Practice Regulations Questions and Answers (I)

Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities (I) 4/6/2001

Guideline for Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices (I) 12/1/1987

Monitoring of Clinical Investigations (I) 1/1/1988

| | |
|--------------------------------------------------------------------------------------------------|-----------|
| Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment (I) | 5/1/1984 |
| Possible Dioxin/PCB Contamination of Drug and Biological Products (I) | 8/23/1999 |
| Sterile Drug Products Produced by Aseptic Processing (I) | 5/1/1987 |
| Street Drug Alternatives (I) | 4/3/2000 |

Compliance Draft

Issued Date

| | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------|
| Good Manufacturing Practice for Positron Emission Tomography Drug Products (I) | 4/1/2002 |
| Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (I) | 5/12/2000 |
| Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production (I) | 9/30/1998 |
| Manufacture, Processing or Holding of Active Pharmaceutical Ingredients (I) | 4/17/1998 |
| Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics (I) | 6/27/2002 |
| Repackaging of Solid Oral Dosage Form Drug Products | 2/1/1992 |

Electronic Submissions

Issued Date

| | |
|-------------------------------------------------------------------------|-----------|
| Providing Electronic Submissions in Electronic Format - ANDAs (I) | 6/27/2002 |
| Regulatory Submissions in Electronic Format; General Considerations (I) | 1/28/1999 |
| Regulatory Submissions in Electronic Format; New Drug Applications (I) | 1/28/1999 |

Electronic Submissions Draft

Issued Date

| | |
|---------------------------------------------------------------|------------|
| Providing Regulatory Submissions in Electronic Format - ANDAs | 11/16/2001 |
|---------------------------------------------------------------|------------|

Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports (I) 5/4/2001

Providing Regulatory Submissions in Electronic Format, Prescription Drug Advertising and Promotional Labeling (I) 1/31/2001

Generic Drug

Issued Date

Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs (I) 12/12/2000

ANDAs: Impurities in Drug Substances (I) 12/3/1999

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

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

Major, Minor, Facsimile, and Telephone Amendments to Original Abbreviated New Drug Applications (Revised) (I) 5/1/2000

Organization of an ANDA (I) 3/2/1999

Revising ANDA Labeling Following Revision of the RLD Labeling (I) 4/25/2000

Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products (I) 2/3/2000

Variations in Drug Products that May Be Included in a Single ANDA (I) 1/27/1999

Generic Drug Draft

Issued Date

ANDAs: Impurities in Drug Products (I) 1/5/1999

Content and Format of an Abbreviated New Drug Application (ANDA) - Positron Emission Tomography (PET) Drug Products - With specific information for ANDAs for Fludeoxyglucose F18 Injection (I) 4/18/1997

Handling and Retention of Bioavailability and Bioequivalence Testing Samples (I) 8/21/2002

Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing (I) 8/7/2002

Good Review Practices

Issued Date

Pharmacology/Toxicology Review Format (I) 5/10/2001

Good Review Practices Draft

Issued Date

Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review (I) 11/22/1996

ICH - Efficacy

Issued Date

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

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| 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 |
| E2BM - Data Elements for Transmission of Individual Case Safety Reports (I) | 4/3/2002 |
| E2C - Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (I) | 5/19/1997 |
| 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 |
| E6 - Good Clinical Practice: Consolidated Guideline (I) | 5/9/1997 |
| E7 - Studies in Support of Special Populations: Geriatrics (I) | 8/2/1994 |
| E8 - General Considerations for Clinical Trials (I) | 12/24/1997 |
| E9 - Statistical Principles for Clinical Trials (I) | 9/16/1998 |

ICH - Joint Safety/Efficacy (Multidisciplinary)

Issued Date

| | |
|--------------------------------------------------------------------------------------------------|------------|
| M3 - Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals (I) | 11/25/1997 |
| M4 - Common Technical Document (I) | 10/16/2001 |

ICH - Quality

Issued Date

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Q1A(R) - Stability Testing of New Drug Substances and Products (I) | 11/7/2001 |
| Q1B - Photostability Testing of New Drug Substances and Products (I) | 5/16/1997 |
| Q1C - Stability Testing for New Dosage Forms (I) | 5/9/1997 |
| Q2A - Text on Validation of Analytical Procedures (I) | 3/1/1995 |
| Q3C - Impurities: Residual Solvents (I) | 12/24/1997 |
| 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 |
| 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 |

ICH - Safety

Issued Date

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|------------------------------------------------------------------------------------|-----------|
| 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 |

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| S1C - Dose Selection for Carcinogenicity Studies of Pharmaceuticals (I) | 3/1/1995 |
| S1C(R) - Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes (I) | 12/4/1997 |
| 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 |

ICH Draft - Efficacy

Issued Date

| | |
|-----------------------------------------------------------------------------|----------|
| E12A - Principles for Clinical Evaluation of New Antihypertensive Drugs (I) | 8/9/2000 |
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ICH Draft - Joint Safety/Efficacy (Multidisciplinary)

Issued Date

| | |
|-------------------------------------------------------------------|-----------|
| M2 - Electronic Common Technical Document Specification (I) | 6/14/2002 |
| M2 Electronic Common Technical Document Speciafication (eCTD) (I) | |

ICH Draft - Quality

Issued Date

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|---------------------------------------------------------------------------------------------------|-----------|
| Q1D - Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products | 9/25/2001 |
| Q1E - Evaluation of Stability Data (I) | 6/14/2002 |
| Q1F - Stability Data Package for Registration in Climatic Zones III and IV (I) | 6/14/2002 |
| Q3A(R) - Impurities in New Drug Substances (I) | 7/20/2000 |
| Q3B(R) - Impurities in New Drug Products (I) | 7/19/2000 |

ICH Draft - Safety

Issued Date

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| S7B - Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (I) | 6/14/2002 |
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Industry Letters

Issued Date

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| 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 |

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| 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

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|------------------------------------------------------------------|-----------|
| Barbiturate, Single Entity-Class Labeling | 3/1/1981 |
| Chlordiazepoxide Hydrochloride Capsules | 1/1/1988 |
| Clorazepate Dipotassium Capsules/Tablets | 3/1/1993 |
| Combination Oral Contraceptives - Physician and Patient Labeling | 1/1/1994 |
| Content and Format for Geriatric Labeling (I) | 10/5/2001 |
| Cyproheptadine Hydrochloride Tablets/Syrup | 12/1/1986 |
| Dipivefrin Hydrochloride Ophthalmic Solution, 0.1% | 11/2/1998 |
| Ergoloid Mesylates Tablets | 1/1/1988 |
| Hydroxyzine Hydrochloride Injection | 12/1/1989 |

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| Hypoglycemic Oral Agents - Federal Register | 4/1/1984 |
| Informal Labeling Guidance Texts for Estrogen Drug Products - Patient Labeling | 8/1/1992 |
| Informal Labeling Guidance Texts for Estrogen Drug Products - Professional Labeling | 8/1/1992 |
| Isoetharine Inhalation Solution | 3/1/1989 |
| Local Anesthetics - Class Labeling | 9/1/1982 |
| Meclofenamate Sodium Capsules | 7/1/1992 |
| Naphazoline Hydrochloride Ophthalmic Solution | 3/1/1989 |
| Niacin Tablets | 7/1/1992 |
| Phendimetrazine Tartrate Capsules/Tablets, and Extended-Release Capsules | 2/1/1991 |
| Phentermine Hydrochloride Capsules/Tablets | 8/1/1988 |
| Promethazine Hydrochloride Tablets | 3/1/1990 |
| Propantheline Bromide Tablets | 8/1/1988 |
| Pyridoxine Hydrochloride Injection | 6/1/1984 |
| Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets | 2/1/1992 |
| Thiamine Hydrochloride Injection | 2/1/1988 |
| Vitamin A Capsules | 2/1/1992 |

Labeling Draft

Issued Date

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| Clinical Studies Section of Labeling for Prescription Drugs and Biologics; Content and Format (I) | 7/9/2001 |
| Combined Oral Contraceptives - Labeling for Healthcare Providers and Patients (I) | 7/10/2000 |
| Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics (I) | 6/21/2000 |
| Non-Contraceptive Estrogen Drug Products -- Prescribing Information for Healthcare Providers and Patient Labeling (I) | 9/27/1999 |
| OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis) (I) | 7/16/1998 |
| Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications (I) | 10/26/2000 |
| Therapeutic Equivalence Code Placement on Prescription Drug Labels and Labeling | 1/28/1999 |

OTC

Issued Date

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|------------------------------------------------------------------------------|------------|
| Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16) (I) | |
| General Guidelines for OTC Combination Products (I) | |
| Labeling OTC Human Drug Products Using a Column Format (I) | 12/19/2000 |
| Upgrading Category III Antiperspirants to Category I (43 FR 46728-46731) (I) | |

OTC Draft

Issued Date

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|-----------------------------------------------------------------------------------------|------------|
| Labeling OTC Human Drug Products - Submitting Requests for Exemptions and Deferrals (I) | 12/19/2000 |
| Labeling Over-the-Counter Human Drug Products; Updating Labeling In ANDA's (I) | 2/22/2001 |
| OTC Actual Use Studies | 7/22/1994 |

OTC Nicotine Substitutes

3/1/1994

Pharmacology/ Toxicology

Issued Date

Carcinogenicity Study Protocol Submissions (I)

5/23/2002

Content and Format of INDs for Phase 1 Studies of Drugs Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (I)

10/4/2000

Format and Content of the Nonclinical Pharmacology/ Toxicology Section of an Application* (I)

2/1/1987

Nonclinical Pharmacology/ Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or for the Development of Drugs Intended to Act as Vaginal Contraceptives (I)

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

Single Dose Acute Toxicity Testing Toxicity Testing for Pharmaceuticals (I)

8/26/1996

Pharmacology/ Toxicology Draft

Issued Date

Immunotoxicology Evaluation of Investigational New Drugs (I)

5/11/2001

Integration of Study Results to Assess Concerns About Human Reproductive and Developmental Toxicities

11/13/2001

Photosafety Testing (I)

1/10/2000

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

Court Decisions, AND 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

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| Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act (I) | 11/23/1998 |
| Fast Track Drug Development Programs: Designation, Development, and Application Review (I) | 11/18/1998 |
| Formal Dispute Resolution: Appeals Above the Division Level (I) | 3/7/2000 |
| Formal Meetings With Sponsors and Applicants For PDUFA Products (I) | 3/7/2000 |
| 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 | 3/18/2002 |
| Levothyroxine Sodium Products - Enforcement of August 14, 2001, Compliance Date and Submission of New Applications (I) | 7/13/2001 |
| National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs (I) | 4/9/1998 |
| Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (I) | 12/11/2001 |
| 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 |
| Special Protocol Assessment (I) | 5/17/2002 |
| Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements (I) | 5/15/1998 |
| Women and Minorities Guidance Requirements | 7/20/1998 |

Procedural Draft

Issued Date

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Applications Covered by Section 505(b)(2) (I) | 12/8/1999 |
| Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products (I) | 3/10/2000 |
| 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 |
| Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (I) | 5/15/2001 |
| Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank (I) | 3/29/2000 |
| Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (I) | 3/12/2001 |
| Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (I) | 4/4/2001 |
| Submitting Debarment Certification Statements (I) | 10/2/1998 |
| Submitting Marketing Applications According to the ICH/CTD Format; General Considerations (I) | 9/5/2001 |

Small Entity Compliance Guides

Issued Date

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| Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (I) | 11/7/2001 |
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User Fee

Issued Date

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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 |

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| 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 and Reviewing Complete Responses to Clinical Holds (Revised) (I) | 10/26/2000 |

User Fee Draft

Issued Date

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| Document for Waivers of and Reductions in User Fees (Attachment G) | 7/16/1993 |
| Submitting Separate Marketing Applications and Definitions of Clinical Data for Purposes of Assessing User Fees (I) | 2/22/2001 |