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# Center For Drug Evaluation and Research

## List of Guidance Documents

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## Table of Contents (by Subject Category)

Advertising .....	Page 3
Biopharmaceutics .....	Page 3
Chemistry .....	Page 4
Clinical Antimicrobial .....	Page 7
Clinical Medical .....	Page 10
Clinical Pharmacology .....	Page 15
CMC - Microbiology .....	Page 16
Combination Products (Drug/Device/Biologic) .....	Page 16
Current Good Manufacturing Practices/Compliance .....	Page 16
Drug Safety .....	Page 19
Electronic Submissions .....	Page 19
Generic Drug .....	Page 20
Good Review Practices .....	Page 22
ICH .....	Page 22
IND .....	Page 29
Industry Letters .....	Page 29
Labeling .....	Page 30
OTC .....	Page 31
Pharmacology/Toxicology .....	Page 32
Procedural .....	Page 33
Small Entity Compliance Guides .....	Page 37
User Fee .....	Page 37

## **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**

"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (I)

2/10/2004

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

3/26/1999

Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements(I)

2/10/2004

Presenting Risk Information in Prescription Drug and Medical Device Promotion (I)

5/27/2009

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

## **Biopharmaceutics**

## **Issued Date**

Bioanalytical Method Validation (I)

5/23/2001

Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (Revised) (I)

3/19/2003

Cholestyramine Powder In Vitro Bioequivalence (I)

7/15/1993

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

6/20/2005

Corticosteroids, Dermatologic (topical) In Vivo (I)	6/2/1995
Dissolution Testing of Immediate Release Solid Oral Dosage Forms (I)	8/25/1997
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
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (I)	9/26/1997
Food-Effect Bioavailability and Fed Bioequivalence Studies (I)	1/31/2003
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro (I)	6/27/1989
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) (I)	2/24/1990
Antifungal (vaginal)	2/24/1990
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (I)	4/3/2003

## **Chemistry**

## **Issued Date**

Botanical Drug Products (I)	6/9/2004
Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products (I)	7/24/1997

Changes to an Approved NDA or ANDA (Revised) (I)	4/8/2004
Changes to an Approved NDA or ANDA: Questions and Answers (I)	1/22/2001
Changes to an Approved New Drug Application or Abbreviated New Drug Application; Specifications - Use of Enforcement Discretion for Compendial Changes (I)	11/22/2004
Container Closure Systems for Packaging Human Drugs and Biologics (I)	7/7/1999
Demonstration of Comparability of Human Biological Products Including Therapeutic Biotechnology Derived Products (I)	3/26/1996
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
Filing Protocol - Residual Solvents	11/25/2009
Format and Content for the CMC Section of an Annual Report (I)	9/1/1994
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
INDs for Phase 2 and 3 Studies; Chemistry, Manufacturing, and Controls Information (I)	5/20/2003
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
Orally Disintegrating Tablets (I)	12/16/2008
PAC-ALTS: Postapproval Changes - Analytical Testing Laboratory Sites (I)	4/28/1998
Submitting Documentation for the Manufacturing of and Controls for Drug Products* (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 Questions and Answers (I)	2/18/1997
SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum (I)	2/26/1999
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
Validation of Chromatographic Methods -- Reviewer's Guidance (I)	11/1/1994

## **Chemistry Draft**

## **Issued Date**

Analytical Procedures and Methods Validation (I)	8/30/2000
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Assay Development for Immunogenicity Testing of Therapeutic Proteins (I)	12/4/2009
CMC Postapproval Manufacturing Changes Reportable in Annual Reports (I)	6/25/2010
Comparability Protocols - Chemistry, Manufacturing, and Controls Information (I)	2/25/2003
Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals (I)	9/12/2002
Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting (I)	7/14/2009
Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations (I)	7/26/1999
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 (I)	11/19/1998
Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications*	11/1/1991
SUPAC-SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum (I)	1/5/1999

## **Clinical Antimicrobial**

## **Issued Date**

Antiretroviral Drugs Using Plasma Human Immunodeficiency Virus Ribonucleic Acid Measurements - Clinical Considerations for Accelerated and Traditional Approval (I)	11/1/2002
Antiviral Product Development - Conducting and Submitting Virology Studies to the Agency	6/5/2006
Clinical Development and Labeling of Anti-Infective Drug Products (I)	10/26/1992
Clinical Evaluation of Anti-Infective Drugs (Systemic) (I)	9/1/1977
Role of HIV Drug Resistance Testing in Antiretroviral Drug Development (I)	10/31/2007

## **Clinical Antimicrobial Draft**

## **Issued Date**

Acute Bacterial Exacerbation of Chronic Bronchitis in Patients with COPD; Developing Antimicrobial Drugs for Treatment (I)	8/22/2008
Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Acute Bacterial Otitis Media: Developing Drugs for Treatment (I)	1/18/2008
Acute Bacterial Sinusitis: Developing Drugs for Treatment (I)	10/30/2007
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
Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval (I)	10/15/2007
Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Catheter-Related Bloodstream Infections - Developing Antimicrobial Drugs for Treatment (I)	10/18/1999
Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment (I)	3/20/2009
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 Antimicrobial 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
Helicobacter pylori-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment (I)	10/5/2009
Influenza: Developing Drugs for Treatment and/or Prophylaxis (I)	2/20/2009
Lyme Disease; Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Microbiological Data for Systemic Antibacterial Drug Products - Development, Analysis, and Presentation (I)	9/17/2009
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
Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention (I)	11/23/2007
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 -- Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Uncomplicated Urinary Tract Infections - Developing Antimicrobial Drugs for Treatment (I)	7/22/1998
Vaccinia Virus -- Developing Drugs to Mitigate Complications From Smallpox Vaccination (I)	3/9/2004
Vulvovaginal Candidiasis - Developing Antimicrobial Drugs for Treatment (I)	7/22/1998

## **Clinical Medical**

## **Issued Date**

Acceptance of Foreign Clinical Studies (I)	3/13/2001
Antianxiety Drugs -- Clinical Evaluation (I)	9/1/1977
Antidepressant Drugs -- Clinical Evaluation (I)	9/1/1977
Antiepileptic Drugs (adults and children) -- Clinical Evaluation (I)	1/1/1981
Available Therapy (I)	7/23/2004
Calcium DTPA and Zinc DTPA Drug Products -- Submitting a New Drug Application (I)	8/13/2004
Cancer Drug and Biological Products - Clinical Data in Marketing Applications (I)	10/5/2001
Chronic Cutaneous Ulcer and Burn Wounds - Developing Products for Treatment (I)	6/2/2006
Clinical and Statistical Sections of an Application -- Format and Content* (I)	7/1/1988
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (I)	2/17/1999
Clinical Endpoints for the Approval of Cancer Drugs and Biologics (I)	5/16/2007
Collection of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products (I)	9/19/2005
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
Developing Medical Imaging Drug and Biological Products, Part 1: Conducting Safety Assessments (I)	6/22/2004
Developing Medical Imaging Drug and Biological Products, Part 2: Clinical Indications (I)	6/22/2004

Developing Medical Imaging Drug and Biological Products, Part 3: Design, Analysis, and Interpretation of Clinical Studies (I)	6/22/2004
Development and Use of Risk Minimization Action Plans (I)	3/29/2005
Development of Vaginal Contraceptive Drugs (NDA) (I)	4/19/1995
Diabetes Mellitus -- Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes (I)	12/19/2008
Establishing Pregnancy Exposure Registries (I)	9/23/2002
Evaluating the Risks of Drug Exposure in Human Pregnancies	4/28/2005
Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children (I)	3/6/2007
Exocrine Pancreatic Insufficiency Drug Products-Submitting New Drug Applications (I)	4/14/2006
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
Formatting, Assembling and Submitting New Drug and Antibiotic Applications* (I)	2/1/1987
General Anesthetics -- Clinical Evaluation (I)	5/1/1982
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
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (I)	3/29/2005
Hypnotic Drugs -- Clinical Evaluation (I)	9/1/1977

IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (Revised) (I)	1/15/2004
Integration of Dose-Counting Mechanisms Into Metered-Dose Inhaler Drug Products (I)	3/13/2003
Internal Radioactive Contamination - Development of Decorporation Agents (I)	3/2/2006
Levothyroxine Sodium Tablets -- In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing (I)	3/8/2001
Local Anesthetics -- Clinical Evaluation (I)	5/1/1982
Lupus Nephritis Caused By Systemic Lupus Erythematosus — Developing Medical Products for Treatment (I)	6/22/2010
MDI and DPI Drug Products -- Clinical Development and Programs (I)	9/19/1994
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
Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims (I)	12/9/2009
Pediatric Use Supplements -- Content and Format (I)	5/24/1996
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
Premarketing Risk Assessment (I)	3/29/2005
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

Prussian Blue for Treatment of Internal Contamination With Thallium or Radioactive Cesium (I)	2/4/2003
Psychoactive Drugs in Infants and Children -- Clinical Evaluation (I)	7/1/1979
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
Summary for New Drug and Antibiotic Applications -- Format and Content* (I)	2/1/1987
Systemic Lupus Erythematosus - Developing Drugs for Treatment (I)	6/22/2010

### **Clinical Medical Draft**

### **Issued Date**

Acne Vulgaris: Developing Drugs for Treatment (I)	9/19/2005
Allergic Rhinitis: Clinical Development Programs for Drug Products (I)	6/21/2000
Anti-Anginal Drugs -- Clinical Evaluation (I)	1/1/1989
Anti-Arrhythmic Drugs -- Clinical Evaluation	7/1/1985
Antihypertensive Drugs -- Clinical Evaluation	5/1/1988
Assessment of Abuse Potential of Drugs (I)	1/27/2010
Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment (I)	11/9/2007
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA) (I)	7/15/1999

Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure (I)	12/1/1987
Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees (I)	11/20/2001
Combination Products Timeliness of Premarket Reviews (I)	5/4/2004
Computerized Systems Used in Clinical Trials (I)	10/4/2004
Developing Products for Weight Management Revision 1 (I)	2/15/2007
Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis (I)	6/14/2000
Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention (I)	3/3/2008
Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals	9/12/2002
Estrogen and Estrogen/ Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms - Recommendations for Clinical Evaluation (I)	1/31/2003
Exercise-Induced Bronchospasm (EIB) - Development of Drugs to Prevent EIB (I)	2/20/2002
Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention (I)	6/28/2005
Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (I)	3/30/2000
Inhalation Drug Products Packaged in Semipermeable Container Closure Systems (I)	7/26/2002
Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis (I)	6/7/2007
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

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
Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment (I)	11/22/2006
The Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application (I)	6/3/2009
The Use of Clinical Holds Following Clinical Investigator Misconduct (I)	9/2/2004

## **Clinical Pharmacology**

## **Issued Date**

Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (I)	4/7/1997
Exposure-Response Relationships - Study Design, Data Analysis, and Regulatory Applications (I)	5/6/2003
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
Pharmacogenomic Data Submissions	3/23/2005
Pharmacokinetics in Patients With Impaired Hepatic Function; Study Design, Data Analysis, and Impact on Dosing and Labeling (I)	5/30/2003
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**

Clinical Lactation Studies - Study Design, Data Analysis and Recommendations for Labeling	2/8/2005
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Drug Interaction Studies--Study Design, Data Analysis, and Implications for Dosing and Labeling (I) 9/12/2006

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

Pharmacokinetics in Pregnancy - Study Design, Data Analysis, and Impact on Dosing and Labeling (I) 11/1/2004

### **CMC Microbiology**

### **Issued Date**

Submission Documentation for Sterilization Process Validation Applications for Human and Veterinary Drug Products (I) 11/1/1994

### **CMC Microbiology Draft**

### **Issued Date**

Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes (I) 8/5/2008

### **Combination Products (Drug/Device/Biologic)**

### **Issued Date**

Application User Fees for Combination Products 4/21/2005

### **Combination Products (Drug/Device/Biologic) Draft**

### **Issued Date**

Combination Products Timeliness of Premarket Reviews; Dispute Resolution (I) 5/4/2004

Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies (I) 3/27/2008

### **Current Good Manufacturing Practices/Compliance**

### **Issued Date**

A Review of FDA's Implementation of the Drug Export Amendments of 1986 (I) 5/1/1990

Bar Code Label Requirements - Questions and Answers (Revised) (I) 10/5/2006

Compressed Medical Gases (I) 12/1/1989

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



Current Good Manufacturing Practice for Phase 1 Investigational Drugs (I)	7/15/2008
Current Good Manufacturing Practice for Positron Emission Tomography Drug Products (I)	12/10/2009
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (I)	6/27/1997
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practices (I)	1/12/2006
General Principles of Process Validation (I)	5/1/1987
Good Laboratory Practice Regulations -- Questions and Answers (I)	6/1/1981
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
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production (I)	10/12/2006
Marketed Unapproved Drugs; Compliance Policy Guide (I)	6/9/2006
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
Part 11, Electronic Records, Electronic Signatures - Scope and Application	9/5/2003
Pharmaceutical Components at Risk for Melamine Contamination (I)	8/7/2009
Pharmacy Compounding -- Compliance Policy Guide (I)	6/7/2002
Possible Dioxin/PCB Contamination of Drug and Biological Products (I)	8/23/1999

Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics (I)	3/14/2006
Process Analytical Technology -- A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance (I)	10/4/2004
Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations (I)	10/2/2006
Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations (I)	10/2/2006
Sterile Drug Products Produced by Aseptic Processing (I)	10/4/2004
Street Drug Alternatives (I)	4/3/2000
Testing of Glycerin for Diethylene Glycol (I)	5/2/2007
The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 - Good Manufacturing Practice (CGMP) (I)	1/27/2010

### **Current Good Manufacturing Practices/Compliance Draft**

### **Issued Date**

Comparability Protocols -- Protein Drug Products and Biological Products -- Chemistry, Manufacturing, and Controls Information (I)	9/5/2003
Current Good Manufacturing Practices for Combination Products (I)	10/4/2004
Current Good Manufacturing Practices for Medical Gases (3rd Revision) (I)	5/6/2003
Dosage Delivery Devices for OTC Liquid Drug Products (I)	11/5/2009
Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide	5/31/2005
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

Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting, Availability (I)	7/14/2009
Manufacturing, Processing or Holding of Active Pharmaceutical Ingredients (I)	4/17/1998
Powder Blends and Finished Dosage Units--Stratified In-Process Dosage Unit Sampling and Assessment (I)	11/7/2003
Process Validation: General Principles and Practices (I)	11/18/2008
Repackaging of Solid Oral Dosage Form Drug Products	2/1/1992

## **Drug Safety**

## **Issued Date**

Drug Safety Information--Food and Drug Administration's Communication to the Public (I)	3/7/2007
Drug-Induced Liver Injury: Premarketing Clinical Evaluation (I)	7/30/2009

## **Drug Safety Draft**

## **Issued Date**

Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications (I)	10/1/2009
Postmarketing Studies and Clinical Trials — Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act (I)	7/15/2009

## **Electronic Submissions**

## **Issued Date**

Indexing Structured Product Labeling (I)	6/2/2008
Providing Electronic Submissions in Electronic Format - ANDAs (I)	6/27/2002
Providing Regulatory Submissions in Electronic Format -- Content of Labeling (I)	4/21/2005
Providing Regulatory Submissions in Electronic Format -- Human Pharmaceutical Product Applications and Related Submissions (I)	10/19/2005
Regulatory Submissions in Electronic Format; General Considerations (I)	1/28/1999

Regulatory Submissions in Electronic Format; NDAs (I)	1/28/1999
SPL Standard for Content of Labeling Technical Qs & As (I)	10/28/2009

## **Electronic Submissions Draft**

## **Issued Date**

Providing Regulatory Submissions in Electronic Format -- Annual Reports for New Drug Applications and Abbreviated New Drug Applications (I)	8/28/2003
Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports (I)	5/4/2001
Providing Regulatory Submissions in Electronic Format - Postmarketing Individual Case Safety Reports (I)	6/12/2008
Providing Regulatory Submissions in Electronic Format -- Postmarketing Periodic Adverse Drug Experience Reports (I)	6/24/2003
Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising and Promotional Labeling (I)	1/31/2001
Providing Regulatory Submissions in Electronic Format--General Considerations (I)	10/22/2003
Providing Regulatory Submissions in Electronic Format--Receipt Date (I)	6/5/2007

## **Generic Drug**

## **Issued Date**

180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day (I)	8/1/2003
Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs (I)	12/12/2000
ANDAs: Impurities in Drug Substances; Chemistry, Manufacturing and Controls Information (I)	7/15/2009
ANDAs: Pharmaceutical Solid Polymorphism; Chemistry, Manufacturing and Controls Information (I)	7/9/2007
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (I)	3/30/2000

Handling and Retention of Bioavailability and Bioequivalence Testing Samples (I)	5/26/2004
Individual Product Bioequivalence Recommendations - List of Product Bioequivalence Recommendations (I)	6/11/2010
Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past (I)	8/18/1995
Letter describing efforts by the CDER & the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new & abbreviated drug approval process in order to reduce duplication or redundancy in the process (I)	10/14/1994
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
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)

8/29/2005

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

Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications (I)

4/17/2009

## **Good Review Practices**

## **Issued Date**

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

2/18/2005

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**

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

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
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
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**

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
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**

Q10 - Pharmaceutical Quality System	7/8/2008
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
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; 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)	5/5/2010
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
E16 Genomic Biomarkers Related to Drug Response: Context, Structure, and Format of Qualification Submissions (I)	7/30/2009
E2B(R) - Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (I)	10/3/2005
E2D - Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting (I)	9/15/2003
E2F Development Safety Update Report (I)	8/5/2008

E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers (I) 11/10/2009

### **ICH Draft - Joint Safety/Efficacy (Multidisciplinary)**

### **Issued Date**

M5 - Data Elements and Standards for Drug Dictionaries (I) 9/6/2005

Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (I) 9/5/2001

### **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 7: Dissolution Test 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

Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 11: Capillary Electrophoresis General Chapter (I) 12/17/2009

Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 12 on Analytical Sieving General Chapter (I) 12/17/2009

### **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 (I) 3/26/2008

**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
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 Products and Antimicrobial Susceptibility Testing Devices (I)	7/2/2009

## **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

Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims (I)	3/13/2008
Labeling for Combined Oral Contraceptives (I)	3/5/2004
Labeling for Human Prescription Drug and Biological Products - Implementing the New Content and Format Requirements (I)	1/24/2006
Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis) (I)	7/16/1998
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
Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products - Content and Format (I)	1/24/2006

<b><u>OTC</u></b>	<b><u>Issued Date</u></b>
Enforcement Policy on Marketing OTC Combination Products (CPG 71320.16) (I)	5/1/1984
General Guidelines for OTC Combination Products (I)	11/28/1978
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
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
Upgrading Category III Antiperspirants to Category I (43 FR 46728 - 46731) (I)	10/10/1978

## **OTC Draft**

## **Issued Date**

Label Comprehension Studies for Nonprescription Drug Products (I)	5/1/2009
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
Time and Extent Applications (I)	2/10/2004

## **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 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
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
Integration of Study Results to Address Concerns About Human Reproductive and Developmental Toxicities	11/13/2001
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals (I)	6/20/2005
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
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Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions (I)	12/29/2009
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
Potassium Iodide (KI) in Radiation Emergencies - Questions and Answers (I)	12/23/2002
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (I)	12/11/2001
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
Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (I)	1/21/2009
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
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 Authorization of Medical Products: Availability (I)	7/5/2005
End-of-Phase 2A Meetings (I)	9/26/2008
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
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
Pharmacogenomic Data Submissions (I)	11/4/2003
Pharmacogenomic Data Submissions -Companion Guidance (I)	8/29/2007
Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products (I)	1/8/2010
Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic (I)	12/16/2008
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (I)	3/12/2001
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

### **Small Entity Compliance Guides**

### **Issued Date**

Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation (I)	11/7/2001
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### **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 Draft**

**Issued Date**

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