Advertising

- Accelerated Approval Products — Submission of Promotional Materials
- Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling
- Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements
- Example of Fictional Highlights of Prescribing Information (Based on Proposed Physician Labeling Rule)
- Example of Fictional Highlights of Prescribing Information (Based on Proposed Physician Labeling Rule) Translated in Consumer-Friendly Language and Formatted for Use in Consumer-Directed Advertisement
- Consumer-Directed Broadcast Advertisements
- Consumer-Directed Broadcast Advertising of Restricted Devices
- “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms
- Industry-Supported Scientific and Educational Activities
- Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling
- Promoting Medical Products in a Changing Health care Environment; I. Medical Product Promotion by Health care Organizations or Pharmacy Benefits Management Companies (PBM)

Biopharmaceutics

- Bioanalytical Method Validation
- Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action
- Statistical Information from the June 1999 Draft Guidance and Statistical Information for In Vitro Bioequivalence Data Posted on August 18, 1999
- Bioavailability and Bioequivalence Studies for Orally Administered Drug Products — General Considerations
- Chlorestyramine Powder
- Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing
- Topical Dermatologic Corticosteroids
- Dissolution Testing of Immediate Release Solid Oral Dosage Forms
- Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In VivoCorrelations
- Food-Effect Bioavailability and Fed Bioequivalence Studies
- Guidance for the In Vitro Portion of Bioequivalence Requirements for Metaproteremol Sulfate and Albuterol
- Review of a Communication Statistical Approaches to Establishing Bioequivalence
- Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System
Current Good Manufacturing Practice

- Comparability Protocols - Protein Drug Products and Biological Products - Chemistry, Manufacturing, and Controls Information
- Current Good Manufacturing Practice for Combination Products
- Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP
- INDs — Approaches to Complying with CGMP During Phase 1
- Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations
- Part 11, Electronic Records; Electronic Signatures — Scope and Application
- PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance
- Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment
- Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice

Chemistry

- Analytical Procedures and Methods Validation
- Current Good Manufacturing Practice for Combination Products
- Botanical Drug Products
- Changes to an Approved NDA or ANDA
- Questions and Answers
- Use of Enforcement Discretion for Compendial Changes
- Comparability Protocols — Chemistry, Manufacturing, and Controls Information
- Container Closure Systems for Packaging Human Drugs and Biologics
- Questions and Answers
- FDA Guidance Concerning Demonstration of Comparability of Human Biological Products
- FDA’s Policy Statement For The Development Of New Stereoisomeric Drugs
- Guideline For Drug Master Files
- Drug Master Files for Bulk Antibiotic Drug Substances
- Drug Substance Chemistry, Manufacturing, and Controls Information
- INDs for Phase 2 and Phase 3 Studies Chemistry, Manufacturing, and Controls Information
- IND Meetings for Human Drugs and Biologics
- Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations
- Monoclonal Antibodies Used as Reagents in Drug Manufacturing
- Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products
- NDAs: Impurities in Drug Substances
- PAC-ATLS: Postapproval Changes — Analytical Testing Laboratory Sites
- Reviewer Guidance Validation of Chromatographic Methods
- Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products
- Guidance for the Submission of Chemistry, Manufacturing, and Controls Information for SyntheticPeptide Substances
• Good Guidance Practices
• Guideline For Submitting Supporting Documentation In Drug Applications For The Manufacture Of Drug Substances
• Immediate Release Solid Oral Dosage Forms
• SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum
• Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation

Clinical/Medical

• Acceptance of Foreign Clinical Studies
• Acne Vulgaris: Developing Drugs for Treatment
• Allergic Rhinitis: Clinical Development Programs for Drug Products
• Evaluation of Anti Anxiety Drugs
• Evaluation of Antidepressant Drugs
• Calcium DTPA and Zinc DTPA Drug Products — Submitting a New Drug Application
• Cancer Drug and Biological Products — Clinical Data in Marketing Applications
• Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)
• Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)
• Anti-Inflammatory and Antirheumatic Drugs
• Antiepileptic Drugs
• General Anesthetics
• Lipid-Altering Agents In Adults And Children
• Weight-Control Drugs
• Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics
• Collection of Race and Ethnicity Data in Clinical Trials
• Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products
• Developing Medical Imaging Drug and Biological Products
  • Part 1: Conducting Safety Assessments
  • Part 2: Clinical Indications
  • Part 3: Design, Analysis, and Interpretation of Clinical Studies
• Development and Use of Risk Minimization Action Plans
• Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis
• Drugs, Biologics, and Medical Devices 3 Derived from Bioengineered Plants for 4 Use in Humans and Animals
• Establishing Pregnancy Exposure Registries
• Establishing Pregnancy Exposure Registries
• Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms — Recommendations for Clinical Evaluation
• Evaluating the Risks of Drug Exposure in Human Pregnancies
• Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children
• Exercise-Induced Bronchospasm (EIB) — Development of Drugs to Prevent EIB
• Exocrine Pancreatic Insufficiency Drug Products – Submitting NDAs
Clinical Anti-Microbial

- Complicated Urinary Tract Infections and Pyelonephritis — Developing Antimicrobial Drugs for Treatment
- Acute Bacterial Meningitis — Developing Antimicrobial Drugs for Treatment
- Acute Bacterial Sinusitis — Developing Antimicrobial Drugs for Treatment
- Acute or Chronic Bacterial Prostatitis — Developing Antimicrobial Drugs for Treatment
- Acute Otitis Media — Developing Antimicrobial Drugs for Treatment
- Antiviral Drug Development — Conducting Virology Studies and Submitting the Data to the Agency
• Antiretroviral Drugs Using Plasma HIV RNA Measurements — Clinical Considerations for Accelerated and Traditional Approval
• Bacterial Vaginosis — Developing Antimicrobial Drugs for Treatment
• Catheter-Related Bloodstream Infections — Developing Antimicrobial Drugs for Treatment
• Clinical Development and Labeling of Anti-Effective Drug Products
• Anti-Effective Drugs
• Community-Acquired Pneumonia — Developing Antimicrobial Drugs for Treatment
• Complicated Urinary Tract Infections and Pyelonephritis — Developing Antimicrobial Drugs for Treatment
• Developing Antimicrobial Drugs — General Considerations for Clinical Trials
• Inhalational Anthrax (Post-Exposure) — Developing Antimicrobial Drugs
• Empiric Therapy of Febrile Neutropenia — Developing Antimicrobial Drugs for Treatment
• Lyme Disease — Developing Antimicrobial Drugs for Treatment
• Nosocomial Pneumonia — Developing Antimicrobial Drugs for Treatment
• Role of HIV Drug Resistance Testing in Antiretroviral Drug Development
• Secondary Bacterial Infections of Acute Bronchitis — Developing Antimicrobial Drugs for Treatment
• Streptococcal Pharyngitis and Tonsillitis — Developing Antimicrobial Drugs for Treatment
• Uncomplicated and Complicated Skin and Skin Structure Infections — Developing Antimicrobial Drugs for Treatment
• Uncomplicated Gonorrhea — Developing Antimicrobial Drugs for Treatment
• Uncomplicated Urinary Tract Infections — Developing Antimicrobial Drugs for Treatment
• Vaccinia Virus — Developing Drugs to Mitigate Complications from Smallpox Vaccination
• Vulvovaginal Candidiasis — Developing Antimicrobial Drugs for Treatment

Pharmacology

• Carcinogenicity Study Protocol Submissions
• Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products
• Developing Medical Imaging Drug and Biological Products Part 1: Conducting Safety Assessments
• Exploratory IND Studies
• Nonclinical Pharmacology/Toxicology Section of an Application
• Immunotoxicology Evaluation of Investigational New Drugs
• Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities
• Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals
• Nonclinical Safety Evaluation of Drug or Biologic Combinations
• Nonclinical Safety Evaluation of Pediatric Drug Products
• Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients
• Photosafety Testing
• Recommended Approaches to Integration of Genetic Toxicology Study Results
• Reference Guide
• Safety Testing of Drug Metabolites
• Single Dose Acute Toxicity Testing for Pharmaceuticals
• Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals
Compliance

- Bar Code Label Requirements Questions and Answers
- Computerized Systems used in Clinical Trials
- Draft Guidance- Erratum
- Current Good Manufacturing Practice for Medical Gases
- Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron
- Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide
- Good Laboratory Practice Regulations
- Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities
- Exception from Informed Consent Requirements for Emergency Research
- Guideline on Validation of the Limus Amebocyte Lysate Test
- Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production
- Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients
- Marketed Unapproved Drugs — Compliance Policy Guide
- Guideline for the Monitoring of Clinical Investigations
- Nuclear Pharmacy Guideline
- Compliance Policy Guides Manual
- PET Drug Products—Current Good Manufacturing Practice (CGMP)
- Possible Dioxin/PCB Contamination of Drug and Biological Products
- Prescription Drug Marketing Act — Donation of Prescription Drug Samples to Free Clinics
- Street Drug Alternatives

Drug Safety

- Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review
- FDA’s “Drug Watch” for Emerging Drug Safety Information
- Questions and Answers

Electronic Submissions

- Part 11, Electronic Records; Electronic Signatures — Scope and Application
- Providing Regulatory Submissions in Electronic Format — ANDAs
- Providing Regulatory Submissions in Electronic Format — Annual Reports for NDAs and ANDAs
- Providing Regulatory Submissions in Electronic Format — Content of Labeling
- Providing Regulatory Submissions in Electronic Format — Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
- Providing Regulatory Submissions in Electronic Format — General Considerations
- Providing Regulatory Submissions in Electronic Format — Postmarketing Expedited Safety Reports
- Providing Regulatory Submissions in Electronic Format — Postmarketing Periodic Adverse Drug Experience Reports
- Providing Regulatory Submissions in Electronic Format — Prescription Drug Advertising and Promotional Labeling
• Providing Regulatory Submissions in Electronic Format—General Considerations
• Providing Regulatory Submissions in Electronic Format—NDAs
• SPL Standard for Content of Labeling Technical Qs & As

Generics

• 180-Day Exclusivity When Multiple ANDAs Resubmitted on the Same Day
• Alternate Source of the Active Pharmaceutical Ingredient in Pending ANDAs
• ANDAs: Impurities in Drug Products
• ANDAs: Impurities in Drug Substances
• ANDAs: Impurities in Drug Substances Draft Guidance
• ANDAs: Pharmaceutical Solid Polymorphism Chemistry, Manufacturing, and Controls Information
• Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act
• Handling and Retention of BA and BE Testing Samples
• Letter to ANDA and AADA Applicants
• Letter of The Center for Drug Evaluation and Research and the Office of Regulatory Affairs
• Letter on Office of Generic Drugs
• Letter on OGD for New Bioequivalence Guidances and OGD’s Recent Experience With Refuse-to-File Letters
• Letter Regarding The Generic Drug Review Process
• Letter on Commentaries for the Generic Drug Review Program
• Letter to Messrs. Mossinghoff and Stetler
• Letter on Generic Drug Enforcement Act of 1992
• Letter on Details About Labeling Scale-Up, Packaging, Minor/Major Amendment Criteria, and Bioequivalence Requirements
• 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
• Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications
• Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing
• Revising ANDA Labeling Following Revision of the RLD Labeling
• Variations in Drug Products that May Be Included in a Single ANDA

Good Review Practices

• Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review
• Pharmacology/Toxicology Review Format
Industry Letters

- Letter to NDA or ANDA Holders and Applicants
- Drug Pricing and Patent Term Restoration Act
- Series Four Letters
- President Signs Patent Term Restoration
- CDER Letter
- Series Seven Letters
- Series Six Letters
- ANDAs
- Series Three Letters
- Year 2000 Letter from Dr. Janet Woodcock

International Conference on Harmonisation - Efficacy

- The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions
- Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
- E2B(M): Data Elements for Transmission of Individual Case Safety Reports Questions and Answers
- Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
- E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs
- Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs
- ICH Harmonised Tripartite Guideline draft
- E2E Pharmacovigilance Planning
- Structure and Content of Clinical Study Reports
- Dose-Response Information to Support Drug Registration
- International Conference on Harmonisation; Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data; Availability
- E5 – Ethnic Factors in the Acceptability of Foreign Clinical Data Questions and Answers
- Studies in Support of Special Populations: Geriatrics
- E9 Statistical Principles for Clinical Trials
- E 10 Choice of Control Group and Related Issues in Clinical Trials
- E11 Clinical Investigation of Medicinal Products in the Pediatric Population
- E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs
- DRUGS Draft ICH Consensus Principle
International Conference on Harmonisation - Joint Safety

- M2: eCTD Specification Questions & Answers and Change Requests
- M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals
- M4: Organization of the CTD
- Granularity Document Annex to M4: Organization of the CTD
- M4: The CTD — General Questions and Answers
- M4Q: The CTD — Quality
- M4: The CTD — Quality Questions and Answers/Location Issues
- M4E: The CTD — Efficacy
- M4S: The CTD — Safety
- M4S: The CTD — Safety Appendices
- M4: The CTD — Safety Questions and Answers
- ICH Consensus Guideline Released for Consultation on 10 May 2005, at Step 2 of the ICH Process Data Elements and Standards for Drug Dictionaries M5
- Submitting Marketing Applications According to the ICH-CTD Format — General Considerations

International Conference on Harmonisation - Quality

- Q1A(R2) Stability Testing of New Drug Substances and Products
- Q1B Photostability Testing of New Drug Substances and Products
- Q1C Stability Testing for New Dosage Forms
- Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products
- Q1E Evaluation of Stability Data
- Text on Validation of Analytical Procedures
- Q2B Validation of Analytical Procedures: Methodology
- Q3B(R) Impurities in New Drug Products
- Q3C Impurities: Residual Solvents
- Q3C — Tables and List
- Appendix 4. Toxicological Data For Class 1 Solvents
- Appendix 5. Toxicological Data For Class 2 Solvents
- Appendix 6. Toxicological Data For Class 3 Solvents
- Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin
- Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products
- Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products
- International Conference on Harmonisation; Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability Food
- Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process
- International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New
Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products
Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

International Conference on Harmonisation - Safety

- The Need for Long-term Rodent Carcinogenicity Studies of Pharmaceuticals
- S1B Testing for Carcinogenicity Pharmaceuticals
- Dose Selection for Carcinogenicity Studies of Pharmaceuticals
- S1C(R) Addendum to Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addition of a Limit Dose and Related Notes
- Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals
- S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals
- Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies
- Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies
- International Conference on Harmonisation; Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing); Availability
- Detection of Toxicity to Reproduction for Medicinal Products
- Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility
- S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals
- S7A Safety Pharmacology Studies for Human Pharmaceuticals
- S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals
- S8 Immunotoxicity Studies for Human Pharmaceuticals
- Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products

Investigational New Drug Applications

- Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products

Labeling

- Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format
- Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format
- Content and Format for Geriatric Labeling
- Labeling for Combined Oral Contraceptives
- Labeling for Human Prescription Drug and Biological Products — Implementing the New Content and Format Requirements
- Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)
- 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

- Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products —Content and Format

Microbiology

- Guideline for the Format and Content of the Microbiology Section of An Application

Modernization Act

- Changes to an Approved NDA or ANDA
- Classifying Resubmissions in Response to Action Letters
- Fast Track Drug Development Programs — Designation, Development, and Application Review
- Formal Dispute Resolution: Appeals Above the Division Level —Guidelines on the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce-
- Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997
- Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 — Elimination of Certain Labeling Requirements
- Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions
- Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions
- National Uniformity for Nonprescription Drugs — Ingredient Listing for OTC Drugs
- PET Drug Applications — Content and Format for NDAs and ANDAs
- Attachment II
- Attachment III
- Attachment IV
- Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products
- Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act
- Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act
- Reports on the Status of Postmarketing Study Commitments — Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997
- Submission of Abbreviated Reports and Synopses in Support of Marketing Applications
- Submitting and Reviewing Complete Responses to Clinical Holds
Over-the Counter Drugs

- Food and Drug Administration Compliance Policy Guides
- Notices
- Labeling OTC Human Drug Products Questions and Answers
- Labeling OTC Human Drug Products — Submitting Requests for Exemptions and Deferrals
- Labeling OTC Human Drug Products (Small Entity Compliance Guide)
- Labeling OTC Human Drug Products Updating Labeling in ANDAs
- Example Drug Facts Label for Acetaminophen 120 mg in a Suppository Dosage Form
- Example Drug Facts Label for Acetaminophen 325 mg in a Suppository Dosage Form
- Example Drug Facts Label for Acetaminophen 650 mg in a Suppository Dosage Form
- Example Drug Facts Label for Cimetidine 200 mg in a Tablet Dosage Form
- Example Drug Facts Label for Clemastine Fumarate 1.34 mg in a Tablet Dosage Form
- Example Drug Facts Label for Doxylamine Succinate 25 mg Tablet Dosage Form
- Example Drug Facts Label for Ibuprofen 200 mg in a Tablet/Capsule Dosage Form
- Example Drug Facts Label for Loperamide HCl in a Liquid Dosage Form
- Example Drug Facts Label for Loperamide HCl in a Tablet/Caplet Dosage Form
- Example Drug Facts Label for Miconazole Nitrate Vaginal Products
- Example Drug Facts Label for Minoxidil Topical Solution 2% for Men and Women
- Example Drug Facts Label for Minoxidil Topical Solution 5% for Men
- Example Drug Facts Label for Naproxen Sodium 220 mg in a Tablet/Caplet/Gelcap Dosage Form
- Example Drug Facts Label for Pseudoephedrine HCl Extended-Release Tablets120 mg
- Labeling OTC Human Drug Products Using a Column Format
- Time and Extent Applications
- Guideline for Upgrading Category III Antiperspirants to Category I

Pharmacology

- Carcinogenicity Study Protocol Submissions
- Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products
- Developing Medical Imaging Drug and Biological Products Part 1: Conducting Safety Assessments
- Exploratory IND Studies
- Nonclinical Pharmacology/Toxicology Section of an Application
- Immunotoxicology Evaluation of Investigational New Drugs
- Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities
- Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals
- Nonclinical Safety Evaluation of Drug or Biologic Combinations
- Nonclinical Safety Evaluation of Pediatric Drug Products
- Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients
- Photosafety Testing
- Recommended Approaches to Integration of Genetic Toxicology Study Results
- Reference Guide
- Safety Testing of Drug Metabolites
Single Dose Acute Toxicity Testing for Pharmaceuticals
- Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals

Procedural
- 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act
- Applications Covered by Section 505(b)(2)
- Continuous Marketing Applications: Pilot 1 – Review able Units for Fast Track Products Under PDUFA
- Continuous Marketing Applications: Pilot 2 – Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA
- Court Decisions, ANDA Approvals, and and180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act
- 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 the Center for Drug Evaluation and Research, Beginning on January 1, 2000
- Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees
- 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
- 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
- Emergency Use Authorization of Medical Products
- Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act
- Fast Track Drug Development Programs —Designation, Development, and Application Review
- Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Procedure for Drugs Intended To Treat Life-Threatening and Severely Debilitating Illness
- Manual Of Policies And Procedures Center For Drug Evaluation And Research
- New Drug Antibiotic, and Biological Drug Product Regulations; Accelerated Approval
- Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV
- FDA Export Certificates
- Formal Dispute Resolution: Appeals Above the Division Level
- Formal Meetings With Sponsors and Applicants for PDUFA Products
- Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution
- Good Review Management Principles and Practices for PDUFA Products
- Process for Handling Referrals to Dander 21 CFR 50.54Additional Safeguards for Children in Clinical Investigations
- The Leveraging Handbook An Agency Resource for Effective Collaborations FINAL GUIDANCE
- How to Comply with the Pediatric Research Equity Act
- Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997
- Implementation of Section 126 of the Food and Drug Administration Modernization Act of
1997 — Elimination of Certain Labeling Requirements

- Independent Consultants for Biotechnology Clinical Trial Protocols
- Information Program nonclinical Trials for Serious or Life-Threatening Diseases and Conditions
- Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions-2
- Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act
- Levothyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications
- National Uniformity for Nonprescription Drugs — Ingredient Listing for OTC Drugs
- PET Drug Applications — Content and Format for NDAs and ANDAs
  - Fludeoxyglucose F 18 Injection
  - Ammonia N 13 Injection
  - Sodium Fluoride F 18 Injection
- Attachment I Sample Formats — Application To Manufacture Ammonia N 13 Injection
  - Fludeoxyglucose F 18 Injection (FDG F 18) and Sodium Fluoride F 18 Injection Chemistry, Manufacturing, and Controls Section
- Attachment I Sample Formats — Application To Manufacture Ammonia N 13 Injection
  - Fludeoxyglucose F 18 Injection (FDG F 18) and Sodium Fluoride F 18 Injection Chemistry, Manufacturing, and Controls Section
- Attachment I Sample Formats — Labeling for Ammonia N 13 Injection
  - Fludeoxyglucose F 18 Injection [18F] FDA and Sodium Fluoride F 18 Injection
- Attachment III Sample Formats — Form FDA 356h for Ammonia N 13 Injection Fludeoxyglucose F 18 Injection (FDG F 18) and Sodium Fluoride F 18 Injection
- Attachment IV Sample Formats — User Fee Form FDA 3397 for Ammonia N 13 Injection Fludeoxyglucose F 18 Injection (FDG F 18) and Sodium Fluoride F 18 Injection
- Pharmacogenomic Data Submissions
- Examples of Voluntary Submissions or Submissions Required Under 21 CFR 312, 314, or 601
- Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines
- Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies
- KI in Radiation Emergencies — Questions and Answers
- Potassium Iodide Tablets Shelf Life Extension
- Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act
- New Drug Evaluation Guidance Document: Refusal to File
- Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act
- Reports on the Status of Postmarketing Study Commitments — Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997
- Special Protocol Assessment
- Standards for the Prompt Review efficacy Supplements, Including Priority Efficacy Supplements
- Submitting and Reviewing Complete Responses to Clinical Holds
- Submitting Debarment Certification Statements
- Submitting Marketing Applications According to the ICH-CTD Format — General Considerations
- The Use of Clinical Holds Following Clinical Investigator Misconduct
- Useful Written Consumer Medication Information (CMI)
- Using a Centralized IRB Review Process in Multicenter Clinical Trials
- Waiver of IRB Requirements for Drug and Biological Product Studies
Director, Center for Drug Evaluation and Research FDAMA - Women and Minorities Guidance Requirements

User Fees

- Interim Guidance Document for Waivers of the Reductions in User Fees
- Classifying Resubmissions in Response to Action Letters
- Classifying Resubmissions in Response to Action Letters
- Application User Fees for Combination Products
- Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act
- Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees
- User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR