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Part III

Department of Health and Human Services

Food and Drug Administration

Comprehensive List of Guidance Documents at the Food and Drug Administration; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–N–0050] (formerly Docket No. 1998N–0046)

Comprehensive List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a comprehensive list of all guidance documents currently in use at the agency. This list is being published under FDA's Good Guidance Practices (GGPs). It is intended to inform the public of the existence and availability of all of our current guidance documents. It also provides information on guidance documents that have been added or withdrawn in the past 5 years.

DATES: We welcome general comments on this list and on agency guidance documents at any time.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

For information on a specific guidance or to obtain a paper copy, please refer to each Center's section of this document.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's GGPs were published in the **Federal Register** of September 19, 2000 (65 FR 56468), and became effective October 19, 2000. GGPs (21 CFR 10.115) are intended to ensure involvement of the public in the development of guidance documents, and to enhance understanding of the availability, nature, and legal effect of such guidance.

FDA has adopted a new format for the publication of its comprehensive guidance list. This new format is intended to increase the timeliness of the comprehensive list. For information on a specific guidance or to obtain a paper copy, please refer to each Center's section of this document. The lists of guidance documents are either a printout of FDA's Web site as of April 2010 or a list compiled by the issuing office. You should note that some guidance documents pertain to more than one product area (e.g., drugs and biologics), and are, therefore, listed under both Centers involved or pertain to more than one subject matter (e.g., "Food Defense and Emergency Response" and "Imports"), and are, therefore, listed under more than one category within a Center. So there may be some duplication in the guidance lists. You are encouraged to use FDA's Web site as the most up-to-date source for all current guidance documents in use by the agency, as the Web site is updated on a daily basis.

In accordance with the agency's general policy on guidances, you may comment on this list and on any FDA guidance document at any time.

We have organized the guidance documents by the issuing Center or Office within FDA. The dates in the list refer to the date we issued the guidances or, where applicable, the last date we revised a document. Because each issuing Center or Office maintains its own database, there are slight variations in the way in which they provide the information.

II. Center for Biologics Evaluation and Research (CBER)

For information a specific guidance document or to obtain a paper copy, contact:

Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, e-mail: *ocod@fda.hhs.gov*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

The following is a list of CBER guidance documents that have been withdrawn:

Title of Document	Date of Issuance	Date of Withdrawal
Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing	3/15/2000	4/10/2006
Draft Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier	7/11/2001	4/11/2006
Draft Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research	8/23/2001	August 9, 2010.

The following list of current CBER guidance documents was obtained from FDA's Web site on April 20, 2010:

Administrative

- Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications (PDF - 316KB)
  9/2009
- Formal Meetings Between the FDA and Sponsors or Applicants (PDF - 89KB)
  5/2009
- Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices
  1/2009
- Guidance for Industry, FDA Staff, and FDA-Accredited Third Parties - Manufacturer's Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA)
  9/15/2005

- Guidance for Industry, FDA Staff, and Third Parties - Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria
  10/4/2004
- Guidance for Industry and FDA Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s)
  5/28/2004
- FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment
  5/21/2004
- Guidance for Industry and FDA: User Fees and Refunds for Premarket Approval Applications
  11/24/2003
- Premarket Approval Application Modular Review
  11/3/2003

Adverse Events and Product Deviation Guidances

- Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs—Improving Human Subject Protection (PDF - 61KB)
  1/2009
- Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic (PDF - 246KB)
  12/2008
- Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports (PDF - 107KB)
  6/2008
- Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components
  10/2006
- Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 52KB)
  1/2006
- Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (PDF - 375KB)
  3/2001
- Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report (PDF - 95KB)
  8/1997

Allergenic Guidance Documents

- Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts
  11/20/2008
- Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol
  11/20/2000
- Guidance for Industry On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test
  4/23/1999

Application Submissions

- Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes (PDF - 73KB)
  2/2010
- SPL Standard for Content of Labeling Technical Qs & As (PDF - 58KB)
  10/2009
- Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects (PDF - 163KB)
  10/2009
- Providing Regulatory Submissions in Electronic Format—(PDF - 123KB)
  5/2009
- Guidance for Industry and FDA Staff - Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process (PDF Version) (PDF - 180KB)
  12/2008
- Contents of a Complete Submission for the Evaluation of Proprietary Names (PDF - 306KB)
  11/2008
- Tropical Disease Priority Review Vouchers (PDF - 112KB)
  10/2008
- Integrated Summary of Effectiveness (PDF - 95KB)
  8/2008
- Draft Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers (PDF Version) (PDF - 121KB)
  8/2008
- Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports (PDF - 107KB)
  6/2008
- Providing Regulatory Submissions in Electronic Format -Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (PDF - 133KB)
  6/2008
- Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals (PDF Version) (PDF - 155KB)
  6/2008
- Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements (PDF Version) (PDF - 103KB)
  2/2008
- Guidance for Industry and FDA Staff: Expedited Review of Premarket Submissions for Devices (PDF Version) (PDF - 127KB)
  2/2008
- Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format - Lot Release Protocols (PDF - 76KB)
  11/2007

- In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions (PDF - 268KB)
  10/2007
- Pharmacogenomic Data Submissions—Companion Guidance (PDF - 211KB)
  8/2007
- Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission (PDF Version) (PDF - 145KB)
  6/2007
- Providing Regulatory Submissions in Electronic Format—Receipt Date (PDF - 59KB)
  6/2007
- Draft Guidance for Industry and FDA Staff - Annual Reports for Approved Premarket Approval Applications (PMA) (PDF Version) (PDF - 127KB)
  10/2006
- Real-Time Premarket Approval Application (PMA) Supplements - Guidance for Industry and FDA Staff (PDF Version) (PDF - 82KB)
  4/2006
- Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (PDF - 456KB)
  2/2006
- Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims (PDF - 295KB)
  2/2006
- Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP (PDF - 110KB)
  2/2006
- Fast Track Drug Development Programs - Designation, Development, and Application Review (PDF - 83KB)
  2/2006
- How to Comply with the Pediatric Research Equity Act (PDF - 116KB)
  9/2005
- Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients (PDF - 230KB)
  5/2005
- Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (PDF version) (PDF - 342KB)
  5/2005
- Providing Regulatory Submissions in Electronic Format—Content of Labeling (PDF - 28KB)
  4/2005
- Good Review Management Principles and Practices for PDUFA Products (PDF - 683KB)
  4/2005
- Pharmacogenomic Data Submissions (PDF - 96KB)
  3/2005
- Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (PDF - 211KB)
  12/2004
- Guidance for Industry and FDA Staff: Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA (PDF Version) (PDF - 97KB)
  11/2004
- Guidance for Industry, FDA Staff, and Third Parties - Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria (PDF Version) (PDF - 175KB)
  10/2004
- Guidance for Industry and FDA Staff: User Fees and Refunds for Premarket Notification Submissions (510(k)s) (PDF Version) (PDF - 109KB)
  5/2004
- Guidance for Industry and FDA Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment (PDF Version) (PDF - 515KB)
  5/2004
- Guidance for Industry and FDA: User Fees and Refunds for Premarket Approval Applications (PDF Version) (PDF - 87KB)
  11/2003
- Guidance for Industry and FDA Staff: Premarket Approval Application Modular Review (PDF Version) (PDF - 159KB)
  11/2003
- Providing Regulatory Submissions in Electronic Format - General Considerations (PDF - 288KB)
  10/2003
- Part 11, Electronic Records; Electronic Signatures—Scope and Application (PDF - 215KB)
  8/2003
- Guidance for Industry and FDA Staff: Premarket Approval Application Filing Review (PDF Version) (PDF - 529KB)
  5/2003
- Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products
  2/2003
- Comparability Protocols—Chemistry, Manufacturing, and Controls Information (PDF - 240KB)
  2/2003
- Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff - PDF (PDF - 548KB)
  2/2003
- Special Protocol Assessment (PDF - 36KB)
  5/2002
- Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs) (PDF) (PDF - 80KB)
  3/2002
- Cancer Drug and Biological Products - Clinical Data in Marketing Applications (PDF - 39KB)
  10/2001
- Draft Guidance for Industry - Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research
  9/2001

- Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (PDF - 50KB)
  8/2001
- Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (PDF - 32KB)
  4/2001
- Acceptance of Foreign Clinical Studies (PDF - 12KB)
  3/2001
- Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)) (PDF - 56KB)
  11/2000
- Submitting and Reviewing Complete Responses to Clinical Holds (Revised) (PDF - 26KB)
  10/2000
- Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (PDF - 14KB)
  10/2000
- Formal Meetings With Sponsors and Applicants for PDUFA Products (PDF - 30KB)
  2/2000
- Formal Dispute Resolution: Appeals Above the Division Level (PDF - 30KB)
  2/2000
- Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act (PDF - 57KB)
  9/1999
- Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (PDF - 43KB)
  8/1999
- Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format - Biologics Marketing Applications (PDF - 582KB)
  11/1999
- Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997–Advisory Committees (PDF - 62KB)
  10/1998
- Submitting Debarment Certification Statements (PDF - 144KB)
  9/1998
- Standards for Prompt Review of Efficacy Supplements (PDF - 76KB)
  5/1998
- Classifying Resubmissions in Response to Action Letters (PDF - 76KB)
  4/1998
- Pediatric Use Supplements—Content and Format (PDF - 24KB)
  5/1996
- Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs (PDF - 41KB)
  11/1995
- Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products (PDF - 42KB)
  11/1995
- FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products; Availability (PDF - 34KB)
  7/1995
- Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products (PDF - 57KB)
  11/1994
- Preparation of Investigational New Drug Products (Human and Animal) (PDF - 795KB)
  3/1991
- Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007

Blood Guidance Documents

- Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components, October 2009 (PDF - 858KB)
  10/2009, Updated: 12/2009
- Draft Guidance for Industry: Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus (PDF - 80KB)
  11/13/2009
- Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion (PDF - 68KB)
  11/6/2009
- Draft Guidance for Industry and FDA Staff - Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications (PDF - 91KB)
  10/2009
- Guidance for Industry - Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications (PDF - 462KB)
  10/2009
- Guidance for Industry - Recommendations for Management of Donors at Increased Risk for Human Immunodeficiency Virus Type 1 (HIV-1) Group O Infection
  8/2009
- Guidance for Industry: Nucleic Acid Testing (NAT) to Reduce the Possible Risk of Parvovirus B19 Transmission by Plasma-Derived Products
  7/28/2009
- Draft Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products
  3/2009
- Assay Migration Studies for In Vitro Diagnostic Devices
  1/5/2009

- Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency
  7/17/2008
- Draft Guidance for Industry: Requalification Method for Reentry of Blood Donors Deferred Because of Reactive Test Results for Antibody to Hepatitis B Core Antigen (Anti-HBc)
  5/20/2008
- Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
  4/25/2008
- Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods
  12/17/2007
- Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle
  11/29/2007
- Guidance for Industry: Adequate and Appropriate Donor Screening Tests for Hepatitis B; Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Donors of Whole Blood and Blood Components, Including Source Plasma and Source Leukocytes
  11/21/2007
- Draft Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility
  10/26/2007
- Guidance for Industry: "Lookback" for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV
  8/24/2007
- Guidance for Industry: Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay
  8/08/2007
- Guidance for Industry: Informed Consent Recommendations for Source Plasma Donors Participating in Plasmapheresis and Immunization Programs
  6/20/2007
- Draft Guidance for Industry: "Computer Crossmatch" (Electronic Based Testing for the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type)
  6/20/2007
- Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components
  10/27/2006
- Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments
  10/18/2006
- Guidance for Industry: Bar Code Label Requirements - Questions and Answers
  10/5/2006
- Guidance for Industry: Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels
  9/22/2006
- United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128 (PDF - 1665KB)
  9/22/2006
- Guidance for Industry: Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies
  8/08/2006
- Draft Guidance for Industry: Amendment (Donor Deferral for Transfusion in France Since 1980) to "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products"
  8/08/2006
- Draft Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry
  7/19/2005
- Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection
  6/23/2005
- Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
  11/24/2004
- Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
  11/30/2004
- Draft Guidance for Industry: Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes
  10/28/2004
- Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV
  10/21/2004
- Questions and Answers on "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products"
  1/22/2004
- Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus - Guidance for Industry and FDA Staff
  10/30/2003
- Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion
  9/22/2003
- Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS
  9/16/2003

- Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires
7/3/2003
- Draft Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis
6/25/2003
- Question and Answer on FDA Guidance Entitled "Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Suspected and Probable Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS"
4/25/2003
- Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS
4/17/2003
- Questions and Answers on FDA Guidance Entitled "Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients"
1/15/2003
- Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients
12/30/2002
- Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts
2/1/2002
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff
1/11/2002
- Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products
1/9/2002
- Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices
11/22/2001
- Guidance for Industry - Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax
10/17/2001
- Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis
8/22/2001
- Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture
8/07/2001
- Guidance for FDA Reviewers: Premarket Notification Submissions for Blood and Plasma Warmers
7/19/2001
- Guidance for FDA Reviewers: Premarket Notification Submissions for Transfer Sets (Excluding Sterile Connecting Devices)
7/19/2001
- Guidance for FDA Reviewers: Premarket Notification Submissions for Empty Containers for the Collection and Processing of Blood and Blood Components
7/19/2001
- Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors
7/11/2001
- Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing
3/29/2001
- Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods - Technical Correction February 2001
2/13/2001
- Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion
1/23/2001
- Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens
6/23/2000
- Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria
6/8/2000
- Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts
12/23/1999
- Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2
12/14/1999
- Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations (PDF - 26KB)
7/15/1999
- Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use
5/20/1999
- Draft Guidance for Industry For Platelet Testing and Evaluation of Platelet Substitute Products
5/20/1999
- Guidance for Industry For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h "Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use"
5/10/1999
- Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product
3/8/1999

- Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products
  2/17/1999
- Withdrawal of "Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)"
  9/8/1998
- Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing
  6/11/1998
- Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)
  3/20/1998
- Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products
  1/08/1998
- Guidance for Industry: Donor Screening for Antibodies to HTLV-II
  8/15/1997
- Guidance for Industry: Changes to an Approved Application: Biological Products (PDF - 39KB)
  7/1997
- Guideline for Quality Assurance in Blood Establishments (PDF - 77KB)
  7/11/1995
- Draft Recommended Methods for Blood Grouping Reagents Evaluation (PDF - 2101KB)
  3/1992
- Draft Recommended Methods for Evaluating Potency, Specificity, and Reactivity of Anti-Human Globulin (PDF - 1161KB)
  3/1992
- Draft Points to Consider in the Design and Implementation of Field Trials for Blood Grouping Reagents and Anti-Human Globulin (PDF - 211KB)
  1992
- Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers ("High Risk" Donors) (PDF - 176KB)
  10/26/1989
- Draft Points to Consider in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus Type 1 (PDF - 1784KB)
  8/08/1989
- Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test For Human and Animal Parenteral Drugs, Biological Products and Medical Devices (PDF - 2874KB)
  12/1987
- Guideline for the Uniform Labeling of Blood and Blood Components (PDF - 1189KB)
  8/1985
- Guidelines for Immunization of Source Plasma (Human) Donors with Blood Substances (PDF - 368KB)
  6/1980

Cellular & Gene Therapy Guidance Documents

- Draft Guidance for Industry and FDA Staff - Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications (PDF - 91KB)
  10/2009
- Guidance for Industry - Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications (PDF - 462KB)
  10/2009
- Draft Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines
  9/2009
- Guidance for Industry: Considerations for Allogeneic Pancreatic Islet Cell Products
  09/2009
- Draft Guidance for Industry: Somatic Cell Therapy for Cardiac Disease
  03/2009
- Draft Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products
  10/9/2008
- Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)
  4/9/2008
- Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Somatic Cell Therapy Investigational New Drug Applications (INDs)
  4/9/2008
- Draft Guidance for Industry: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products
  2/11/2008
- Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products
  8/8/2007
- Draft Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage
  7/6/2007
- Guidance for Industry: Gene Therapy Clinical Trials - Observing Subjects for Delayed Adverse Events
  11/28/2006
- Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors
  11/28/2006
- Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy
  3/30/1998

- Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products (TXT - 59KB)
  01/1997

CMC & GMP

- Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes (PDF - 73KB)
  2/2010
- Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics (PDF - 91KB)
  11/2008
- Process Validation: General Principles and Practices (PDF - 194KB)
  11/2008
- Current Good Manufacturing Practice for Phase 1 Investigational Drugs (PDF - 132KB)
  7/2008
- Guidance for Industry: Manufacturing Biological Intermediates and Biological Drug Substances Using Spore-Forming Microorganisms (PDF - 184KB)
  9/6/2007
- Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations (PDF - 443KB)
  9/2006
- Drug Interaction Studies—Study Design, Data Analysis, and Implications for Dosing and Labeling (PDF - 253KB)
  9/2006
- Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP (PDF - 110KB)
  1/2006
- Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients (PDF - 230KB)
  5/2005
- Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (PDF - 734KB)
  9/2004
- Comparability Protocols - Protein Drug Products and Biological Products - Chemistry, Manufacturing, and Controls Information (PDF - 82KB)
  9/2003
- Comparability Protocols—Chemistry, Manufacturing, and Controls Information (PDF - 240KB)
  2/2003
- CVM GFI #153 Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (PDF - 88KB)
  9/2002
- Container Closure Systems for Packaging Human Drugs and Biologics—Questions and Answers (PDF - 15KB)
  5/2002
- IND Meetings for Human Drugs and Biologics Chemistry, Manufacturing, and Controls Information (PDF - 30KB)
  5/2001
- Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing (PDF - 30KB)
  3/2001
- Analytical Procedures and Methods Validation Chemistry, Manufacturing, and Controls Documentation (PDF - 91KB)
  8/2000
- Possible Dioxin/PCB Contamination of Drug and Biological Products (PDF - 8KB)
  8/1999
- Container Closure Systems for Packaging Human Drugs and Biologics (PDF - 164KB)
  5/1999
- Environmental Assessment of Human Drug and Biologics Applications (PDF - 188KB)
  7/1998
- Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients (PDF - 150KB)
  3/1998
- Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for a Therapeutic Recombinant DNA-Derived Product or a Monoclonal Antibody Product for In Vivo Use (PDF - 44KB)
  8/1996
- Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products (PDF - 57KB)
  11/1994
- Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test For Human and Animal Parenteral Drugs, Biological Products and Medical Devices (PDF - 2874KB)
  12/1987
- Guidance on Alternatives to Lot Release for Licensed Biological Products (PDF - 305KB)
  7/14/1993

Clinical

- Drug-Induced Liver Injury: Premarketing Clinical Evaluation (PDF - 206KB)
  7/2009
- Postmarketing Studies and Clinical Trials—Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act (PDF - 173KB)
  7/2009
- The Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application (PDF - 421KB)
  6/2009
- Animal Models—Essential Elements to Address Efficacy Under the Animal Rule (PDF - 135KB)
  2/2009
- Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs—Improving Human Subject Protection (PDF - 61KB)
  1/2009
- Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (PDF - 145KB)
  5/2007
- Computerized Systems Used in Clinical Trials (PDF - 53KB)
  5/2007

- Drug Interaction Studies—Study Design, Data Analysis, and Implications for Dosing and Labeling (PDF - 253KB)
  9/2006
- Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment (PDF - 205KB)
  6/2006
- Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable (PDF Version) (PDF - 65KB)
  4/25/2006
- The Establishment and Operation of Clinical Trial Data Monitoring Committees for Clinical Trial Sponsors
  3/2006
- Using a Centralized IRB Review Process in Multicenter Clinical Trials (PDF - 87KB)
  3/2006
- Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (PDF - 456KB)
  2/2006
- Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 127KB)
  2/2006
- Collection of Race and Ethnicity Data in Clinical Trials (PDF - 70KB)
  9/2005
- Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers (PDF - 702KB)
  7/2005
- Evaluating the Risks of Drug Exposure in Human Pregnancies (PDF - 3151KB)
  4/2005
- Premarketing Risk Assessment (PDF - 88KB)
  3/2005
- Development and Use of Risk Minimization Action Plans (PDF - 225KB)
  3/2005
- Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (PDF - 220KB)
  3/2005
- Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling (PDF - 363KB)
  2/2005
- Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (PDF - 211KB)
  12/2004
- Available Therapy (PDF - 176KB)
  7/2004
- Vaccinia Virus—Developing Drugs to Mitigate Complications from Smallpox Vaccination (PDF - 139KB)
  3/2004
- Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (PDF - 40KB)
  1/2004
- IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (PDF - 188KB)
  1/2004
- Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices (PDF Version) (PDF - 389KB)
  7/2003
- Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling (PDF - 222KB)
  5/2003
- Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications (PDF - 221KB)
  4/2003
- Establishing Pregnancy Exposure Registries (PDF - 268KB)
  8/2002
- Special Protocol Assessment (PDF - 36KB)
  5/2002
- FDA Guidance on Clinical Trial Data Monitoring Committees (DMC's) Open Public Meeting (PDF - 394KB)
  11/2001
- Cancer Drug and Biological Products - Clinical Data in Marketing Applications (PDF - 39KB)
  10/2001
- IDE Financial Disclosure
- Acceptance of Foreign Clinical Studies (PDF - 12KB)
  3/2001
- Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)) (PDF - 56KB)
  11/2000
- Submitting and Reviewing Complete Responses to Clinical Holds (Revised) (PDF - 26KB)
  10/2000
- Pediatric Oncology Studies In Response to a Written Request (PDF - 30KB)
  6/2000
- In Vivo Drug Metabolism/Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling (PDF - 44KB)
  11/2009
- Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (PDF - 40KB)
  7/1999
- Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (PDF - 369KB)
  2/1999
- Population Pharmacokinetics (PDF - 135KB)
  2/1999
- FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products (PDF - 58KB)
  12/1998

- General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products (PDF - 37KB) 11/1998
- Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (PDF - 129KB) 5/1998
- Pharmacokinetics in Patients with Impaired Renal Function (PDF - 128KB) 5/1998
- Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products (PDF - 42KB) 11/1995

Devices

- Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials (PDF Version) (PDF - 388KB)
- Guidance for Industry, FDA Staff, and Third Parties - Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria (PDF Version) (PDF - 175KB)
- Guidance for Industry and FDA Staff: User Fees and Refunds for Premarket Notification Submissions (510(k)s) (PDF Version) (PDF - 109KB)
- Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products (PDF - 112KB)
- Guidance for Industry and FDA Staff - Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process (PDF Version) (PDF - 180KB)
- Guidance for Industry and FDA Staff - Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process (PDF Version) (PDF - 180KB)
- Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals (PDF Version) (PDF - 155KB)
- Guidance for Industry and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers (PDF Version) (PDF - 196KB)
- Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements (PDF Version) (PDF - 103KB)
- Guidance for Industry and FDA Staff: Expedited Review of Premarket Submissions for Devices (PDF Version) (PDF - 127KB)
- In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions (PDF - 268KB)
- Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions (PDF Version) (PDF - 139KB)
- In Vitro Diagnostic Multivariate Index Assays (PDF version) (PDF - 72KB)
- Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission (PDF Version) (PDF - 145KB)
- Draft Guidance for Industry and FDA Staff - Annual Reports for Approved Premarket Approval Applications (PMA) (PDF Version) (PDF - 127KB)
- Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (PDF version) (PDF - 342KB)
- Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 127KB)
- Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable (PDF Version) (PDF - 65KB)
- Real-Time Premarket Approval Application (PMA) Supplements - Guidance for Industry and FDA Staff (PDF Version) (PDF - 82KB)
- Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
- Guidance for Industry and FDA Staff: Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA (PDF Version) (PDF - 97KB)
- Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices (PDF Version) (PDF - 389KB)
- Guidance for Industry and FDA Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment (PDF Version) (PDF - 515KB)
- Guidance for Industry and FDA Staff: Premarket Approval Application Modular Review (PDF Version) (PDF - 159KB)
- Guidance for Industry and FDA Staff: Premarket Approval Application Filing Review (PDF Version) (PDF - 529KB)
- Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products
- Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff - PDF (PDF - 548KB)
- Guidance for Industry, FDA Staff, and Third Parties - Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria (PDF Version) (PDF - 175KB)

Labeling & Promotion

- Content and Format of the Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products (PDF - 163KB)
- Contents of a Complete Submission for the Evaluation of Proprietary Names (PDF - 306KB)
- Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims (PDF - 295KB)
- Labeling for Human Prescription Drug and Biological Products—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information (PDF - 65KB)
- Presenting Risk Information in Prescription Drug and Medical Device Promotion (PDF - 387KB)
- Indexing Structured Product Labeling (PDF - 59KB)
- Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions (PDF Version) (PDF - 139KB)
- Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 52KB)
- Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 127KB)
- Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 58KB)
- Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements (PDF - 213KB)
- Providing Regulatory Submissions in Electronic Format—Content of Labeling (PDF - 28KB)
- Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling (PDF - 363KB)
- Guidance for Industry and FDA Staff: Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use (PDF Version) (PDF - 1385KB)
- Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (PDF - 192KB)
- "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (PDF - 188KB)
- Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling (PDF - 222KB)

- Content and Format for Geriatric Labeling (PDF - 38KB)
- Prescription Drug Advertising and Promotional Labeling (PDF - 28KB)
- In Vivo Drug Metabolism/Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling (PDF - 44KB)
- Consumer-Directed Broadcast Advertisements (PDF - 36KB)
- Accelerated Approval Products—Submission of Promotional Materials (PDF - 17KB)
- Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling (PDF - 86KB)
- Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements (PDF - 979KB)

Tissue Guidance Documents

- Draft Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components for Transfusion and Human Cells, Tissues, and Cellular and Tissue-Based Products
  3/2009
- Draft Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
  1/16/2009
- Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide
  8/24/2007
- Draft Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage
  7/6/2007
- Guidance for Industry and FDA Staff: Minimal Manipulation of Structural Tissue Jurisdictional Update
  9/20/2006
- Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation
  3/8/2002
- Draft Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
  4/25/2008
- Guidance for Industry: Certain Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Recovered from Donors Who Were Tested for Communicable Diseases Using Pooled Specimens or Diagnostic Tests
  4/16/2008
- Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products
  8/8/2007
- Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
  11/12/2004
- Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens
  6/23/2000
- Guidance for Industry: Compliance with 21 CFR Part 1271.150(c)(1)—Manufacturing Arrangements
  9/8/2006
- Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
  11/30/2005
- Draft Guidance for Industry: Cell Selection Devices for Point of Care Production of Minimally Manipulated Autologous Peripheral Blood Stem Cells (PBSCs)
  7/23/2007
- Guidance for Industry: Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container
  1/31/2007
- Draft Guidance for Industry: Minimally Manipulated, Unrelated, Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Hematological Malignancies
  1/16/2007
- Guidance for Industry: Screening and Testing of Donors of Human Tissue Intended for Transplantation (PDF - 59KB)

Vaccine Guidance Documents

- Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications (PDF - 406KB)
  3/2010
- Draft Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines
  09/2009
- Guidance for Industry: General Principles for the Development of Vaccines to Protect Against Global Infectious Diseases
  9/8/2008
- Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications
  10/29/2007
- Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials
  9/27/2007
- Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines
  5/31/2007
- Guidance for Industry: Clinical Data Needed to Support the Licensure of Seasonal Inactivated Influenza Vaccines
  5/31/2007
- Draft Guidance for Industry: Characterization and Qualification of Cell Substrates and Other Biological Starting Materials Used in the Production of Viral Vaccines for the Prevention and Treatment of Infectious Diseases
  9/28/2006
- Guidance for Industry: Development of Preventive HIV Vaccines for Use in Pediatric Populations
  5/4/2006
- Guidance for Industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications
  2/13/2006

- Draft Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications
  2/17/2005
- Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information
  10/1/2004
- Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines
  3/12/2001
- Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol
  11/20/2000
- Draft Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications
  9/8/2000
- Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product
  1/5/1999
- Guidance for Industry: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS-1) (PDF - 63KB)
  9/8/1998
- Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies (PDF - 49KB)
  4/10/1997

Xenotransplantation Guidance Documents

- Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans
  4/3/2003
- Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts
  2/1/2002
- Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts
  12/23/1999
- PHS Guideline on Infectious Disease Issues in Xenotransplantation
  1/19/2001
- Guidance For Industry: Public Health Issues Posed by the Use of Non-Human Primate Xenografts in Humans
  4/6/1999

III. Center for Drug Evaluation and Research (CDER)

For information on a specific guidance document or to obtain a paper copy, contact:

Division of Drug Information, Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993, 1–888–463–6332 or 301–796–3400, e-mail: *druginfo@fda.hhs.gov*, *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/default.htm*.

The following list of withdrawn CDER guidance documents was obtained from FDA's Web site on April 21, 2010:

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products under PDUFA	Procedural	Level 1	04/09/2010	Withdrawn
Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions during Development of Fast Track Products under PDUFA	Procedural	Level 1	04/09/2010	Withdrawn
Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions during Development of Fast Track Products under PDUFA; Paperwork Reduction Act Burden Statement	Procedural	Level 1	04/09/2010	Withdrawn
Clinical Evaluation of Lipid-Altering Agents	Clinical Medical Draft	Level 1	04/16/2010	Withdrawn

The following list of current CDER guidance documents was obtained from FDA's Web site on April 21, 2010:

Title and Format	Type	Issue Date
Advertising		
Accelerated Approval Products: Submission of Promotional Materials (PDF - 17 KB)	Draft	3/26/1999
Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling (PDF - 84 KB)	Final	12/1997
Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (PDF - 192 KB)	Draft	2/4/2004
• Labeling Example (PDF - 105 KB)		
• Labeling Example; Consumer-Friendly Version (PDF - 95KB)		

Title and Format	Type	Issue Date
Consumer-Directed Broadcast Advertisements (PDF - 36KB) Questions and Answers (PDF - 83 KB)	Final	8/1999
Consumer-Directed Broadcast Advertising of Restricted Devices (PDF - 41 KB)	Draft	1/26/2004
"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (PDF - 188 KB)	Draft	1/26/2004
Industry-Supported Scientific and Educational Activities (PDF - 429 KB)	Final	12/3/1997
Presenting Risk Information in Prescription Drug and Medical Device Promotion (PDF - 387 KB)	Draft	5/26/2009
Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling (PDF - 86KB)	Draft	1/1999
Biopharmaceutics		
Bioanalytical Method Validation (PDF - 63 KB)	Final	5/2001
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (PDF - 519 KB) • Statistical Information from the June 1999 Draft Guidance and Statistical Information for In Vitro Bioequivalence Data (PDF - 186 KB)	Draft	4/2/2003 4/11/2003
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (PDF - 268 KB)	Final	3/2003
Cholestyramine Powder in Vitro Bioequivalence (PDF - 35 KB) (Intermin Guidance)	Final	7/15/93
Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing (PDF - 78 KB)	Final	6/17/2005
Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence.	Draft Withdrawn FR Notice	8/12/2005
Corticosteroids, Dermatologic (topical) In Vivo (PDF - 3 MB) (Issued 6/2/1995, Posted 3/6/1998)	Final	6/2/1995
Dissolution Testing of Immediate Release Solid Oral Dosage Forms (PDF - 130 KB) (Issued 8/1997, Posted 8/25/1997)	Final	8/1997
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (PDF - 170 KB)	Final	9/1997
Food-Effect Bioavailability and Fed Bioequivalence Studies(PDF - 166 KB)	Final	12/2002
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro (PDF - 744 KB)	Final	6/27/1989
Potassium Chloride (slow-release tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing (PDF - 718 KB)	Final	6/6/1994
Statistical Approaches to Establishing Bioequivalence (PDF - 130 KB)	Final	2/2001
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System.(PDF - 143 KB).	Final	8/2000
CMC - Microbiology (Chemistry, Manufacturing, and Controls)		
Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products (PDF - 57 KB)	Final	11/1994
Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes (PDF - 76 KB)	Final	2/25/2010
Chemistry, Manufacturing, and Controls (CMC)		
Analytical Procedures and Methods Validation.(PDF - 91 KB)	Draft	8/2000
Assay Development for Immunogenicity Testing of Therapeutic Proteins (PDF - 161 KB)	Draft	12/3/2009
BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation 2/2001	Final	Withdrawn as per FR notice June 1, 2006
Botanical Drug Products (PDF - 437 KB)	Final	6/2004
Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products (PDF - 33 KB)	Final	7/1997
Changes to an Approved NDA or ANDA (PDF - 108 KB)	Final	4/2004
Changes to an Approved NDA or ANDA: Questions and Answers (PDF - 35 KB)	Final	1/2001
Changes to an Approved NDA or ANDA; Specifications—Use of Enforcement Discretion for Compendial Changes (PDF - 18 KB)	Final	11/19/2004
Comparability Protocols—Chemistry, Manufacturing, and Controls Information (PDF - 240 KB)	Draft	2/2003
Container Closure Systems for Packaging Human Drugs and Biologics (PDF - 164 KB) • [Container Closure Systems for Packaging Human Drugs and Biologics—Questions and Answers (PDF - 15 KB)	Final	5/1999 5/2002
Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products	Final	4/1996
Development of New Stereoisomeric Drugs	Final	5/1/1992
Drug Master Files Current DMF Information(e.g. lists, addresses, guidances, etc.)	Final	9/1/1989
Drug Master Files for Bulk Antibiotic Drug Substances (PDF - 23 KB)	Final	11/1999
Drug Product: Chemistry, Manufacturing, and Controls Information 1/2003	Draft	Withdrawn as per FR notice June 1, 2006
Drug Substance: Chemistry, Manufacturing, and Controls Information 1/2004	Draft	Withdrawn as per FR notice June 1, 2006
Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (PDF - 88 KB)	Draft	9/11/2003
Environmental Assessment of Human Drug and Biologics Applications (PDF - 188 KB)	Final	7/1998
Format and Content of the Chemistry, Manufacturing and Controls Section of an Application* 2/1987	Final	Withdrawn as per FR notice June 1, 2006
Format and Content for the CMC Section of an Annual Report (PDF - 29 KB)	Final	9/1/1994

Title and Format	Type	Issue Date
Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting (PDF - 79 KB)	Draft	7/13/2009
INDs for Phase 2 and Phase 3 Studies Chemistry, Manufacturing, and Controls Information (PDF - 193 KB)	Final	5/20/2003
IND Meetings for Human Drugs and Biologics Chemistry, Manufacturing, and Controls Information (PDF - 30 KB)	Final	5/2001
Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations (PDF - 26 KB)	Draft	7/24/1999
Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.(PDF - 45 KB)	Draft	7/2002
Monoclonal Antibodies Used as Reagents in Drug Manufacturing (PDF - 29 KB)	Final	3/2001
Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products (PDF - 361 KB)	Draft	11/13/1998
Nasal Spray and Inhalation Solution, Suspension, and Drug Products (PDF - 116 KB)	Final	7/2002
NDAs: Impurities in Drug Substances (PDF - 11 KB)	Final	2/2000
Orally Disintegrating Tablets (PDF - 52 KB)	Final	12/17/2008
PAC-ATLS: Postapproval Changes - Analytical Testing Laboratory Sites (PDF - 76 KB)	Final	4/28/1998
Residual Solvents in Drug Products Marketed in the United States (PDF - 52 KB)	Final	11/24/2009
Reviewer Guidance, Validation of Chromatographic Methods (PDF - 703 KB) (revised to include graphics, 5/14/2007)	Final	11/1994
The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE)(PDF - 790 KB)	Final	12/20/2000
Stability Testing of Drug Substances and Drug Products 6/5/1998	Draft	Withdrawn as per FR notice June 1, 2006
Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances 11/1994	Final	Withdrawn as per FR notice June 1, 2006
Submitting Documentation for the Manufacturing of and Controls for Drug Products*(PDF - 1.02 MB)	Final	2/1987
Submitting Documentation for the Stability of Human Drugs and Biologics* (Issued , Posted 3/2/1998)	Final	Withdrawn as per FR notice June 1, 2006
Submitting Samples and Analytical Data for Methods Validation	Final	2/1987
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances (PDF - 94 KB)	Final	2/1987
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 (PDF - 60 KB)	Final	11/1995
SUPAC-IR Questions and Answers about SUPAC-IR Guidance	Final	2/18/1997
SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum (PDF - 117 KB)	Final	1/1999
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 (PDF - 215 KB)	Final	Issued 10/6/1997
SUPAC-SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum (PDF - 61 KB)	Draft	12/1998
SUPAC-SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation (PDF - 118 KB)	Final	5/1997
Clinical / Antimicrobial		
Acute Bacterial Exacerbations of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment(PDF - 422 KB)	Draft	8/21/2008
Acute Bacterial Meningitis—Developing Antimicrobial Drugs for Treatment(PDF - 42 KB)	Draft	7/22/1998
Acute Bacterial Sinusitis—Developing Antimicrobial Drugs for Treatment (PDF - 155 KB)	Draft	10/29/2007
Acute or Chronic Bacterial Prostatitis—Developing Antimicrobial Drugs for Treatment (PDF - 42 KB)	Draft	7/22/1998
Acute Bacterial Otitis Media: Developing Drugs for Treatment (PDF - 173 KB)	Draft	1/17/2008
Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval (PDF - 41 KB)	Draft	10/12/2007
Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency (PDF - 208 KB) • Guidance for Submitting HIV Resistance Data (PDF - 293 KB) • Guidance for Submitting Influenza Resistance Data (PDF - 385 KB) • Guidance for Submitting HBV Resistance Data (PDF - 123 KB) • Guidance for Submitting HCV Resistance Data (PDF - 122 KB)	Final	6/2/2006
Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval (PDF - 254 KB)	Final	10/2002
Bacterial Vaginosis—Developing Antimicrobial Drugs for Treatment (PDF - 53 KB)	Draft	7/22/1998
Catheter-Related Bloodstream Infections - Developing Antimicrobial Drugs for Treatment (PDF - 54 KB)	Draft	10/1999
Clinical Development and Labeling of Anti-Infective Drug Products (PDF - 5 MB)	Final	10/1992 Revised 2/12/2001
Clinical Evaluation of Anti-Infective Drugs (Systemic)(PDF - 1 MB)	Final	9/77
Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment (PDF - 418 KB)	Draft	3/19/2009
Complicated Urinary Tract Infections and Pyelonephritis—Developing Antimicrobial Drugs for Treatment (PDF - 35 KB)	Draft	7/22/1998
Developing Antimicrobial Drugs—General Considerations for Clinical Trials (PDF - 134 KB) [Main Document]	Draft	7/22/1998
Developing Antimicrobial Drugs to Treat Inhalational Anthrax (Post Exposure)—(PDF - 51 KB)	Draft	3/15/2002
Empiric Therapy of Febrile Neutropenia—Developing Antimicrobial Drugs for Treatment (PDF - 33 KB)	Draft	7/22/1998
Evaluating Clinical Studies Of Antimicrobials In The Division Of Anti-Infective Drug Products (PDF - 267 KB)	Draft	2/18/1997

Title and Format	Type	Issue Date
Helicobacter pylori-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment (PDF - 145 KB)	Draft	10/2/2009
Influenza: Developing Drugs for Treatment and/or Prophylaxis(PDF - 225 KB)	Draft	2/19/2009
Lyme Disease—Developing Antimicrobial Drugs for Treatment (PDF - 42 KB)	Draft	7/22/1998
Microbiological Data for Systemic Antibacterial Drug Products—Development, Analysis, and Presentation (PDF - 272 KB)	Draft	9/16/2009
Nosocomial Pneumonia—Developing Antimicrobial Drugs for Treatment (PDF - 49 KB)	Draft	7/22/1998
Role of HIV Drug Resistance Testing in Antiretroviral Drug Development (PDF - 244 KB)	Final	10/30/2007
Secondary Bacterial Infections of Acute Bronchitis—Developing Antimicrobial Drugs for Treatment (PDF - 10 KB)	Draft	7/22/1998
Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention (PDF - 257 KB)	Draft	11/21/2007
Streptococcal Pharyngitis and Tonsillitis—Developing Antimicrobial Drugs for Treatment (PDF - 29 KB)	Draft	7/22/1998
Uncomplicated and Complicated Skin and Skin Structure Infections—Developing Antimicrobial Drugs for Treatment (PDF - 49 KB)	Draft	7/22/1998
Uncomplicated Gonorrhea—Developing Antimicrobial Drugs for Treatment (PDF - 30 KB)	Draft	7/22/1998,
Uncomplicated Urinary Tract Infections—Developing Antimicrobial Drugs for Treatment (PDF - 42 KB)	Draft	7/22/1998
Vaccinia Virus—Developing Drugs to Mitigate Complications from Smallpox Vaccination (PDF - 139 KB)	Draft	3/8/2004
Vulvovaginal Candidiasis—Developing Antimicrobial Drugs for Treatment (PDF - 42 KB)	Draft	7/22/1998
Clinical / Medical		
Acceptance of Foreign Clinical Studies (PDF - 12 KB)	Final	3/12/2001
Acne Vulgaris: Developing Drugs for Treatment (PDF - 284 KB)	Draft	9/16/2005
Adaptive Design Clinical Trials for Drugs and Biologics (PDF - 424 KB)	Draft	2/25/2010
Allergic Rhinitis: Clinical Development Programs for Drug Products (PDF - 68 KB)	Draft	6/2000
Antianxiety Drugs—Clinical Evaluation (PDF - 2 MB)	Final	9/1977
Antidepressant Drugs—Clinical Evaluation (PDF - 2 MB)	Final	9/1977
Assessment of Abuse Potential of Drugs (PDF - 138 KB)	Draft	1/26/2010
Available Therapy (PDF - 176 KB)	Final	7/22/2004
Calcium DTPA and Zinc DTPA Drug Products - Submitting a New Drug Application (PDF - 157 KB)	Final	8/13/2004
Cancer Drug and Biological Products - Clinical Data in Marketing Applications (PDF - 39 KB)	Final	10/11/2001
Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment(PDF - 205 KB)	Final	6/1/2006
Chronic Obstructive Pulmonary Disease: Developing Drugs for Treatment (PDF - 153 KB)	Draft	11/8/2007
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (PDF - 40 KB)	Draft	7/07/1999
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (PDF - 369 KB)	Final	1/1999
Clinical Evaluation of Analgesic Drugs (Withdrawn per August 5, 2003, Federal Register Notice)	Final	Withdrawn 8/5/2003
Clinical Evaluation of Antacid Drugs (Withdrawn per July 20, 2004, Federal Register notice.)	Final	Withdrawn 7/20/2004
Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children)	Final	Withdrawn 5/29/2008
Clinical Evaluation of Antidiarrheal Drugs (Withdrawn per July 20, 2004, Federal Register notice.)	Final Withdrawn	Withdrawn 7/20/2004
Clinical Evaluation of Antiepileptic Drugs (adults and children) (PDF - 1,007 KB)	Final	1/1981
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs (Withdrawn per July 20, 2004, Federal Register notice.)	Final Withdrawn	Withdrawn 7/20/2004
Clinical Evaluation of General Anesthetics (PDF - 890 KB)	Final	5/1982
Clinical Evaluation of Laxative Drugs (Withdrawn per July 20, 2004, Federal Register notice.)	Final Withdrawn	Withdrawn 7/20/2004
Clinical Evaluation of Lipid-Altering Agents (PDF - 36 KB)	Draft	Withdrawn 4/19/2010
Clinical Evaluation of Radiopharmaceutical Drugs (Withdrawn per July 20, 2004, Federal Register notice.)	Final Withdrawn	Withdrawn 7/20/2004
Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (PDF - 145 KB)	Final	5/15/2007
Collection of Race and Ethnicity Data in Clinical Trials (PDF - 70 KB)	Final	9/16/2005
Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products (PDF - 42 KB) ○ Questions and Answers: Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (PDF - 14 KB) (10/2000)	Final	11/1995
Developing Medical Imaging Drug and Biological Products • Part 1: Conducting Safety Assessments (PDF - 271 KB) • Part 2: Clinical Indications (PDF - 231 KB) • Part 3: Design, Analysis, and Interpretation of Clinical Studies(PDF - 307 KB)	Final	6/17/2004
Developing Products for Weight Management Revision 1 (PDF - 150 KB)	Draft	2/14/2007
Development and Use of Risk Minimization Action Plans (PDF - 225 KB)	Final	3/24/2005
Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis (PDF - 20 KB)	Draft	5/2000
Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention (PDF - 265 KB)	Draft	2/29/2008
Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes (PDF - 51 KB)	Final	12/17/2008
Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (PDF - 88 KB)	Draft	9/6/2002
Establishing Pregnancy Exposure Registries (PDF - 268 KB)	Final	8/2002
Establishment and Operation of Clinical Trial Data Monitoring Committees (PDF - 333 KB)	Final	3/27/2006

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Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommendations for Clinical Evaluation (PDF - 198 KB)	Draft	1/2003
Evaluating the Risks of Drug Exposure in Human Pregnancies (PDF - 3 MB)	Final	4/27/2005
Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB (PDF - 27 KB)	Draft	2/2002
Exocrine Pancreatic Insufficiency Drug Products—Submitting New Drug Applications(PDF - 149 KB)	Final	4/13/2006
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment (PDF - 23 KB)	Draft	5/2000
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products (PDF - 58 KB)	Final	12/1998
FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer (PDF - 2 MB)	Final	Posted 3/2/1998
FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer (Withdrawn per July 20, 2004, Federal Register notice.)	Final Withdrawn	Withdrawn 7/20/2004
Format and Content of the Clinical and Statistical Sections of an Application (PDF - 1 MB)	Final	7/1988
Formatting, Assembling and Submitting New Drug and Antibiotic Applications* (PDF - 2 MB)	Final	2/1987
General Considerations for the Clinical Evaluation of Drugs (PDF - 1 MB)	Final	
General Considerations for the Clinical Evaluation of Drugs in Infants and Children (PDF 2 MB)	Final	9/77
Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention (PDF -91KB)	Draft	6/24/ 2005
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (PDF - 220 KB)	Final	3/24/2005
Guidance for Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees (PDF - 333KB)	Final	3/27/2006
Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (PDF - 2 MB)	Draft	8/29/2006
Guidance for the Development of Vaginal Contraceptive Drugs (NDA)(PDF - 465 KB)	Final	3/2/1998
Hypnotic Drugs—Clinical Evaluation (PDF - 2MB)	Final	9/77
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (PDF - 188 KB)	Final	Revised 1/15/2004
Inhalation Drug Products Packaged in Semipermeable Container Closure Systems (PDF - 27 KB)	Draft	7/2002
Integration of Dose-Counting Mechanisms into MDI Drug Products (PDF - 126 KB)	Final	3/2003
Internal Radioactive Contamination—Development of Decorporation Agents (PDF - 177 KB)	Final	3/1/2006
Irritable Bowel Syndrome—Clinical Evaluation of Products for Treatment (PDF 221 KB)	Draft	3/22/2010
Levothyroxine Sodium Tablets - In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing (PDF - 27 KB)	Final	2/2001
Local Anesthetics—Clinical Evaluation (PDF - 1 MB	Final	3/2/1998
Malaria: Developing Drug and Nonvaccine Biological Products for Treatment and Prophylaxis (PDF - 344 KB)	Draft	6/6/2007
MDI and DPI Drug Products—Clinical Development Programs for (PDF - 699 KB)	Final	9/19/1994
Non-Inferiority Clinical Trials (PDF - 565 KB)	Draft	2/26/2010
Pediatric Use Supplements—Content and Format (PDF - 24 KB)	Final	5/1996
Oncologic Drugs Advisory Committee Discussion on FDA Requirements or Approval of New Drugs for Treatment of Colon and Rectal Cancer (PDF - 2 MB)	Final	Posted 3/2/1998
Orally Inhaled and Intranasal Corticosteroids: Evaluation of the Effects on Growth in Children (PDF - 247 KB)	Final	3/5/2007
OTC Treatment of Herpes Labialis with Antiviral Agents (PDF - 15 KB)	Draft	Withdrawn 3/18/2010
Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims (PDF -295 KB)	Final	12/8/2009
Pediatric Oncology Studies In Response to a Written Request (PDF - 30 KB)	Draft	6/2000
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report (PDF - 95 KB)	Final	8/27/1997
Postmarketing Reporting of Adverse Drug Experiences (PDF - 7 MB)	Final	3/1992
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis (PDF - 50 KB) Withdrawn	Draft Withdrawn	Withdrawn 12/2009
Premarketing Risk Assessment(PDF - 88 KB)	Final	3/24/2005
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (PDF - 129 KB)	Final	5/14/1998
Prussian Blue Drug Products—Submitting a New Drug Application (PDF - 178 KB)	Final	1/2003
Psychoactive Drugs in Infants and Children—Clinical Evaluation (PDF - 18 MB)	Final	3/2/1998
The Radioactive Drug Research Committee: Human Research Without An Investigational New Drug Application (PDF - 421 KB)	Draft	6/2/2009
Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)) (PDF - 56 KB)	Draft	Posted 12/1/2000
Sinusitis: Designing Clinical Development Programs of Nonantimicrobial Drugs for Treatment (PDF - 113 KB)	Draft	Posted 11/21/2006
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (PDF - 2 MB)	Final	7/22/1993
Study of Drugs Likely to be used in the Elderly (PDF - 1MB)	Final	11/1989
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (PDF - 43 KB)	Final	8/1999
Summary for New Drug and Antibiotic Applications—Format and Content of the Summary for New Drug and Antibiotic Applications (PDF - 1 MB)	Final	2/1987
Systemic Lupus Erythematosus—Developing Drugs for Treatment (PDF - 403 KB)	Draft	3/28/2005
The Use of Clinical Holds Following Clinical Investigator Misconduct (PDF - 33 KB)	Final	9/2004
Waiver of IRB Requirements for Drug and Biological Product Studies (PDF - 33 KB)	Final	1/2006
Clinical Pharmacology		
Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling (PDF - 363 KB)	Draft	Issued 2/7/05
Drug Interaction Studies—Study Design, Data Analysis, and Implications for Dosing and Labeling (PDF - 253 KB)	Draft	Issued 9/11/2006

Title and Format	Type	Issue Date
Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (PDF - 109 KB)	Final	4/1997
Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications (PDF - 221 KB)	Final	5/5/2003
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application (PDF - 519 KB)	Final	2/1987
General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products (PDF - 37 KB)	Draft	11/1998
In Vivo Drug Metabolism/Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling (PDF - 44 KB)	Final	11/24/1999
Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling (PDF - 151 KB)	Draft	3/17/2010
Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling (PDF - 222 KB)	Final	Posted 5/30/2003
Pharmacokinetics in Patients with Impaired Renal Function (PDF - 128 KB)	Final	5/14/1998
Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling (PDF - 324 KB)	Draft	10/29/2004
Population Pharmacokinetics (PDF - 135 KB)	Final	2/1999
Combination Products		
Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies (PDF - 120 KB) • Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies -Companion Document (PDF - 295 KB)		
Current Good Manufacturing Practices (CGMPs)/Compliance		
Bar Code Label Requirements—Questions and Answers (PDF - 101 KB)	Final	10/5/2006
Comparability Protocols - Protein Drug Products and Biological Products - Chemistry, Manufacturing, and Controls Information (PDF - 82 KB)	Draft	9/3/2003
Compressed Medical Gases	Final	2/1989
Computerized Systems Used in Clinical Investigations (PDF - 53 KB)	Final	5/10/2007
Current Good Manufacturing Practice for Combination Products (PDF - 350 KB)	Draft	9/29/2004
Current Good Manufacturing Practice for Medical Gases (PDF - 437 KB)	Draft	5/6/2003
Current Good Manufacturing Practice for Phase 1 Investigational Drugs (PDF - 132 KB)	Final	7/14/2008
Dosage Delivery Devices for OTC Liquid Drug Products (PDF -93 KB)	Draft	11/04/2009
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (PDF - 88 KB)	Final	6/27/1997
Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide (PDF - 19 KB)	Draft	5/27/2005
Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP (PDF - 110 KB)	Final	1/11/2006
General Principles of Process Validation	Final	5/1987
Good Laboratory Practice Regulations Questions and Answers (PDF - 2 MB)	Final	3/2/1998
Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities - FDA Public Health Advisory (PDF - 19 KB)	Final	4/5/2001
Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (21 CFR 50.24) (PDF - 3 MB) Draft released for comment	Draft	8/29/2006
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 (PDF - 4 MB)	Final	Posted 3/2/1998
Investigating Out-of-Specification Test Results for Pharmaceutical Production (PDF - 98 KB)	Final	10/11/2006
Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients (PDF - 150 KB)	Draft	4/17/1998
Marketed Unapproved Drugs—Compliance Policy Guide (PDF - 66 KB)	Final	6/8/2006
Monitoring of Clinical Investigations (PDF - 433 KB)	Final	Posted 3/2/1998
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment (PDF - 3 MB)	Final	Posted 3/2/1998
Part 11, Electronic Records; Electronic Signatures—Scope and Application (PDF - 215 KB)	Final	9/3/2003
PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance (PDF - 315 KB)	Final	9/29/2004
PET Drug Products - Current Good Manufacturing Practice (CGMP) (PDF - 399 KB)	Final	9/15/2005
Pharmaceutical Components at Risk for Melamine Contamination (PDF - 137 KB)	Final	8/6/2009
Pharmacy Compounding—Compliance Policy Guide (PDF - 793 KB)	Final	5/2002
Possible Dioxin/PCB Contamination of Drug and Biological Products (PDF - 8 KB)	Final	8/23/1999
Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment (PDF - 297 KB) • Revised Attachments (PDF - 159 KB)	Draft	11/2003
Preparation of Investigational New Drug Products (Human and Animal)(PDF - 795 KB)	Final	11/1992
Prescription Drug Marketing Act—Donation of Prescription Drug Samples to Free Clinics (PDF - 38 KB) • Prescription Drug Marketing Act (PDMA) Requirements- Questions and Answers (PDF - 112 KB) (Issued and Posted 11/13/2006)	Final	3/2006
Process Validation: General Principles and Practices (PDF - 194 KB)	Draft	11/17/2008
Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations (PDF - 443 KB)	Final	9/27/2006
Questions and Answers on Current Good Manufacturing Practices (cGMP) for Drugs(updated 6/29/2009	Final	8/4/2004
Review of FDA's Implementation of the Drug Export Amendments of 1986 (PDF - 2 MB)	Final	11/1989
Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice (PDF - 734 KB)	Final	9/29/2004
Street Drug Alternatives (PDF - 11 KB)	Final	3/2000
Testing of Glycerin for Diethylene Glycol (PDF - 36 KB)	Final	5/1/2007

Title and Format	Type	Issue Date
The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2—Current Good Manufacturing Practice (CGMP)(PDF - 38 KB)	Final	1/26/2010
Drug Safety		
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review (PDF - 1516 KB)	Final	2/2005
Drug-Induced Liver Injury: Premarketing Clinical Evaluation (PDF - 206 KB)	Final	7/29/2009
Drug Safety Information - FDA's Communication to the Public (PDF - 114 KB)	Final	3/2/2007
Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications (PDF - 316 KB)	Draft	9/30/2009
Postmarketing Studies and Clinical Trials—Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act (PDF - 173 KB)	Draft	7/15/2009
Electronic Submissions		
Indexing Structured Product Labeling (PDF - 59 KB)	Final	6/2/2008
Part 11, Electronic Records; Electronic Signatures—Scope and Application (PDF - 215 KB)	Final	9/3/2003
Providing Regulatory Submissions in Electronic Format—ANDAs	Final	6/2002
Withdrawn FR Notice 10/5/2006	Withdrawn FR Notice	
Providing Regulatory Submissions in Electronic Format -Annual Reports for NDAs and ANDAs	Draft	Posted
Withdrawn FR Notice 10/5/2006	Withdrawn FR Notice	8/27/2003
Providing Regulatory Submissions in Electronic Format—Content of Labeling (PDF - 28 KB)	Final	4/20/2005
Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing (PDF - 123 KB)	Final	5/28/2009
Providing Regulatory Submissions in Electronic Format -Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications(PDF - 133 KB) To ensure that you have the most recent versions of the specifications referenced in this document, check the appropriate center's Web page. CBER Topics page. CDER Topics page.	Final	Revised 06/11/2008
Providing Regulatory Submissions in Electronic Format -General Considerations (PDF - 288 KB) (Issued, Posted 10/22/2003)	Draft	10/2003
Providing Regulatory Submissions in Electronic Format-Postmarketing Individual Case Safety Reports (PDF - 107 KB) To ensure that you have the most recent versions of the specifications referenced in this document, check the appropriate center's Web page. CBER Topics page. CDER Topics page.	Draft	6/11/2008
Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising and Promotional Labeling (PDF - 28 KB)	Draft	1/2001
Providing Regulatory Submissions in Electronic Format—Receipt Date (PDF - 59 KB)	Draft	6/4/2007
Regulatory Submissions in Electronic Format; General Considerations (PDF - 54 KB)	Final	1/1999
Regulatory Submissions in Electronic Format; New Drug Applications	Final	1/1999
Withdrawn FR Notice 10/5/2006	Withdrawn FR Notice	
SPL Standard for Content of Labeling Technical Qs & As (PDF - 58 KB)	Draft	10/2009
FDAAA (Food and Drug Administration Amendments Act)		
Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 4020) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007 (PDF - 314 KB)	Draft	4/2008
Generics		
180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day (PDF - 162 KB)	Final	7/2003
Alternate Source of the Active Pharmaceutical Ingredient in Pending ANDAs (PDF - 14 KB)	Final	12/2000
ANDAs: Impurities in Drug Products (PDF - 104 KB)	Draft	8/26/2005
ANDAs: Impurities in Drug Substances (PDF - 136 KB)	Final	7/15/2009
ANDAs:Pharmaceutical Solid Polymorphism: Chemistry, Manufacturing, and Controls Information (PDF - 125 KB)	Final	7/6/2007
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (PDF - 25 KB)	Final	3/2000
Handling and Retention of Bioavailability and Bioequivalence Testing Samples (PDF - 166 KB)	Final	5/25/2004
Individual Product Bioequivalence Recommendations (PDF - 45 KB)	Draft	5/30/2007
List of Product Bioequivalence Recommendations		
Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past. (PDF - 194 KB)	Final	8/1995
Letter describing efforts by the CDER and the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new and abbreviated drug approval process in order to reduce duplication or redundancy in the process (PDF - 274 KB)	Final	10/1994
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 (PDF - 1915 KB)	Final	4/1994
Letter on the Provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters (PDF - 254 KB)	Final	7/1992
Letter on the provision of new procedures and policies affecting the generic drug review process (PDF - 608 KB)	Final	3/1989
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 (PDF - 917 KB)	Final	11/1990
Letter on the response to 12/20/1984 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act(PDF - 392 KB)	Final	3/1985

Title and Format	Type	Issue Date
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 (PDF - 233 KB)	Final	1/1993
Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria and bioequivalence requirements (PDF - 908 KB)	Final	8/1993
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 (PDF - 57 KB)	Draft	10/2004
Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications (PDF - 24 KB)	Final	12/2001
Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing (PDF - 48 KB)	Final	10/25/2005
Revising ANDA Labeling Following Revision of the RLD Labeling (PDF - 19 KB)	Final	4/26/2000
Submission of Summary Bioequivalence Data for Abbreviated New Drug Applications (PDF - 183 KB)	Draft	4/16/2009
Variations in Drug Products that May Be Included in a Single ANDA (PDF - 107 KB)	Final	12/1998
Good Review Practices		
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review (PDF - 1516 KB)	Final	2/2005
Guidance for Sponsors, Industry, Researchers, Investigators, and Food and Drug Administration Staff : Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007	Final	1/21/2009
Pharmacology/Toxicology Review Format (PDF - 55 KB)	Final	5/2001
International Conference on Harmonisation - Efficacy		
E1A The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions (PDF - 17 KB)	Final	3/1995
E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (PDF - 49 KB)	Final	3/1995
E2B International Conference on Harmonisation; Guidance on Data Elements for Transmission of Individual Case Safety Reports (PDF - 69 KB)	Final	1/15/1998
• E2BM Data Elements for Transmission Of Individual Case Safety Reports (PDF - 74 KB) (Issued 4/2002, Posted 4/4/2002)		
○ E2B(M) Questions and Answers (PDF - 55 KB) (Revised 3/09/2005, Posted, 3/16/2005)		
E2B(R) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (PDF - 269 KB) (Issued , Posted 9/30/2005)	Draft	9/30/2005
E2C(R1) Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs Note: In November 2005, the ICH incorporated the E2C addendum with the E2C parent guidance and retitled the combined document E2C(R1). The contents of the two guidances were not revised.		
• E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (PDF - 169 KB)	Final	5/19/1997
• E2C Addendum to ICH E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (PDF - 35 KB)	Final	2/5/2004
E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting (PDF - 184 KB)	Draft	9/12/2003
E2E Pharmacovigilance Planning (PDF - 73 KB)	Final	3/31/05
E2F Development Safety Update Report (PDF - 118 KB)	Draft	8/4/2008
E3 Structure and Content of Clinical Study Reports (PDF - 240 KB)	Final	7/1996
E4 Dose-Response Information to Support Drug Registration (PDF - 49 KB)	Final	7/1996
E5 Ethnic Factors in the Acceptability of Foreign Clinical Data		
• E5 Questions and Answers (PDF - 48 KB) [Issued 9/27/2006; Posted 9/28/2006]	Final	6/2004
E6 Good Clinical Practice: Consolidated Guideline (PDF - 262 KB)	Final	5/9/1997
Spanish Version (PDF - 151 kb)		
E7 Studies in Support of Special Populations: Geriatrics (PDF - 25 KB)	Final	8/1994
E7 Studies in Support of Special Populations; Geriatrics; Questions and Answers (PDF - 125 KB)	Draft	11/9/2009
E8 General Considerations for Clinical Trials (PDF - 67 KB)	Final	12/1997
E9 Statistical Principles for Clinical Trials (PDF - 110 KB)	Final	9/1/1998
E10 Choice of Control Group and Related Issues in Clinical Trials (PDF - 93 KB)	Final	5/2001
E11 Clinical Investigation of Medicinal Products in the Pediatric Population (PDF - 60 KB)	Final	12/2000
E12A Principles for Clinical Evaluation of New Antihypertensive Drugs. (PDF - 27 KB)	Draft	8/2000
E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (PDF - 67 KB)	Final	10/19/2005
Questions and Answers (PDF - 108 KB)		11/18/2008
E15 Pharmacogenomics Definitions and Sample Coding (PDF - 90 KB)	Final	4/7/2008
E16 Genomic Biomarkers Related to Drug Response: Context, Structure, and Format of Qualification Submissions (PDF - 135 KB)	Draft	7/30/2009
International Conference on Harmonisation - Joint Safety/Efficacy (Multidisciplinary)		
M2 eCTD: Electronic Common Technical Document Specification (PDF - 1,020 KB)	Final	4/1/2003
• M2: eCTD Specification Questions and Answers and Change Requests (PDF 17 KB)		3/14/05
• Companion Document: Current Q & As and Change Requests		7/10/2008
M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (PDF - 295 KB)	Final	1/20/2010
M4: Common Technical Document for the Registration of Pharmaceuticals for Human Use	Final	Originally Issued 10/15/2001
• M4: Organization of the CTD (PDF - 31 KB)		

Title and Format	Type	Issue Date
• M4 Granularity Annex (PDF - 124 KB) (Issued 10/18/2005, Posted 10/18/2005) • M4: The CTD—General Questions and Answers (PDF - 29 KB) (Issued 12/04, Posted 12/22/2004) • M4: The CTD—Quality (PDF - 79 KB) • M4: The CTD—Quality Questions and Answers /Location Issues (PDF - 49 KB) (Issued 6/2004, Posted 6/8/2004) • M4: The CTD—Efficacy (PDF - 156 KB) • M4: The CTD—Efficacy Questions and Answers (PDF - 34 KB) (Issued 12/2004, Posted 12/22/2004) Clarification for Q&A 10 on submitting integrated summaries of safety and effectiveness (ISS/ISE) in the eCTD format [esrs/eCTD page]. • M4: The CTD—Safety (PDF - 60 KB) • M4: The CTD—Safety Appendices (PDF - 178 KB) ○ M4: The CTD—Safety Questions and Answers (PDF - 16 KB) (Issued 2/2003, Posted 2/4/2003)		
M5 International Conference on Harmonisation; Draft Guidance on M5 Data Elements and Standards for Drug Dictionaries (PDF - 288 KB)	Draft	9/2005
Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (PDF - 50 KB)	Draft	9/2001
International Conference on Harmonisation - Quality		
Q1A(R2) Stability Testing of New Drug Substances and Products (PDF - 58 KB)	Final	11/2003
Q1B Photostability Testing of New Drug Substances and Products (PDF - 339 KB)	Final	11/1996
Q1C Stability Testing for New Dosage Forms (PDF - 101 KB)	Final	5/9/1997
Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products (PDF - 31 KB)	Final	1/2003
Q1E Evaluation of Stability Data (PDF - 221 KB)	Final	6/2004
Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV, revision 1	Final	Withdrawn 7/6/2006
Q2(R1) Validation of Analytical Procedures: Text and Methodology Note: In November 2005, the ICH incorporated Q2B on methodology with the parent guidance Q2A and retitled the combined Q2 document. The contents of the two guidances were not revised.		
• Q2A Text on Validation of Analytical Procedures (PDF - 25 KB)	Final	3/1995
• Q2B Validation of Analytical Procedures: Methodology (PDF - 132 KB)	Final	5/19/1997
Q3A(R) Impurities in New Drug Substances (PDF - 55 KB)	Final	6/6/2008
Q3B(R) Impurities in New Drug Products (Revision 2)(PDF - 171 KB)	Final	8/4/2006
Q3C Impurities: Residual Solvents (PDF - 41 KB)	Final	12/24/1997
Q3C Tables and List (PDF - 33 KB)	Final	11/12/2003
• Appendix 4 (PDF - 120 KB); Appendix 5 (PDF - 216 KB); Appendix 6 (PDF - 128 KB) (Appendices were issued with the Q3C draft guidance documents) Maintenance Procedures for Updating	Final	2/11/2002
Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions (PDF - 55 KB)	Final	2/20/2007
• Annex I: Residue on Ignition/Sulphated Ash General Chapter (PDF - 36 KB)	Final	2/20/2007
• Annex 2: Test for Extractable Volume of Parenteral Preparations General Chapter (PDF - 79 KB)	Final	1/8/2009
• Annex 3: Test for Particulate Contamination: Subvisible Particles General Chapter (PDF - 1208 KB)	Final	1/8/2009
• Annex 4A: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter (PDF - 81 KB)	Final	4/7/2009
• Annex 4B: Microbiological Examination of Non-Sterile Products: Tests for Specified Micro-organisms General Chapter (PDF - 82 KB)		
• Annex 4C: Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter (PDF - 75 KB)		
• Annex 5: Disintegration Test General Chapter (PDF - 32 KB)	Final	12/22/2009
• Annex 6:Uniformity of Dosage Units General Chapter (PDF - 87 KB)	Final	4/2/2010
• Annex 7:Dissolution Test General Chapter (PDF - 93 KB)		
• Annex 8: Sterility Test General Chapter (PDF - 32 KB)	Final	12/22/2009
• Annex 9: Tablet Friability General Chapter (PDF - 84 KB)	Final	4/2/2010
• Annex 10: Polyacrylamide Gel Electrophoresis General Chapter (PDF - 84 KB)	Final	4/9/2010
• Annex 11: Capillary Electrophoresis General Chapter (PDF - 90 KB)		
• Annex 12: Analytical Sieving General Chapter (PDF - 313 KB)	Draft	12/16/2009
Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin (PDF - 71 KB)	Final	Posted 9/1998
Q5B Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products (PDF - 109 KB)	Final	2/1996
Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products (PDF - 70 KB)	Final	7/1996
Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability (PDF - 52 KB)34 (Issued , Posted 9/21/1998)	Final	9/21/1998
Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process (PDF - 58 KB)	Final	6/2005
Q6A International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances.	Final	12/29/2000
Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (PDF - 64 KB)	Final	8/1999
Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (PDF - 175 KB) Note: In November 2005, the ICH redesignated this guidance. Q7 The guidance was not revised.	Final	8/2001
Q8(R2) Pharmaceutical Development (PDF - 402 KB)	Final	11/20/2009

Title and Format	Type	Issue Date
Q9 Quality Risk Management (PDF - 113 KB)	Final	6/1/2006
Q10 Pharmaceutical Quality System (PDF - 274 KB)	Final	4/7/2009
International Conference on Harmonisation - Safety		
S1A The Need for Long-term Rodent Carcinogenicity Studies of Pharmaceuticals (PDF - 100 KB)	Final	3/1996
S1B Testing for Carcinogenicity of Pharmaceuticals (PDF - 145 KB)	Final	2/28/1998
S1C(R2) Dose Selection for Carcinogenicity Studies of Pharmaceuticals (PDF - 185 KB)	Final	9/17/2008
S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals (PDF - 123 KB)	Final	4/1996
S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals (PDF - 131 KB)	Final	11/21/1997
S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use(PDF - 242 KB)	Draft	3/24/2008
S3A Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies (PDF - 46 KB)	Final	3/1995
S3B Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies (PDF - 14 KB)	Final	3/1995
S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)(PDF - 21 KB)	Final	Posted 6/25/99
S5(R2) Detection of Toxicity to Reproduction for Medicinal Products Toxicity to Male Fertility Note: In November 2005, the ICH incorporated the S5B addendum with S5A and retitled the combined S5 document. The contents of the two guidances were not revised.		
• S5A Detection of Toxicity to Reproduction for Medicinal Products (PDF - 87 KB)	Final	9/1994
• S5B Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility (PDF - 98 KB)	Final	4/1996
S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (PDF - 137 KB)	Final	11/1997
• Addendum to ICH S6:(PDF - 160 KB) Preclinical Safety Evaluation of Biotechnology -Derived Pharmaceuticals S6(R1)	Draft	12/16/2009
S7A Safety Pharmacology Studies for Human Pharmaceuticals (PDF - 44 KB)	Final	7/2001
S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (PDF - 52 KB)	Final	10/19/2005
S8 Immunotoxicity Studies for Human Pharmaceuticals (PDF - 72 KB)	Final	4/12/2006
S9 Nonclinical Evaluation for Anticancer Pharmaceuticals (PDF - 170 KB)	Final	3/5/2010
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 (PDF - 42 KB)	Final	11/1995
• Questions and Answers: Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (PDF - 14 KB) (10/2000)		
Exploratory IND Studies (PDF - 220 KB)	Final	1/12/2006
Labeling		
Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 52 KB)	Final	1/18/2006
Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 144 KB)	Draft	3/3/2009
Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format(PDF - 127 KB)	Final	1/18/2006
Content and Format for Geriatric Labeling (PDF - 38 KB)	Final	10/2001
Contents of a Complete Submission for the Evaluation of Proprietary Names (PDF - 306 KB)	Final	2/5/2010
Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products - Content and Format (PDF - 143 KB)	Final	3/22/2010
Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims (PDF - 53 KB)	Draft	3/12/2008
Labeling for Combined Oral Contraceptives (PDF - 92 KB)	Draft	3/2/2004
Labeling for Human Prescription Drugs—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information (PDF - 66 KB)	Final	10/16/2009
Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements (PDF - 213 KB)	Draft	1/18/2006
Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis) (PDF - 71 KB)	Draft	6/1998
Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommended Prescribing Informtion for Health Care Providers and Patient Labeling (PDF - 458 KB)	Draft	11/15/2005
Public Availability of Labeling Changes in "Changes Being Effected" Supplements (PDF - 26 KB)	Draft	9/19/2006
Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications (PDF - 32 KB)	Draft	10/26/2000
Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices (PDF - 188 KB)	Final	6/26/2009
Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format (PDF - 58 KB)	Draft	1/18/2006
Microbiology		
Format and Content of the Microbiology Section of an Application* (PDF - 546 KB)	Final	1990
Modernization Act		
Changes to an Approved NDA or ANDA (PDF - 108 KB)	Final	4/2004
Classifying Resubmissions in Response to Action Letters (PDF - 76 KB)	Final	5/14/1998
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act	Final	Withdrawn 9/2008
Fast Track Drug Development Programs - Designation, Development, and Application Review (PDF - 311 KB) (Posted 7/22/2004) Appendix 2 [(PDF - 3930 KB)] [Appendices are scanned copies, which will be replaced by final versions]	Final	11/17/1998
Formal Dispute Resolution: Appeals Above the Division Level(PDF - 30 KB)	Final	2/2000
Formal Meetings With Sponsors and Applicants for PDUFA Products (PDF - 89 KB)	Final	5/19/2009

Title and Format	Type	Issue Date
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997–Advisory Committees (PDF - 62 KB)	Final	10/1998
Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements (PDF - 979 KB)	Final	7/1998
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions(PDF - 34 KB)	Final	3/2002
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (PDF - 40 KB)	Draft	1/2004
National Uniformity for Nonpresciption Drugs - Ingredient Listing for OTC Drugs (PDF - 74 KB)	Final	4/1998
PET Drug Applications - Content and Format for NDAs and ANDAs (PDF - 153 KB)	Draft	3/7/2000
• Sample formats for chemistry, manufacturing, and controls sections (PDF - 125 KB)		
• Sample formats for labeling (PDF - 94 KB)		
• Sample formats for Form FDA 356h (PDF - 51 KB)		
• Sample formats for user fee Form FDA 3397(PDF - 42 KB)		
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (PDF - 129 KB)	Final	5/14/1998
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act (PDF - 57 KB)	Final	9/1999
• Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric "Rule," and Their Interaction		Posted 7/27/1999
Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act (PDF - 85 KB)	Final	Revised 5/1998
Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (PDF - 456 KB)	Final	2/15/2006
Standards for Prompt Review of Efficacy Supplements (PDF - 76 KB)	Final	5/15/1998
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (PDF - 43 KB)	Final	8/1998
Submitting and Reviewing Complete Responses to Clinical Holds (Revised) (PDF - 26 KB)	Final	10/2000
Over-the-Counter		
Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16)(PDF - 294 KB)	Final	5/1984
General Guidelines for OTC Combination Products (PDF - 270 KB)	Final	11/1978
Label Comprehension Studies for Nonprescription Drug Products (PDF - 204 KB)	Draft	4/30/2009
Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvo-vaginal Candidiasis) (PDF - 71 KB)	Draft	6/1998
Labeling OTC Human Drug Products—Questions and Answers (PDF - 599 KB)	Final	1/2/2009
Labeling OTC Human Drug Products -Submitting Requests for Exemptions and Deferrals (PDF - 34 KB)	Draft	12/2000
Labeling OTC Human Drug Products; Small Entity Compliance Guide (PDF - 270 KB)	Final	5/12/2009
Labeling OTC Human Drug Products Updating Labeling in ANDAs (PDF - 32 KB)	Draft	2/21/2001
• Additional examples 1 (PDF - 32 KB) (3/19/2001)		
• Additional examples 2 (PDF - 15 KB) (3/26/2001)		
• Additional examples 3 (PDF - 17 KB) (3/26/2001)		
Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs (PDF - 30 KB)	Final	10/2002
Example Drug Facts Labels		
• Acetaminophen 120 mg in a Suppository Dosage Form (PDF - 13 KB)		
• Acetaminophen 325 mg in a Suppository Dosage Form (PDF - 14 KB)		
• Acetaminophen 650 mg in a Suppository Dosage Form (PDF - 14 KB)		
• Cimetidine 200 mg in a Tablet Dosage Form (PDF - 13 KB)		
• Clemastine Fumerate 1.34 mg in a Tablet Dosage Form(PDF - 14 KB)		
• Doxylamine Succinate 25 mg Tablet Dosage Form (PDF - 12 KB)		
• Ibuprofen 200 mg in a Tablet/Capsule Dosage Form (PDF - 14 KB)		
• Loperamide HCl in a Liquid Dosage Form (PDF - 15 KB)		
• Loperamide HCl in a Tablet/Caplet Dosage Form (PDF - 15 KB)		
• Miconazole Nitrate Vaginal Products (PDF - 16 KB)		
• Minoxidil Topical Solution 2% for Men and Women (PDF - 14 KB)		
• Minoxidil Topical Solution 5% for Men (PDF - 17 KB)		
• Naproxen Sodium 220 mg in a Tablet/Caplet/Gelcap Dosage Form (PDF - 14 KB)		
• Pseudoephedrine HCl Extended-Release Tablets 120 mg (PDF - 15 KB)		
Labeling OTC Human Drug Products Using a Column Format (PDF - 57 KB)	Final	12/2000
Labeling OTC Skin Protectant Drug Products (PDF - 274 KB)	Draft	Removed 3/18/2010
Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application (PDF - 298 KB)	Final	7/13/2009
Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers (PDF - 83 KB)	Final	8/31/2009
Time and Extent Applications (PDF - 46 KB)	Draft	2/2004
Upgrading Category III Antiperspirants to Category I (43 FR 46728-46731) (PDF - 583 KB)	Final	10/1978
Pharmacology/Toxicology		
Animal Models—Essential Elements to Address Efficacy Under the Animal Rule (PDF - 135 KB)	Draft	1/16/2009
Carcinogenicity Study Protocol Submissions (PDF - 29 KB)	Final	5/22/2002
Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products (PDF - 42 KB)	Final	11/1995
• Questions and Answers: Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (PDF - 14 KB) (10/2000)		
Developing Medical Imaging Drug and Biological Products	Final	6/17/2004
• Part 1: Conducting Safety Assessments (PDF - 271 KB)		

Title and Format	Type	Issue Date
Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers (PDF - 702 KB)	Final	7/21/2005
Exploratory IND Studies (PDF - 220 KB)	Final	1/12/2006
Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application* (PDF -1300 KB)	Final	2/1987
Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches (PDF - 169 KB)	Draft	12/15/2008
Immunotoxicology Evaluation of Investigational New Drugs (PDF - 100 KB)	Final	10/2002
Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities (PDF - 142 KB) (Issued , Posted 11/9/2001)	Draft	11/2001
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals (PDF - 233 KB)	Draft	6/17/2005
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	Final	10/96 Updated 7/2005
Nonclinical Safety Evaluation of Drug or Biologic Combinations (PDF - 100 KB)	Final	3/14/2006
Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route (PDF - 76 KB)	Draft	3/7/2008
Nonclinical Safety Evaluation of Pediatric Drug Products (PDF - 479 KB)	Final	2/14/2006
Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients(PDF - 230 KB)	Final	05/18/2005
Photosafety Testing (PDF - 179 KB)	Final	5/7/2003
Recommended Approaches to Integration of Genetic Toxicology Study Results (PDF - 190 KB)	Final	1/3/2006
Reference Guide for the Nonclinical Toxicity Studies of Antivial Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease Evaluation of Drug Toxicity Prior to Phase I Clinical Studies (PDF - 837 KB)	Final	3/2/1998
Safety Testing of Drug Metabolites (PDF - 86 KB)	Final	2/14/2008
Single Dose Acute Toxicity Testing for Pharmaceuticals (PDF - 63 KB)	Final	8/1996
Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals (PDF - 135 KB)	Draft	5/2001
Procedural		
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (PDF - 77 KB)	Final	6/1998
Applications Covered by Section 505(b)(2)(PDF - 41 KB)	Draft	10/1999
Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (PDF - 164 KB)	Draft	1/16/2009
Complementary and Alternative Medicine Products and Their Regulation by the Food and Drug Administation	Draft	12/2006
Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products (PDF - 64 KB)	Final	2/22/2008
Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under PDUFA (PDF - 195 KB)	Final	Withdrawn 4/9/2010
Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA (PDF - 168 KB) • Paperwork Reduction Act Burden Statement (PDF - 72 KB) (Posted 7/27/2004)	Final	Withdrawn 4/9/2010
Cooperative Manufacturing Arrangements for Licensed Biologics	Final	12/3/2008
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (PDF - 25 KB)	Final	Posted 3/27/2000
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 the Center for Drug Evaluation and Research, Beginning on January 1, 2000 (PDF - 30 KB)	Draft	12/1999
Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees	Draft	2/14/2002
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 (PDF - 10 KB)	Final	11/1999
Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy (PDF - 159 KB)	Final	6/3/2003
Emergency Use Authorization of Medical Products; Availability (PDF - 4070 KB)	Draft	7/5/2005
End-of-Phase 2A Meetings (PDF - 163 KB)	Final	9/18/2009
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act	Withdrawn	9/2008
Fast Track Drug Development Programs - Designation, Development, and Application Review (PDF - 83 KB) Appendix 2 (PDF - 3930 KB)15 [Appendices are scanned copies, which will be replaced by final versions] (Issued 11/17/1998, Posted 11/17/1998)	Final	1/12/2006
FDA Export Certificates	Final	7/2004
Financial Disclosure by Clinical Investigators	Final	3/27/2001
Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV (PDF - 343 KB)	Final	10/17/2006
Formal Dispute Resolution: Appeals Above the Division Level (PDF - 30 KB)	Final	2/2000
Formal Meetings Between the FDA and Sponsors or Applicants (PDF - 89 KB)	Final	5/19/2009
Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (PDF - 32 KB)	Draft	5/14/2001
Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices U.S.	Final	1/14/2009
Good Review Management Principles and Practices for PDUFA Products (PDF - 683 KB)	Final	3/2005

Title and Format	Type	Issue Date
Guidance for FDA Staff: The Leveraging Handbook; An Agency Resource for Effective Collaborations (PDF - 143 KB)	Final	Revised 6/2003
Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs—Improving Human Subject Protection (PDF - 61 KB)	Final	1/14/2009
Guidance to Pharmacies: Compounding Tamiflu Oral Suspension in Advance to Provide for Multiple Prescriptions (PDF - 114KB)	Draft	1/11/2010
Guidance for Sponsors, Clinical Investigators, and IRBs; Data Retention When Subjects Withdraw From FDA-Regulated Clinical Trials (PDF - 399 KB)	Draft	12/2/2008
How to Comply with the Pediatric Research Equity Act (PDF - 116 KB)	Draft	9/7/2005
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997–Advisory Committees (PDF - 62 KB)	Final	10/1998
Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements (PDF - 979 KB)	Final	7/1998
Independent Consultants for Biotechnology Clinical Trial Protocols	Final	8/18/2004
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (PDF - 40 KB) [Revision 1]	Draft	1/2004
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (PDF - 34 KB)	Final	3/2002
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act (PDF - 27 KB)	Final	11/2001
Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions - Statement of Investigator (Form FDA 1572) (PDF - 672 KB)	Draft	7/29/2008
Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document (PDF - 98 KB)	Final	4/20/2009
Integrated Summary of Effectiveness (PDF - 95 KB)	Draft	7/26/2008
Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects (PDF - 163 KB)	Final	10/23/2009
Levothyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications (PDF - 24 KB)	Final	7/2001
Medication Guides—Adding a Toll-Free Number for Reporting Adverse Events (PDF - 67 KB)	Final	6/8/2009
National Uniformity for Nonpresciption Drugs - Ingredient Listing for OTC Drugs (PDF - 74 KB)	Final	4/1998
PET Drug Applications - Content and Format for NDAs and ANDAs (PDF - 153 KB) [(Issued , Posted 3/7/2000) • Sample formats for chemistry, manufacturing, and controls sections (PDF - 125 KB) • Sample formats for labeling (PDF - 94 KB) • Sample formats for Form FDA 356h (PDF - 51 KB) • Sample formats for user fee Form FDA 3397 (PDF - 41 KB)	Draft	3/7/2000
Pharmacogenomic Data Submissions (PDF - 96 KB) • Examples of Voluntary Submissions or Submissions Required Under 21 CFR 312, 314, or 601 (PDF - 63 KB)	Final	3/2005
Pharmacogenomic Data Submissions—Companion Guidance (PDF - 211 KB)	Draft	8/28/2007
Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products (PDF - 47KB)	Draft	1/7/2010
Postmarketing Adverse Even Reporting for Medical products and Dietary Supplements During an Influenza Pandemic (PDF - 246 KB)	Draft	12/15/2008
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (PDF - 375 KB)	Draft	3/9/2001
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (PDF - 40 KB) • KI in Radiation Emergencies-Questions and Answers (PDF - 161 KB)	Final	12/10/2001 12/23/2002
Potassium Iodide Tablets - Shelf Life Extension (PDF - 156 KB)	Final	3/8/2004
Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees (PDF - 68 KB)	Draft	3/21/2007
Process for Handling Referrals to FDA Under 21 CFR 50.54 Additional Safeguards for Children in Clinical Investigations (PDF - 116 KB) [PDF]	Final	12/22/2006
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act (PDF - 57 KB)	Final	9/1999
Refusal to File (PDF - 304KB)	Final	7/12/1993
Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act (PDF - 85 KB)	Final	Revised 5/1998
Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (PDF - 456 KB)	Final	2/15/2006
Special Protocol Assessment (PDF - 36 KB)	Final	5/2002
Standards for Prompt Review of Efficacy Supplements (PDF - 76 KB)	Final	5/15/1998
Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages	Final	3/26/2010
Submission of Patent Information for Certain Old Antibiotics (PDF - 42 KB)	Draft	11/28/2008
Submitting and Reviewing Complete Responses to Clinical Holds (Revised)(PDF - 26 KB)	Final	10/2000
Submitting Debarment Certification Statements (PDF - 144 KB)	Draft	10/2/98
Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (PDF - 50 KB)	Draft	9/5/2001
Target Product Profile—A Strategic Development Process Tool (PDF - 454 KB)	Draft	3/29/2007
Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products (PDF - 112 KB)	Draft	6/2/2009
The Use of Clinical Holds Following Clinical Investigator Misconduct (PDF - 33 KB)	Draft	4/2002
Tropical Disease Priority Review Vouchers (PDF - 112 KB)	Draft	10/21/2008

Title and Format	Type	Issue Date
Useful Written Consumer Medication Information (CMI)(PDF - 73 KB)	Final	7/17/2006
Using a Centralized IRB Review Process in Multicenter Clinical Trials (PDF - 87 KB)	Final	3/15/2006
Waiver of IRB Requirements for Drug and Biological Product Studies (PDF - 35 KB)	Final	1/2006
Women and Minorities Guidance Requirements (PDF - 30 KB)	Final	7/20/1998
Small Entity Compliance Guides		
Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation—Small Entity Compliance Guide (PDF - 18 KB)	Final	11/7/2001
Labeling OTC Human Drug Products (Small Entity Compliance Guide)(PDF - 481 KB)	Draft	12/2004
User Fees		
Attachment G—Draft Interim Guidance Document for Waivers of and Reductions in User Fees (PDF - 897 KB)	Draft	7/16/1993
Classifying Resubmissions in Response to Action Letters (PDF - 76 KB)	Final	5/14/1998
Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act (PDF - 48 KB)	Final	6/1999
Guidance for Industry and FDA Staff: Application User Fees for Combination Products (PDF - 83 KB)	Final	4/2005
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act (PDF - 27 KB)	Final	11/2001
Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (PDF - 211 KB)	Final	12/30/2004
User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR (PDF - 46 KB) (Issued , Posted 2/7/2007)	Final	2/7/2007

IV. Center for Devices and Radiological Health (CDRH)

For information a specific guidance document or to obtain a paper copy, contact:

Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993, 1–800–638–2041, FAX: 301–847–2149, e-mail: *dsmica@fda.hhs.gov, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/Default.htm.*

CDRH has no withdrawn guidance documents at this time.

The following list of current CDRH guidance documents was obtained from FDA's Web site on April 22, 2010:

Title	Organization	Doc #	Date
Cross-Center Guidance Document List			
Guidance for Industry and FDA Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s)	CBER CDRH	1511	08/27/09
Guidance for Industry, FDA Staff, and Third Parties - Inspection by Accredited Persons Under The Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria	CBER CDRH	1200	08/06/09
Presenting Risk Information in Prescription Drug and Medical Device Promotion			
User Fees and Refunds for Premarket Approval Applications	CBER CDRH	1681	03/13/09
Guidance for Industry, FDA Staff, and FDA-Accredited Third Parties - Manufacturer's Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA)	CBER CDRH	1532	03/02/09
Assay Migration Studies for In Vitro Diagnostic Devices	CBER CDRH/ OIVD	1660	01/05/09
Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile	CBER CDRH/ ODE	1615	12/12/08
Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision	CBER CDRH	1584	12/11/08
Draft Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers	CBER CDRH	1668	08/05/08
FY 2009 Medical Device User Fee Small Business Qualification and Certification (PDF only)	CBER CDRH		08/01/08
FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals	CBER CDRH	1218	06/30/08
Guidance for Industry and FDA Staff: Expedited Review of Premarket Submissions for Devices	CBER CDRH	108	02/29/08
Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements	CBER CDRH	1655	02/28/08
Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission	CBER CDRH	1215	06/22/07
Guidance on Pharmacogenetic Tests and Genetic Tests for Heritable Markers	CBER CDER CDRH	1549	02/09/06
Annual Reports for Approved Premarket Approval Applications (PMA)	CBER CDRH	1585	10/26/06
Real-Time Premarket Approval Application (PMA) Supplements	CBER CDRH	673	04/28/06
Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable	CBER CDRH	1588	04/25/06
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	CBER CDRH/ ODE CDRH/ OIVD	337	05/11/05
Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use	CBER CDRH	4444	11/30/04
Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA	CBER CDRH	1303	11/17/04

Title	Organization	Doc #	Date
Guidance for Industry and FDA Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s)	CBER CDRH	1511	08/27/09
FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment	CBER CDRH	1219	05/21/04
Premarket Assessment of Pediatric Medical Devices	CBER CDRH	1220	05/14/04
Guidance for Industry and FDA: User Fees and Refunds for Premarket Approval Applications	CBER CDRH	1224	11/24/03
Premarket Approval Application Modular Review	CBER CDRH/ ODE	835	11/03/03
Premarket Approval Application Filing Review	CBER CDRH/ ODE CDRH/ OIVD	297	05/01/03
Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products	CBER CDRH	1201	02/25/03
The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry	CBER CDRH/ ODE	1332	10/04/02
General Principles of Software Validation; Final Guidance for Industry and FDA Staff	CBER CDRH/ OC	938	01/11/02
OC Guidance Documents			
Guidance for Industry and FDA Staff - Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007	OC/DRMO/ RPSB	1657	10/08/09
Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300	OC/DE2/ OBGUB	1688	12/23/08
Medical Device Tracking; Guidance for Industry and FDA Staff	OC	169	01/25/10
Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves	OC/DE2	1141	07/11/08
Surveillance and Detention Without Physical Examination of Condoms	OC/DE2	1139	07/11/08
The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations	OIVD OC	1566	01/08/08
The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program	OC/DBM	1602	01/08/08
Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices	OC	1227	02/27/07
Decorative, Non-corrective Contact Lenses	OC/DE1	1613	11/24/06
Inspection of Medical Device Manufacturers	OC/DPO/FPB		06/15/06
Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended - Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices	OC	1217	05/01/06
Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex	OC/DE2/ OBGUB	1548	11/14/05
Draft Guidance for Industry and FDA Staff - Functional Indications for Implantable Cardioverter Defibrillators	ODE OC	1304	10/06/05
Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software	ODE OC	1553	01/14/05
Consumer-Directed Broadcast Advertising of Restricted Devices	OC	1513	02/10/04
User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide	OC	1212	04/01/03
Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff	OC/DE3	1140	02/03/03
General Principles of Software Validation; Final Guidance for Industry and FDA Staff	CBER CDRH/ OC	938	01/11/02
Sterilized Convenience Kits for Clinical and Surgical Use	OC	1390	01/07/02
Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance for Industry and FDA	OC/DE3	1392	07/30/01
Implementation of the Biomaterials Access Assurance Act of 1998	OC	1324	04/02/01
Labeling for Electronic Anti-Theft Systems	OC/DE3	1170	08/15/00
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals	OC/DE3	1168	08/14/00
Alternative to Certain Prescription Device Labeling Requirements	OC	1150	01/21/00
Regulating In Vitro Diagnostic Device (IVD) Studies	OC/DBM	1132	12/17/99
Guidance on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables (PDF version)	OC/DE1	1129	11/15/99
Guidance for FDA Staff: Civil Money Penalty Policy	OC	1124	06/08/99
Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects	OC/DBM	2229	03/19/99
Performance Standard for Electrode Lead Wires and Patient Cables	OC	1197	03/16/98
Information about Lasers: An Important Letter to Ophthalmologists About Lasers for Refractive Surgery	OC/DE2	8323	06/27/97
Design Control Guidance For Medical Device Manufacturers	OC/DE3	994	03/11/97
Prospective Manufacturers of Barrier Devices Used During Oral Sex for STD Protection	OC/DE2	1394	10/31/96
Electromagnetic Compatibility - A Letter to Industry	OC/DE3	1087	09/18/96
Shielded Trocars and Needles used for Abdominal Access during Laparoscopy (PDF Version)	OC/DE2	1122	08/23/96
Letter to Manufacturers and Initial Distributors of Hemodialyzers (PDF only)	OC/DE2	2507	05/23/96
Reuse of Medical Disposable Devices Policy	OC/DE3	961	12/27/95
Letter to Medical Device Manufacturer on Pentium processors (PDF only)	OC	456	02/14/95

Title	Organization	Doc #	Date
Medical Devices and EMI: The FDA Perspective	OC/DE3	1082	01/01/95
Pesticide Regulation Notice 94-4 Interim Measures for the Registration of Antimicrobial Products/ Liquid Chemical Germicides with Medical Device Use Claims (PDF only)	OC/DE2	851	06/30/94
All Device Manufacturers/Repackers Using Cotton (PDF Version)	OC/DE2	101	04/22/94
Letter - Condom Manufacturers and Distributors (PDF only)	OC/DE2	56	04/05/94
Letter - Manufacturers, Distributors and Importers of Condom Products (included in Condom Packet 398) (PDF only)	OC/DE2	52	02/23/94
Manufacturers And Initial Distributors Of Sharps Containers And Destroyers Used By Health Care Professionals (PDF Version)	OC/DE2	933	02/03/94
Endoscopy and Laparoscopy Accessories (PDF only)	OC/DE1	545	05/17/93
Letter to Industry, Powered Wheelchair Manufacturers from RMJohnson (PDF Only)	OC/DE2	869	05/10/93
Latex Labeling Letter (Johnson) (PDF only)	OC/DE2	831	03/18/98
Dental Handpiece Sterilization (Dear Doctor Letter) (PDF only)	OC/DE2	589	09/28/92
Computerized Devices/Processes Guidance (PDF Version)	OC/DE3	247	05/01/92
Commercial Distribution/Exhibit Letter (PDF only)	OC	246	04/10/92
Quality Assurance Guidelines for Hemodialysis Devices	OC/DE3	507	02/01/91
Letter - Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt) (PDF only)	OC/DE2	53	02/13/89
Color Additive Status List (PDF Only)	OC	268	02/01/89
Color Additive Petitions (PDF Only)	OC	296	06/01/87
Condoms: Inspection and Sampling at Domestic Manufacturers and of all Repackers; Sampling from all Importers (Damaska Memo to Field on 4/8/87) (PDF only)	OC/DE2	293	04/08/87
All U.S. Condom Manufacturers, Importers and Repackagers (PDF only)	OC/DE2	2510	04/07/87
Standard Specification for Rubber Contraceptives (Condoms) (PDF Only)	OC/DE2	628	10/28/83
Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Levels of Exposure (PDF only)	OC/DE2	1019	06/23/78
Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations (PDF Version)	OC/DE3	1086	
Office of the Center Director Guidance Documents			
Resolving Scientific Disputes Concerning The Regulation Of Medical Devices, A Guide To Use Of The Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA	OCD	1121	07/02/01
OCER Guidance Documents			
Guidance for Industry and FDA Staff: Acceptable Media for Electronic Product User Manuals	OCER/DMQRP/ EPB		03/18/10
Draft Guidance for Industry, MQSA Inspectors and FDA Staff - The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13	OCER/DMQRP	1695	10/09/09
Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use	OCER/DMQRP	1680	12/24/08
Inspection of Domestic and Foreign Manufacturers of Diagnostic X Ray Equipment	OCER/DMQRP/ RPB		05/15/08
Medical Glove Guidance Manual	OCER/DSMICA	1661	01/22/08
Inspection and Field Testing of Radiation-Emitting Electronic Products	OCER/DMQRP		10/31/07
Impact-Resistant Lenses: Questions and Answers	OCER/DSMICA	23	10/26/07
Procedures for Renewal and Amendment of Certain Laser Light Show Variances (Laser Notice 55)	OCER/DMQRP	1639	09/25/07
Compliance Guide for Cabinet X-Ray Systems	OCER/DMQRP	1634	09/19/07
Writing Dear Doctor Letters for Recalls of Implantable Cardioverter Defibrillators (ICDs)	OCER/DHC	1645	07/19/07
Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22; (Laser Notice No. 50)	OCER/DMQRP	1346	06/24/07
Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide	OCER/DMQRP	1640	06/07/07
Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device			05/01/07
Approval of Alternate Means of Labeling for Laser Products (Laser Notice 53)	OCER/DMQRP	1633	03/23/07
The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #12	OCER/DMQRP	1623	02/02/07
Exemption from Certain Reporting and Recordkeeping Requirements for Television Receivers and Computer Monitors with Cathode Ray Tubes	OCER/DMQRP	1612	10/20/06
Exemption from Certain Reporting and Recordkeeping Requirements for Microwave Ovens	OCER/DMQRP	1611	10/20/06
Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography	OCER/DMQRP	1609	10/20/06
Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment	OSB/DPS OCER/DHC	1537	03/10/06
Compliance Program Guidance Manual CP 7386.003 Field Compliance Testing of Diagnostic (Medical) X-ray Equipment - Guidance for FDA Staff	OCER/DMQRP	1600	02/08/06
Exemption from Reporting and Recordkeeping Requirements for Low Power Laser Products (Laser Notice 54)	OCER/DMQRP OCER/ DMQRP/ EPDB	1592	01/06/06
Applicability of the Performance Standard for High-Intensity Mercury Vapor Discharge Lamps (21 CFR 1040.30)	OCER/DMQRP/ EPDB	1565	11/06/05
Mammography Facility Surveys, Mammography Equipment Evaluations, and Medical Physicist Qualification Requirements under MQSA	OCER/DMQRP/ ICB	6409	09/13/05
Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems	OCER/DMQRP/ DDB	2619	09/05/03

Title	Organization	Doc #	Date
Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions	OCER/DHC	1427	07/16/03
Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products (Laser Notice No. 52)	OCER/DMQRP	1412	07/12/02
Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors: Three Additional Questions; Final Guidance for Industry and FDA Staff	OCER/DHC	1408	07/09/02
Compliance Guidance: The Mammography Quality Standards Act Final Regulations: Preparing For MQSA Inspections; Final	OCER/DMQRP/ ICB	6400	11/05/01
Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Final Guidance for Industry and FDA Staff	OCER/DHC	1333	07/06/01
Responsibilities of Laser Light Show Projector Manufacturers, Dealers, and Distributors; (Laser Notice 51)	OCER/DMQRP/ EPDB	1349	05/27/01
Guidance on Medical Device Patient Labeling	OCER/DHC	1128	04/19/01
CDRH Manual for the Good Guidance Practices (GGP) Regulations; Final Guidance for FDA Staff	OCER/DHC	1323	02/09/01
Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties	OCER/DSMICA	1160	02/02/01
Guidance for Industry - Wireless Medical Telemetry Risks and Recommendations		1173	09/27/00
Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management	OCER/DHC	1497	07/18/00
Regulation of Medical Devices: Background Information for International Officials	OCER/DSMICA	610	04/14/99
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies (PDF Only)	OCER/DMQRP	1071	08/13/98
Overview of FDA Modernization Act of 1997, Medical Device Provisions	OCER/DSMICA	1174	02/19/98
Medical Device Appeals and Complaints: A Guidance on Dispute Resolution (PDF Only)	OCER/DSMICA	396	02/19/98
FDA Modernization Act of 1997 - Guidance for the Device Industry on Implementation of Highest Priority Provisions	OCER	434	02/06/98
Medical Device Reporting for Manufacturers	OCER/DSMICA	987	03/01/97
Human Factors Points to Consider for IDE Devices	OCER/DHC	839	01/17/97
In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions	OCER/DSMICA	471	01/01/97
Do It By Design - An Introduction to Human Factors in Medical Devices	OCER/DHC	995	12/01/96
Medical Device Quality Systems Manual	OCER/DSMICA	6303	12/01/96
Emitted Laser Beam as Emission Indicator for Class II and Class IIIa Laser Products (Laser Notice 49) (PDF only)	OCER/DMQRP		09/05/96
Identification Labels for Certain Class I Laser Products (Laser Notice 48) (PDF Only)	OCER/DMQRP		09/05/96
Effective Visual Control of Laser Projections (Laser Notice 47) (PDF Only)	OCER/DMQRP		06/06/96
Medical Device Reporting for User Facilities (PDF Only)	OCER/DHC		04/01/96
A Guide for the Submission of An Abbreviated Radiation Safety Reports on Cephalometric Devices Intended for Diagnostic Use	OCER/DMQRP/ DDB	977	03/01/96
A Guide For The Submission Of An Abbreviated Initial Report On X-Ray Tables, Cradles, Film Changers Or Cassette Holders Intended For Diagnostic Use (PDF Only)	OCER/DMQRP/ DDB	978	
All Holders of Approved Variances For Laser Light Shows and Displays (Laser Notice 46) (PDF Only)	OCER/DMQRP		12/11/95
Guide for Preparing Product Reports for Lasers and Products Containing Lasers (PDF Only)	OCER/DMQRP/ EPDB	277	09/01/95
Labeling of Laser Products (Laser Notice 45) (PDF Only)	OCER/DMQRP		08/15/95
User Instruction for Medical Products (Laser Notice 44) (PDF Only)	OCER/DMQRP		08/11/95
Abbreviated Reports on Radiation Safety for Microwave Products (Other Than Microwave Ovens)- E.G. Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric Heaters, Security Systems (PDF Only)	OCER/DMQRP/ EPDB	236	08/01/95
Certification Statement for the Impact Resistance Test (PDF Only)	OCER/DSMICA	1460	10/25/93
Manufacturers/Assemblers of Diagnostic X-ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g) (PDF Only)	OCER/DMQRP/ DDB	116	10/13/93
Human Factors Principles for Medical Device Labeling (PDF Only)	OCER/DHC	227	09/01/93
Beam Attenuators and Emission Indicators for Class II and IIIa Laser Systems (Laser Notice 43) (PDF Only)	OCER/DMQRP		06/07/93
Compliance Guide for Laser Products (FDA 86-8260) (PDF Only)	OCER/DMQRP/ EPDB	278	06/01/92
Clarification of Compliance Requirements for Certain Manufacturers Who Incorporate Certified Class I Laser Products into Their Products (Laser Notice 42) (PDF Only)	OCER/DMQRP		12/18/89
Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) (PDF Only)	OCER/DSMICA	470	09/01/89
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (FDA 89-8221)	OCER/DMQRP	758	03/01/89
Imports Radiation-Producing Electronic Products (FDA 89-8008) (PDF Only)	OCER/DMQRP/ EPDB	756	11/01/88
Low Power Laser Reporting Exemption (Laser Notice 40) (PDF Only)	OCER/DMQRP		08/09/88
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88-8264)] (PDF Only)	OCER/DMQRP/ EPDB	286	03/01/88
Impact Resistant Lenses: Questions and Answers (FDA 87-4002) (PDF Only)	OCER/DSMICA	23	09/01/87
User Instructions - Multi Axis Workstations (Laser Notice 39) (PDF Only)	OCER/DMQRP		06/24/87
Importation for Investigation And Evaluation (Laser Notice 38) (PDF Only)	OCER/DMQRP		05/22/87
Policy on Lamp Compatibility (sunlamps) (PDF Only)	OCER/DMQRP/ EPDB	2343	09/02/86
Procedures for Laboratory Compliance Testing of Television Receivers (PDF Only)	OCER/DMQRP/ EPDB	945	05/01/86

Title	Organization	Doc #	Date
Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems	OCER/DMQRP/DDB	271	12/01/85
Walk-In Workstations (Laser Notice 37) (PDF Only)	OCER/DMQRP		10/21/85
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A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and their Major Components	OCER/DMQRP/DDB	257	01/01/82
Exemption from Reporting and Record keeping Requirements for Certain Sunlamp Product Manufacturers (PDF Only)	OCER/DMQRP/EPDB	343	09/16/81
Letter to All Manufacturers and Importers of Microwave Ovens: Retention of Records Required by 21 CFR 1002 (PDF Only)	OCER/DMQRP/EPDB	880	08/24/81
Investigational Medical Laser Significant Risk Device (Laser Notice 31) (PDF Only)	OCER/DMQRP		05/18/81
Laser Diodes Used in Fiber Optics Communication Systems (Laser Notice 27) (PDF Only)	OCER/DMQRP		10/16/80
Alternate Wording For Caution Statement (Laser Notice 30) (PDF Only)	OCER/DMQRP		08/25/80
Guide for the filing of Annual Reports for X-Ray Components and Systems (PDF Only)	OCER/DMQRP/EPDB	253	07/01/80
Open Door Operation of Microwave Ovens as a Result of Oven Miswiring (PDF Only)	OCER/DMQRP/EPDB	646	03/28/80
Exemption of Certain Lasers Used By DOE, NOAA and U.S. Dept. of Commerce (Laser Notice 25) (PDF Only)	OCER/DMQRP		09/14/79
Laser Light Shows Subject to Laser Product Performance Standard (Laser Notice 22) (PDF Only)	OCER/DMQRP		11/23/77
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Warning Labels For Dye And Multiple Wavelength Lasers (Laser Notice 16) (PDF Only)	OCER/DMQRP		03/02/77
Certain Military Lasers Exempt From 21 CFR 1040.10 & .11 (Laser Notice 15) (PDF Only)	OCER/DMQRP		12/08/76
Lasers Manufactured and Used In-House (Laser Notice 14) (PDF Only)	OCER/DMQRP		11/23/76
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Emission Indicator - Visibility (Laser Notice 10) (PDF Only)	OCER/DMQRP		08/31/76
Certain Military Lasers Exempt From 21 CFR 1040.10 & .11 (Laser Notice 9) (PDF Only)	OCER/DMQRP		08/23/76
Viewing Optics - Sighting Telescope (Laser Notice 8) (PDF Only)	OCER/DMQRP		08/05/76
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Emission Indicators - Brightness (Laser Notice 6) (PDF Only)	OCER/DMQRP		06/22/76
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Emission Indicators on Energy Source (Laser Notice 3) (PDF Only)	OCER/DMQRP		11/21/75
Laser Energy Source (Laser Notice 2) (PDF Only)	OCER/DMQRP		11/21/75
COMPARISON CHART: 1996 QUALITY System Regulation Versus 1978 GOOD Manufacturing Practices Regulation Versus ANSIIISOIASQC Q9001-1994 AND ISO/DIS 13485:1996 (PDF Version)	OCER/DSMICA		
ODE Guidance Documents 2010			
Draft Guidance for Industry and FDA Staff: Heart Valves - Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications	ODE/DCD/CSPDB	1607	01/20/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator with Limited Output for Pain Relief	ODE/DRARD/ULDB	1574	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended	ODE/DRARD/ULDB	1670	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Muscle Conditioning	ODE/DRARD/ULDB	1580	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation	ODE/DRARD/ULDB	1577	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Rehabilitation	ODE/DRARD/ULDB	1578	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator for Aesthetic Purposes	ODE/DRARD/ULDB	1575	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator with Limited Output for Aesthetic Purposes	ODE/DRARD/ULDB	1576	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning	ODE/DRARD/ULDB	1579	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Cutaneous Electrode	ODE/DRARD/ULDB	1572	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Electroconductive Media	ODE/DRARD/ULDB	1571	04/05/10
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief	ODE/DRARD/ULDB	1573	04/05/10
Guidance for Industry and FDA Staff - Total Product Life Cycle: Infusion Pump - Premarket Notification [510(k)] Submissions	ODE/DAGID/GHDB	1694	
ODE Guidance Documents 2008 - 2009			
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Wound Dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) Additive	ODE/DGRND/PRSDB	1684	10/16/09

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Draft Guidance for Industry and FDA Staff - Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation	ODE/DCD/ CEMB	1708	09/14/09
Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy - Guidance for Industry and FDA Staff	ODE/DAGID/ DEDB	1192	07/28/09
Draft Guidance for Industry and FDA Staff: Investigational Device Exemption (IDE) Guidance for Retinal Prostheses	ODE/DOED/ VEDB	1651	04/17/09
Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products	ODE/DOED/ ENTB	1696	02/25/09
Guidance for Industry: Designation of Special Controls for Male Condoms Made of Natural Rubber Latex (21 CFR 884.5300); Small Entity Compliance Guide	ODE/DRARD/ OGDB	1693	01/05/09
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Expander	ODE/DGRND/ PRSB	1628	12/22/08
Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile	CBER CDRH/ ODE	1615	12/12/08
Draft Guidance for Industry and FDA Staff - Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence	ODE/DRARD/ ULDB	1636	09/19/08
Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers	OSEL ODE/ DRARD	560	09/09/08
Guidance for Industry and FDA Staff: Clinical Study Designs for Catheter Ablation Devices for Treatment of Atrial Flutter	ODE/DCD/ CEMB	1678	08/05/08
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Bone Sonometers	OSEL ODE/ DRARD	1547	07/17/08
Guidance for Industry and FDA Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]	ODE/DAGID/ GHDB	1189	07/11/08
Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin	ODE/DGRND/ PRSB	1630	05/30/08
Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters	ODE/DCD/ICDB	1608	05/30/08
Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions	OSEL ODE/ DRARD	1617	05/30/08
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System	OSEL ODE/ DRARD	1616	05/30/08
Guidance for Industry and FDA Staff: Hemodialysis Blood Tubing Sets - Premarket Notification [510(k)] Submissions	ODE/DRARD/ GRDB	1649	04/23/08
Guidance for Industry and FDA Staff: Investigational Device Exemptions (IDEs) for Devices Indicated for Nocturnal Home Hemodialysis	ODE/DRARD/ GRDB	1650	04/15/08
Guidance for Industry and FDA Staff: Preparation and Review of Investigational Device Exemption Applications (IDEs) for Total Artificial Discs	ODE/DGRND/ ORDB	1637	04/11/08
Coronary Drug-Eluting Stents-Nonclinical and Clinical Studies			
Coronary Drug-Eluting Stents—Nonclinical and Clinical Studies -Companion Document			
Guidance for Industry and FDA Staff: Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions	ODE/DCD/ PVDB ODE/ DCD/ICDB	1658	02/15/08
ODE Guidance Documents 2006 - 2007			
Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Remote Medication Management System	ODE/DAGID/ GHDB	1621	10/19/07
Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)] Submissions	ODE/DGRND/ INCB	1320	10/04/07
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Electrocardiograph Electrodes	ODE/DCD/ CEMB	1597	10/04/07
Guidance for Industry and FDA Staff - Non-clinical Information for Femoral Stem Prostheses	ODE/DGRND/ ORDB	1647	09/17/07
Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology	ODE/DGRND/ PRSB	1629	08/03/07
Draft Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents	ODE	1557	07/19/07
Draft Guidance for Industry and FDA Staff - Pulse Oximeters - Premarket Notification Submissions [510(k)s]	ODE/DAGID/ ARDB	1605	07/19/07
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies	ODE/DAGID/ INCB	1626	07/03/07
Guidance for Industry and FDA Staff - Pre-Clinical and Clinical Studies for Neurothrombectomy Devices	ODE/DGRND/ GSDB	1586	06/18/07
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device	ODE/DGRND/ ORDB	1540	06/12/07
Guidance for Industry and FDA Staff: Dental Handpieces - Premarket Notification [510(k)] Submissions	ODE/DAGID/ DEDB	556	05/02/07
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems	ODE/DRARD/ OGDB	1625	04/24/07
Guidance for Industry and FDA Staff - Saline, Silicone Gel, and Alternative Breast Implants	ODE/DGRND/ PRSB	1239	11/17/06
Draft Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Absorbable Hemostatic Device	ODE/DGRND	1558	10/31/06

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Guidance for Industry and FDA Staff - Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	ODE	1216	09/25/06
Guidance for Industry and FDA Staff - Keratome and Replacement Keratome Blades Premarket Notification [510(k)] Submissions	ODE/DOED/ DSDB	1604	09/18/06
Guidance for Industry and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers	ODE/ODEOD/ POS	1381	07/18/06
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Olfactory Test Device	ODE/DOED/ ENTB	1595	06/07/06
Topical Oxygen Chamber for Extremities - Class II Special Controls Guidance Document - Draft Guidance for Industry and FDA Staff	ODE/DGRND/ PRSB	1582	04/06/06
Guidance for Industry and FDA Staff: Tonometers - Premarket Notification [510(k)] Submissions	ODE/DOED/ DSDB	1593	03/27/06
Dental Curing Lights - Premarket Notification [510(k)]	OSEL/DPS ODE/DAGID/ DEDB	1591	03/27/06
Class II Special Controls Guidance Document: Implantable Intra-Aneurysm Pressure Measurement System - Guidance for Industry and FDA Staff	ODE/DCD/ PVDB	1589	02/15/06
ODE Guidance Documents 2004 - 2005			
Guidance for Industry and FDA Staff: A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures	ODE	1347	11/10/05
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tinnitus Masker Devices	ODE/DOED/ ENTB	1555	11/08/05
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner	ODE/DGRND/ PRSB	1302	11/07/05
Guidance for Industry and FDA Staff: Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions	ODE/DAGID/ DEDB	642	10/26/05
Draft Guidance for Industry and FDA Staff - Functional Indications for Implantable Cardioverter Defibrillators	ODE OC	1304	10/06/05
Guidance for Industry and FDA Staff - Class II Special Controls Document: Oral Rinse to Reduce the Adhesion of Dental Plaque	ODE/DAGID/ DEDB	1559	09/20/05
Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s	OIVD ODE	1567	08/12/05
Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features	ODE/DAGID/ GHDB	934	08/09/05
Guidance for Industry and FDA Staff - Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)	ODE/DRARD/ OGDB	166	07/27/05
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	CBER CDRH/ ODE CDRH/ OIVD	337	05/11/05
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices	ODE/DAGID/ DEDB	1512	04/28/05
Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software	ODE OC	1553	01/14/05
Guidance for Industry and FDA Staff: Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems	ODE/DCD/ PVDB ODE/ DCD/ICDB	1545	01/13/05
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices	ODE/DRARD/ OGDB ODE/ DGRND/ PRSB ODE/ DCD/PVDB	1234	12/29/04
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Assisted Reproduction Laser Systems	ODE/DRARD/ OGDB	1539	12/28/04
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: External Penile Rigidity Devices	ODE/DRARD/ ULDB	1231	12/28/04
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Implantable Radiofrequency Transponder System for Patient Identification and Health Information	ODE/DAGID/ GHDB	1541	12/10/04
Guidance for Industry and FDA Staff: Clinical Data Presentations for Orthopedic Device Applications	ODE/DGRND/ ORDB	1542	12/02/04
Guidance for Industry and FDA Staff - Frequently Asked Questions (FAQs) on the Status of Reprocessed Single Use Devices (SUDs) that receive a Not Substantially Equivalent (NSE) Letter	ODE	1544	11/08/04
Guidance for Industry and FDA Staff - Clinical Trial Considerations: Vertebral Augmentation Devices to Treat Spinal Insufficiency Fractures	ODE/DGRND/ REDB ODE/ DGRND/ ORDB	1543	10/24/04
Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications	OIVD ODE	2237	09/28/04
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Dental Noble Metal Alloys	ODE/DAGID/ DEDB	1415	08/23/04
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Dental Base Metal Alloys	ODE/DAGID/ DEDB	1416	08/23/04
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments	ODE/DAGID/ DEDB	1389	05/12/04

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Guidance for Industry and FDA Staff: Spinal System 510(k)s	ODE/DGRND/ ORDB	636	05/03/04
Guidance for Industry and FDA Staff: Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove	ODE/DAGID/ INCB	1230	04/13/04
Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA	ODE/DAGID/ INCB	94	03/05/04
Guidance for Industry and FDA Staff: Vocal Fold Medialization Devices - Premarket Notification [510(k)] Submissions	ODE/DOED/ ENTB	1535	02/13/04
Guidance for Industry and FDA Staff: Clinical Study Designs for Percutaneous Catheter Ablation for Treatment of Atrial Fibrillation	ODE/DCD/ CEMB	1229	01/09/04
ODE Guidance Documents 2002 - 2003			
Premarket Notification [510(k)] Submissions for Chemical Indicators: Guidance for Industry and FDA Staff	ODE/DAGID/ INCB	1420	12/19/03
Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA	ODE/DGRND/ PRSB	54	12/18/03
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices	ODE/DAGID/ DEDB	1393	12/02/03
Premarket Approval Application Modular Review	CBER CDRH/ ODE	835	11/03/03
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm	ODE/DCD/ CEMB	1363	10/28/03
Guidance for Industry and FDA Staff: Implantable Middle Ear Hearing Device	ODE/DOED/ ENTB	1406	08/01/03
Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Breast Lesion Documentation System	ODE/DRARD/ OGDB	1202	07/28/03
Guidance for Industry and FDA Staff: Coronary and Peripheral Arterial Diagnostic Catheters	ODE/DCD/ CEMB	1228	07/15/03
Guidance for Industry and FDA Staff: Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices	ODE/DRARD	793	07/14/03
Pediatric Expertise for Advisory Panels; Guidance for Industry and FDA Staff	ODE	1208	06/03/03
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Surgical Sutures	ODE/DGRND/ PRSB	1387	06/03/03
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device	ODE/DGRND/ REDB	855	06/02/03
Premarket Approval Application Filing Review	CBER CDRH/ ODE CDRH/ OIVD	297	05/01/03
Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA	ODE/DAGID	1203	04/22/03
Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA	ODE/DGRND/ ORDB	1418	01/16/03
Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA	ODE/DAGID/ ARDB	1335	12/13/02
Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98-1)	OIVD ODE	857	12/03/02
Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA	ODE/DAGID/ DEDB	1378	11/12/02
Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA	ODE/DOED/ ENTB	1414	11/07/02
The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry	CBER CDRH/ ODE	1332	10/04/02
Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA	ODE	361	08/30/02
Regulatory Status of Disinfectants Used to Process Dialysate Delivery Systems and Water Purification Systems for Hemodialysis; Guidance for Industry and FDA	ODE/DAGID/ INCB	1419	08/30/02
Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA	ODE/DGRND/ ORDB	668	07/17/02
Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA	ODE/DAGID	1178	07/17/02
Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry	ODE/DCD/ CEMB	1382	07/01/02
Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry	ODE/DGRND/ PRSB ODE/ DRARD/ OGDB	1356	06/18/02
Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; Guidance for Industry and FDA	ODE/DGRND/ ORDB	1328	04/30/02
Class II Special Controls Guidance Document: Endolymphatic Shunt Tube with Valve; Guidance for Industry and FDA	ODE/DOED/ ENTB	791	04/29/02
Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA	ODE/DAGID/ INCB	1388	03/07/02
Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff	ODE/DAGID/ INCB	1252	02/07/02
ODE Guidance Documents 2000 - 2001			
Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA	ODE/DRARD/ GRDB	1385	11/28/01

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Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA	ODE/DAGID/ ARDB	1126	10/05/01
Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff	ODE	1341	07/18/01
Information for Keratome Manufacturers Regarding LASIK; Final Guidance for Industry	ODE/DOED/ DSDB	1376	06/21/01
Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and CDRH Staff	ODE	1337	05/29/01
Class II Special Controls Guidance Document: Tissue Culture Media for Human ex vivo Tissue and Cell Culture Processing Applications; Final Guidance for Industry and FDA Reviewers	ODE/DRARD/ GRDB	1325	05/16/01
Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA	ODE/DAGID/ GHDB	1326	03/12/01
Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers (PDF Version Only)	ODE/DRARD/ OGDB	820	03/09/01
Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA	ODE/DAGID/ INCB	891	03/02/01
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff	ODE	310	02/28/01
Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA	ODE/DRARD	983	02/16/01
Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff	ODE/DCD/ CSPB	1358	01/31/01
Guidance for Industry and FDA Reviewers: Content of Investigational Device Exemptions for Solutions for Hypothermic Flushing, Transport and Storage of Organs for Transplantation	ODE/DRARD/ GRDB	1164	01/16/01
Deciding When To Submit A 510(k) For A Change To An Existing Wireless Telemetry Medical Device: Final Guidance for FDA Reviewers and Industry	ODE	1073	11/30/00
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA	ODE/DCD/ CSPB	1622	11/29/00
Final Guidance for Industry and FDA: Guidance for Extracorporeal Blood Circuit Defoamer - 510(k) Submissions	ODE/DCD/ CSPB	1632	11/29/00
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff	ODE/DCD/ CSPB	1361	11/13/00
Guidance Document for Dura Substitute Devices; Guidance for Industry	ODE/DGRND/ PRSB	1152	11/09/00
Investigational Device Exemption (IDE) Study Enrollment for Cardiac Ablation of Typical Atrial Flutter; Final Guidance for Industry and FDA Reviewers	ODE/DCD/ CEMB	1199	11/08/00
Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA; Final Guidance for Industry and FDA Staff	ODE	1195	11/02/00
Guidance for Industry and FDA Staff: Guidance Document for Vascular Prostheses 510(k) Submissions	ODE/DCD/ PVDB	1357	11/01/00
Guidance for Industry: Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions	ODE/DCD/ PDLB	372	11/01/00
Guidance for Industry and FDA Staff - Class II Special Controls Guidance: Shoulder Joint Metal/ Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis	ODE/DGRND/ ORDB	1193	10/31/00
Guidance for Industry: A Suggested Approach to Resolving Least Burdensome	ODE	1188	09/11/00
Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997	ODE	1135	08/09/00
Guidance for Industry and for FDA Reviewers: Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi	ODE/DRARD/ ULDB	1226	08/09/00
Guidance for Industry: Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources	ODE/DRARD	1177	08/02/00
Guidance for Industry: Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices	ODE/DRARD	416	07/27/00
Guidance for Industry and FDA Staff: Guidance on Amended Procedures for Advisory Panel Meetings	ODE	413	07/22/00
Guidance for Industry and CDRH Reviewers: 1-Consolidated Annual Report for a Device product line (1-CARD)	ODE/DCD/ PDLB	1167	07/06/00
Guidance for Industry and FDA Reviewers - Class II Special Controls Guidance Document for Clitoral Engorgement Devices	ODE/DRARD/ OGDB	1144	07/03/00
Guidance for Industry and FDA Reviewers: Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices	ODE/DAGID/ ARDB	1138	07/03/00
Guidance for Industry: Guidance for Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses	ODE/DOED/ VEDB	1134	04/10/00
Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers: Guidance for Industry	ODE/DOED/ ENTB	954	03/12/00
Guidance for Industry and for FDA Staff: Use of Standards in Substantial Equivalence Determinations	ODE	1131	03/12/00
Guidance for Industry and FDA Reviewers - Reprocessing and Reuse of Single-Use Devices	ODE/DAGID	1156	02/08/00
Guidance for Industry and for FDA Reviewers - Guidance Document for Premarket Notification Submissions for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer	ODE/DAGID/ ARDB	1157	01/24/00
Guidance for Industry and for FDA Staff: Guidance for the Content of Premarket Notifications for Penile Rigidity Implants	ODE/DRARD/ ULDB	177	01/16/00

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Guidance for Industry and/or FDA Staff: Guidance Document for the Preparation of IDEs for Spinal Systems	ODE/DGRND/ORDB	2250	01/13/00
Guidance for Industry and FDA Reviewers: Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants	ODE/DAGID/INCB	397	01/03/00
ODE Guidance Documents 1998 - 1999			
Guidance for Industry and FDA Staff: Guidance for Cardiovascular Intravascular Filter 510(k) Submissions	ODE/DCD/PVDB	24	11/26/99
Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices	ODE	585	09/09/99
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices	ODE/DRARD	644	08/06/99
Guidance for Industry, FDA Reviewers/Staff and Compliance - Guidance Document for Powered Muscle Stimulator 510(k)s	ODE/DGRND/REDB	2246	06/09/99
Recommended Clinical Study Design for Ventricular Tachycardia Ablation (PDF Version)	ODE/DCD/CEMB	2244	05/07/99
Guidance for Industry and for FDA Reviewers/Staff - Guidance on 510(k) Submissions for Keratoprostheses	ODE/DOED/ICIB	1351	03/03/99
Guidance for Industry - Guidance for Dermabrasion Devices	ODE/DGRND/PRSB	2248	03/02/99
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance - Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh	ODE/DGRND/PRSB	2247	03/02/99
Guidance for Industry and FDA Reviewers/Staff: Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization To Chemicals In Natural Rubber Products	ODE/DAGID/INCB	944	01/13/99
Guidance for Industry - Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems	ODE/DRARD	2240	12/03/98
Guidance for Industry: Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters	ODE/DRARD/ULDB	2235	11/30/98
Guidance for Industry - Guidance for the Submission of Premarket Notifications For Radionuclide Dose Calibrators	ODE/DRARD	2238	11/20/98
Guidance for Industry: Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance - Version 1	ODE/DCD/CEMB	2239	11/19/98
Guidance for Industry and for FDA Reviewers/Staff: Aqueous Shunts - 510(k) Submissions	ODE/DOED/ICIB	2236	11/16/98
Guidance for Industry - Harmonic Imaging with/without Contrast - Premarket Notification Requirements	ODE/DRARD	2234	11/16/98
Guidance for FDA Reviewers and Industry Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices)	ODE	2206	11/06/98
Guidance for Industry: Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices	ODE/DRARD	340	11/14/98
Guidance for Industry: Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm)	ODE/DCD/PDLB	2233	11/05/98
Guidance for Industry: Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement)	ODE/DCD/PDLB	2232	11/05/98
Guidance for Industry: General/Specific Intended Use	ODE	499	11/04/98
Guidance for Industry: Frequently Asked Questions on the New 510(K) Paradigm	ODE	2230	10/22/98
Guidance for Industry - Noise Claims in Hearing Aid Labeling	ODE/DOED	2210	10/21/98
Guidance for Industry: Guidance Document For Nonprescription Sunglasses	ODE/DOED/DSDB	2208	10/09/98
Guidance for Industry and FDA Reviewers/Staff: Guidance Document for Powered Suction Pump 510(k)s	ODE/DGRND/GSDB	2207	09/30/98
Guidance for Industry and FDA Reviewers/Staff - Neonatal and Neonatal Transport Incubators - Premarket Notifications	ODE/DAGID/GHDB	2201	09/18/98
Guidance for Industry and FDA Staff: Dental Cements - Premarket Notification	ODE/DAGID	2204	08/18/98
Guidance for Industry and FDA Staff - OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits	ODE/DAGID	2205	08/18/98
Guidance for Industry and FDA Staff - Dental Impression Materials Premarket Notification	ODE/DAGID	2203	08/17/98
Guidance for Industry and FDA Staff: Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear	ODE/DOED/VEDB	1249	08/11/98
Guidance for Industry and CDRH Reviewers: Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems	ODE/DRARD/GRDB	2202	08/07/98
Guidance for Industry and CDRH Reviewers: Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers	ODE/DRARD/GRDB	421	08/07/98
Guidance for Industry: Latex Condoms for Men - Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions	ODE/DRARD/OGDB	1250	07/23/98
Guidance for Industry - Uniform Contraceptive Labeling	ODE/DRARD/OGDB	1251	07/23/98
Guidance for Industry, FDA Reviewers/Staff and Compliance: Guidance Document for Surgical Lamp 510(k)s	ODE/DGRND/GSDB	1244	07/13/98
Guidance for Industry: Ophthalmoscope Guidance - (Direct and Indirect)	ODE/DOED/DSDB	1241	07/08/98
Guidance for Industry: Slit Lamp Guidance	ODE/DOED/DSDB	1242	07/08/98

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Guidance for Industry: Retinoscope Guidance	ODE/DOED/ DSDB	1240	07/08/98
Guidance Document For Washers And Washer-Disinfectors Intended For Processing Reusable Medical Devices (Text Only)	ODE/DAGID/ INCB	4	06/02/98
Guidance for Industry - Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review (Text Only)	ODE	380	05/20/98
Guidance For Industry - Guidance For The Content Of Premarket Notifications For Esophageal And Tracheal Prostheses	ODE/DGRND/ PRSB	6	04/28/98
The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance	ODE	905	03/20/98
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies - for Use by CDRH and Industry	ODE	322	02/19/98
30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH	ODE	795	02/19/98
New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff	ODE	199	02/19/98
Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff	ODE	159	02/19/98
Guidance For The Content Of Premarket Notifications For Metal Expandable Biliary Stents	ODE/DRARD/ GRDB	2243	02/05/98
Guidance on IDE Policies and Procedures	ODE	882	01/20/98
Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification; Final (PDF only)	ODE/DOED/ ENTB	930	01/14/98
ODE Guidance Documents 1996 - 1997			
Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages - October 10, 1997 (P97-1) (Text Only)	ODE	563	10/10/97
Notice to Manufacturers of Bone Mineral Densitometers	ODE/DRARD	552	09/25/97
Discussion Points for Expansion of the "Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers" Draft Document	ODE/DOED/ DSDB	7093	09/05/97
Testing for Sensitizing Chemicals in Natural Rubber Latex Medical Devices (Addendum to 944) (PDF Only)	ODE/DAGID/ INCB	1944	07/28/97
ORDB 510(K) Sterility Review Guidance	ODE/DGRND/ ORDB	659	07/03/97
Kit Certification for 510(k)s (Text Only)	ODE	562	07/01/97
Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis	ODE/DRARD/ GRDB	842	05/30/97
Convenience Kits Interim Regulatory Guidance	ODE	562	05/20/97
Premarket Notification 510(k) Guidance for Contact Lens Care Products (PDF Only)	ODE/DOED/ VEDB	674	05/01/97
Non-Invasive Blood Pressure (NIBP) Monitor Guidance (Text Only)	ODE/DCD/ CEMB	123	03/10/97
Reviewers Guidance Checklist For Intramedullary Rods	ODE/DGRND/ ORDB	956	02/21/97
Reviewers Guidance Checklist For Orthopedic External Fixation Devices Version #5	ODE/DGRND/ ORDB	829	02/21/97
510(K) Information Needed for Hydroxyapatite Coated Orthopedic Implants	ODE/DGRND/ ORDB	47	02/20/97
Electrocardiograph (ECG) Electrode (PDF Only)	ODE/DCD/ CEMB	25	02/11/97
Electrocardiograph (ECG) Lead Switching Adapter (PDF Only)	ODE/DCD/ CEMB	26	02/11/97
Electrocardiograph (ECG) Surface Electrode Tester (PDF Only)	ODE/DCD/ CEMB	27	02/11/97
Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators	ODE/DGRND/ GSDB	593	02/01/97
Third Party Review Guidance For Vitreous Aspiration & Cutting Device Premarket Notification (510(k))	ODE/DOED/ DSDB	2196	01/31/97
Third Party Review Guidance for Phacofragmentation System Device Premarket Notification (510(k)) (PDF Only)	ODE/DOED/ DSDB	2197	01/31/97
Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)	ODE	935	01/10/97
Guidance for Submitting Reclassification Petition (PDF Only)	ODE	609	01/01/97
Carotid Stent - Suggestions for Content of Submissions to the Food and Drug Administration in Support of Investigational Devices Exemption (IDE) Applications (PDF Only)	ODE/DCD/ PVDB	974	10/26/96
Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers [excimer]	ODE/DOED/ DSDB	2093	10/10/96
Letter to Manufacturers of Prescription Home Monitors for Non-Stress Tests	ODE/DRARD/ OGDB	1342	09/06/96
Letter to Manufacturers of Falloposcopes	ODE/DRARD/ OGDB	1344	09/05/96
Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities (PDF Only)	ODE	1198	09/03/96
Memorandum of Understanding Regarding Patient Labeling Review (Blue Book Memo #G96-3) (Text Only)	ODE	806	08/09/96

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Continued Access to Investigational Devices During PMA Preparation and Review July 15, 1996 (Blue Book Memo) (D96-1) (Text Only)	ODE	872	07/15/96
Suggested Format For IDE Progress Report (Text Only)	ODE	311	06/01/96
Guidance for Testing MR Interaction with Aneurysm Clips, Draft Document	ODE/DGRND/PRSB	958	05/22/96
Guidance Document For Testing Bone Anchor Devices	ODE/DGRND/ORDB	915	04/20/96
Guidance Document for Testing Biodegradable Polymer Implant Devices (Text Only)	ODE/DGRND/ORDB	914	04/20/96
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (PDF Only)	ODE	198	04/01/96
510(k) Quality Review Program (Blue Book Memo I96-1) (Text Only)	ODE	344	03/29/96
Thermal Endometrial Ablation Devices (Submission Guidance for an IDE)	ODE/DRARD/OGDB	547	03/14/96
Hysteroscopes and Gynecologic Laparoscopes - Submission Guidance for a 510(k)	ODE/DRARD/OGDB	907	03/07/96
Suggested Content for Original IDE Application Cover Letter (Text Only)	ODE	797	02/27/96
Indications for Use Statement	ODE	879	02/06/96
ODE Guidance Documents 1994 - 1995			
Guidance On The Content Of Premarket Notification [510(K)] Submissions For Protective Restraints (Text Only)	ODE/DAGID	993	12/01/95
Cover Letter: 510(k) Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices (blue book memo #K95-1) (Text Only)	ODE	406	11/21/95
Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities (Text Only)	ODE/DAGID	1833	09/19/95
Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Att. A Interagency Agreement, Att. B Criteria for Catergorization of Investigational Devices, & Att. C -List #D95-2 (blue book memo) (Text Only)	ODE	106	09/15/95
HCFA Reimbursement Categorization Determinations for FDA-approved IDEs (PDF Only)	ODE	4106	09/15/95
#D95-2, Attachment A (Interagency Agreement between FDA & HCFA) (PDF Only)	ODE	2106	09/15/95
#D95-2, Attachment B (Criteria for Categorization of Investigational Devices (HCFA) (PDF Only)	ODE	3106	09/15/95
Hysteroscopic And Laparoscopic Insufflators: Submission Guidance For A 510(K) (Text Only)	ODE/DRARD/OGDB	1907	08/01/95
Guidance Document for the Preparation of Notification (510(k)) Applications for Therapeutic Massagers and Vibrators	ODE/DGRND/REDB	818	07/26/95
Guidance Document For the Preparation of Premarket Notification [510(K)] Applications For Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems	ODE/DGRND/REDB	762	07/26/95
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Electromyograph Needle Electrodes	ODE/DGRND/GSDB	325	07/26/95
Guidance Document for the Preparation of Premarket Notification [510(K)] Applications for Exercise Equipment	ODE/DGRND/REDB	326	07/26/95
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices	ODE/DGRND/REDB	828	07/26/95
Guidance Document For the Preparation of Premarket Notification [510(K)] Applications For Immersion Hydrobaths	ODE/DGRND/REDB	729	07/26/95
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables	ODE/DGRND/REDB	735	07/26/95
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Submerged (Underwater) Exercise Equipment	ODE/DGRND/REDB	307	07/26/95
Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	ODE/DGRND/REDB	346	07/26/95
Goals and Initiatives for the IDE Program #D95-1 (blue book memo) (Text Only)	ODE	405	07/12/95
Draft Reviewer Guidance for Ventilators (PDF Only)	ODE/DAGID/ARDB	500	07/01/95
Testing guidance for Male Condoms Made from New Material (Non-Latex) (Text Only)	ODE/DRARD/OGDB	455	06/29/95
Memorandum: Electromagnetic Compatibility for Medical Devices: Issues and Solutions (PDF Only)	ODE	639	06/13/95
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	ODE/DGRND/GSDB	386	06/01/95
Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components	ODE/DGRND/ORDB	916	05/01/95
Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (Replaces #G87-1 #8294) (blue book memo) (Text Only)	ODE	164	05/01/95
Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters (PDF Only)	ODE/DAGID/GHDB	824	03/15/95
Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems	ODE/DGRND/ORDB	355	01/10/95
Coronary and Cerebrovascular Guidewire Guidance (PDF Only)	ODE/DCD/ICDB	964	01/01/95
Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology (PDF Only)	ODE/DRARD/ULDB	98	11/01/94

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510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments (Text Only)	ODE/DRARD/ ULDB	892	09/19/94
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters (Text Only)	ODE/DRARD/ ULDB	97	09/12/94
Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices (ELD)	ODE/DGRND/ GSDB	667	08/30/94
Guidance For The Content Of Premarket Notifications For Urodynamic/Uroflowmetry Systems (Text Only)	ODE/DRARD/ ULDB	490	07/29/94
Premarket Approval Application (PMA) Closure #P94-2 (blue book memo) (Text Only)	ODE	403	07/08/94
Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses	ODE/DOED/ VEDB	896	06/28/94
Guidance for the Content of Premarket Notifications for Urine Drainage Bags (PDF Only)	ODE/DRARD/ ULDB	96	06/07/94
510(k) Sign-Off Procedures #K94-2 (blue book memo) (Text Only)	ODE	308	06/01/94
Letter to Industry, Powered Wheelchair/Scooter or Accessory/Component Manufacturer from Susan Alpert, Ph.D.,M.D. (PDF Only)	ODE	883	05/26/94
510(k) Refuse to Accept Procedures #K94-1 (blue book memo) (Text Only)	ODE	401	05/20/94
IDE Refuse to Accept Procedures #D94-1 (blue book memo) (Text Only)	ODE	410	05/20/94
Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone Or Bone Cement	ODE/DGRND/ ORDB	827	04/28/94
Preamendments Class III Strategy (Text Only)	ODE	611	04/19/94
Draft Reviewer Guidance on Face Masks and Shield for CPR (PDF Only)	ODE/DAGID/ ARDB	996	03/16/94
Premarket Notification [510(k)] Status Request Form	ODE	858	03/07/94
Draft 510(K) Submission Requirements for Peak Flow Meters (PDF Only)	ODE/DAGID/ ARDB	999	01/13/94
Battery Guidance (PDF Only)	ODE/DCD	873	01/01/94
ODE Guidance Documents 1992 - 1993			
Documentation and Resolution of Differences of Opinion on Product Evaluations #G93-1 (blue book memo) (Text Only)	ODE	920	12/23/93
Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch (includes EMI standard) (PDF Only)	ODE/DAGID/ ARDB	638	11/01/93
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	ODE/DAGID/ ARDB	784	10/01/93
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers (PDF Only)	ODE/DAGID/ INCB	895	10/01/93
Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (PDF Only)	ODE/DAGID/ INCB	881	08/01/93
Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes (PDF Only)	ODE/DAGID/ INCB	888	08/01/93
510(k) Additional Information Procedures #K93-1 (blue book memo) (Text Only)	ODE	886	07/23/93
Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy (PDF Only)	ODE	4859	06/30/93
Center for Devices and Radiological Health's Premarket Notification [510(k)] Refuse to Accept Policy - (updated Checklist 3/14/1995) (PDF Only)	ODE	3859	06/30/93
Classified Convenience Kits (PDF Only)	ODE	789	04/30/93
Draft Emergency Resuscitator Guidance (PDF Only)	ODE/DAGID/ ARDB	985	04/14/93
Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles (Text Only)	ODE/DAGID/ GHDB	450	04/01/93
Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes (Text Only)	ODE/DAGID/ GHDB	821	04/01/93
Draft Guidance for Preparation of PMA Applications for Testicular Prostheses (Text Only)	ODE/DRARD/ ULDB	809	03/16/93
Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities (PDF Only)	ODE/DAGID	833	03/01/93
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers (Text Only)	ODE/DAGID/ GHDB	822	03/01/93
Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament Devices	ODE/DGRND/ ORDB	233	02/18/93
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology (Text Only)	ODE/DRARD/ ULDB	482	02/10/93
Guidance for the Content of Premarket Notifications for Ureteral Stents (Text Only)	ODE/DRARD/ ULDB	431	02/10/93
Telephone Communications Between ODE Staff and Manufacturers #I93-1 (blue book memo) (Text Only)	ODE	360	01/29/93
Policy for Expiration Dating (DCRND RB92-G) (PDF Only)	ODE/DCD	137	10/30/92
General Guidance Document: Non-Invasive Pulse Oximeter (PDF Only)	ODE/DAGID/ ARDB	997	09/07/92
Important Information About Rophae Intraocular Lenses (PDF Only)	ODE/DOED/ ICIB	811	08/20/92
Guidance for Peak Flow Meters for Over-the-Counter Sale (PDF Only)	ODE/DAGID/ ARDB	998	06/23/92

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SMDA Changes - Premarket Notification; Regulatory Requirements for Medical Devices (510k) Manual Insert (PDF Only)	ODE	655	04/17/92
Preamendment Class III Devices (PDF Only)	ODE	584	03/11/92
Nondisclosure of Financially Sensitive Information #I92-1 (blue book memo) (Text Only)	ODE	587	03/05/92
Document Review Processing #I91-1 (blue book memo) (Text Only)	ODE	446	02/12/92
ODE Guidance Documents 1990 - 1991			
Heated Humidifier Review Guidance (PDF Only)	ODE/DAGID/ ARDB	780	08/30/91
Integrity of Data and Information Submitted to ODE #I91-2 (blue book memo) (Text Only)	ODE	447	05/29/91
Panel Review of Premarket Approval Applications #P91-2 (blue book memo) (Text Only)	ODE	444	05/03/91
PMA Compliance Program #P91-3 (blue book memo) (Text Only)	ODE	445	05/03/91
Shelf Life of Medical Devices (PDF Only)	ODE	415	04/01/91
Device Labeling Guidance #G91-1 (blue book memo) (Text Only)	ODE	414	03/08/91
Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices #G90-2 (blue book memo) (Text Only)	ODE	30	10/19/90
Consolidated Review of Submissions for Lasers and Accessories #G90-1 (blue book memo) (Text Only)	ODE	31	10/19/90
Guidance on 510(k) Submissions for Implanted Infusion Ports (PDF Only)	ODE/DAGID/ GHDB	392	10/01/90
Assignment of Review Documents #I90-2 (blue book memo) (Text Only)	ODE	366	08/24/90
Premarket Testing Guidelines for Female Barrier Contraceptive Devices also intended to prevent sexually transmitted diseases (PDF Only)	ODE/DRARD/ OGDB	384	04/04/90
Policy Development and Review Procedures #I90-1 (blue book memo) (Text Only)	ODE	368	02/15/90
Reviewer Guidance for Automatic X-Ray Film Processor 510(k) (PDF Only)	ODE/DRARD	788	02/01/90
Implantable Pacemaker Testing Guidance (PDF Only)	ODE/DCD/ PDLB	383	01/12/90
Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)	ODE	390	01/01/90
Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical Devices Marketed Prior to May 28, 1976 (PDF Only)	ODE	352	01/01/90
ODE Guidance Documents 1976 - 1989			
Meetings with the Regulated Industry #I89-3 (blue book Memo)	ODE	367	11/20/89
Toxicology Risk Assessment Committee #G89-1 (blue book memo) (Text Only)	ODE	363	08/09/89
New FDA Recommendations & Results of Contact Lens Study (7 day letter) (PDF Only)	ODE/DOED/ VEDB	265	05/30/89
Review of IDEs for Feasibility Studies #D89-1 (blue book memo) (Text Only)	ODE	362	05/17/89
Premarket Notification - Consistency of Reviews #K89-1 (blue Book memo) (Text Only)	ODE	339	02/28/89
Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II (PDF Only)	ODE/DAGID/ ARDB	583	02/01/89
Balloon Valvuloplasty Guidance For The Submission Of an IDE Application and a PMA Application (Text Only)	ODE/DCD	370	01/01/89
Guidance for Studies for Pain Therapy Devices - General Consideration in the Design of Clinical Studies for Pain-Alleviating Devices	ODE/DGRND/ REDB	640	05/12/88
Review of Laser Submissions #G88-1 (blue book memo) (Text Only)	ODE	330	04/22/88
Limulus Amebocute Lysate; Reduction of Samples for Testing (PDF Only)	ODE	178	10/23/87
ODE Executive Secretary Guidance Manual G87-3	ODE	1338	08/07/87
Master Files Part III; Guidance on Scientific and Technical Information (PDF Only)	ODE	338	06/01/87
Industry Representatives on Scientific Panel (PDF Only)	ODE	329	03/23/87
Panel Report and Recommendations on PMA Approvals #P86-5 (blue book memo) (Text Only)	ODE	306	04/18/86
Points to Consider in the Characterization of Cell Lines Used to Produce Biological Products	ODE	269	06/01/84
Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices (PDF Only)	ODE	267	12/01/83
Guidance ('Guidelines') for Evaluation of Hysteroscopic Sterilization Devices	ODE/DRARD/ OGDB	248	05/10/78
Guidance ('Guidelines') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories) (PDF Only)	ODE/DRARD/ OGDB	232	05/01/78
Guidance ('Guidelines') for Evaluation of Tubal Occlusion Devices (PDF Only)	ODE/DRARD/ OGDB	245	11/22/77
Guidance ('Guidelines') for Evaluation of Fetal Clip Electrode (PDF Only)	ODE/DRARD/ OGDB	244	03/08/77
Guidelines for Evaluation of Non-Drug IUDs	ODE/DRARD/ OGDB	641	09/26/76
Review Guidance for Oxygen Generators and Oxygen Equipment (PDF Only)	ODE/DAGID/ ARDB	986	
OIVD Guidance Documents			
Guidance for Industry and FDA Staff - In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency	OIVD	1706	11/06/09
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Cardiac Allograft Gene Expression Profiling Test Systems	OIVD/DCTD	1686	10/21/09
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Assays	OIVD/DMD	1672	10/09/09
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays	OIVD/DMD	1673	10/09/09
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay	OIVD/DMD	1669	10/09/09

Title	Organization	Doc #	Date
Draft Guidance for Industry and FDA Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses	OIVD/DMD	1699	09/09/09
Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems	OIVD/DMD	631	08/28/09
Recommendations for Anti-Nuclear Antibody (ANA) Test System Premarket (510(k)) Submissions	OIVD/DIHD	848	01/22/09
Assay Migration Studies for In Vitro Diagnostic Devices	CBER CDRH/ OIVD	1660	01/05/09
Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA	OIVD/DMD	1665	01/02/09
Class II Special Controls Guidance Document: Plasmodium Species Antigen Detection Assays	OIVD/DMD	1646	05/20/08
Guidance for Industry and FDA Staff: Administrative Procedures for CLIA Categorization	OIVD	1143	05/07/08
Establishing Performance Characteristics of In Vitro Diagnostic Devices for Detection or Detection and Differentiation of Influenza Viruses	OIVD/DMD	1638	02/12/08
Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices	OIVD	1171	01/30/08
The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations	OIVD OC	1566	01/08/08
Draft Guidance for Industry and FDA Staff - In Vitro Diagnostic (IVD) Device Studies—Frequently Asked Questions	CBER CDRH/ OIVD	1587	10/25/07
Guidance for Industry and FDA Staff - Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions	CBER CDRH/ OIVD	1590	09/14/07
Guidance for Industry and FDA Staff - Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices	OIVD/DIHD	772	08/08/07
Draft Guidance for Industry, Clinical Laboratories, and FDA Staff - In Vitro Diagnostic Multivariate Index Assays	CBER CDRH/ OIVD	1610	07/26/07
Guidance on Pharmacogenetic Tests and Genetic Tests for Heritable Markers	CBER CDER CDRH	1549	02/09/06
Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material	OIVD	2231	06/07/07
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis	OIVD/DIHD	1627	05/09/07
In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path - Guidance for Industry and FDA Staff	OIVD/DMD	1594	05/01/07
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays	OIVD/DMD	1305	04/03/07
Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests	OSB/DB	1620	03/13/07
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays	OIVD/DIHD	1614	01/10/07
Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems	OIVD/DCTD	1603	10/24/06
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems	OIVD/DIHD	1599	07/27/06
Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable	CBER CDRH	1588	04/25/06
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses	OIVD/DMD	1596	03/22/06
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays	OIVD/DMD	1536	02/09/06
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems	OIVD/DIHD	1564	10/26/05
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: AFP-L3 Immunological Test Systems	OIVD/DIHD	1570	10/04/05
Guidance for Industry - Review Criteria for Assessment of C Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays	OIVD/DCTD	1246	09/22/05
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing)	OIVD/DIHD	1563	08/25/05
Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s	OIVD ODE	1567	08/12/05
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	CBER CDRH/ ODE CDRH/ OIVD	337	05/11/05
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems	OIVD/DIHD	1550	03/23/05
Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems - Guidance for Industry and FDA Staff	OIVD/DCTD	1546	03/10/05
Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping System - Guidance for Industry and FDA Staff	OIVD/DCTD	1551	03/10/05
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry	OIVD/DCTD	1301	11/24/04
Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Sirolimus Test Systems	OIVD/DCTD	1300	09/30/04
Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications	OIVD ODE	2237	09/28/04

Title	Organization	Doc #	Date
Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan	OIVD/DMD	1825	09/23/04
Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System - Guidance for Industry and FDA Staff	OIVD/DIHD	1531	05/11/04
Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems - Guidance for Industry and FDA Staff	OIVD/DIHD	1236	03/16/04
Guidance for Industry and FDA Staff; Replacement Reagent and Instrument Family Policy	OIVD	950	12/11/03
Premarket Submissions and Labeling Recommendations for Drugs of Abuse Screening Tests - Draft Guidance for Industry and FDA Staff	OIVD/DCTD	152	12/02/03
Class II Special Controls Guidance Document: Endotoxin Assay - Guidance for Industry and FDA Staff	OIVD/DMD	1222	10/31/03
Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus - Guidance for Industry and FDA Staff	OIVD/DMD	1206	10/30/03
Class II Special Controls Guidance Document: Breath Nitric Oxide Test System - Guidance for Industry and FDA Staff	OIVD/DCTD	1211	07/07/03
510(k) Submissions for Coagulation Instruments - Guidance for Industry and FDA Staff	OIVD/DIHD	1223	06/19/03
Premarket Approval Application Filing Review	CBER CDRH/ ODE CDRH/ OIVD	297	05/01/03
Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff (Update to K98-1)	OIVD ODE	857	12/03/02
Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA	OIVD/DCTD	1380	09/16/02
Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA	OIVD/DIHD	1184	12/04/01
Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k)s; Final Guidance for Industry and FDA	OIVD/DIHD	800	08/22/01
Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers; Final Guidance for Industry and FDA Reviewers; Final Guidance for Industry and FDA Reviewers	OIVD/DCTD	1072	11/30/00
Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) Premarket Notifications - Guidance for Industry and FDA Reviewers	OIVD/DIHD	1183	08/23/00
Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s - Guidance for Industry and FDA Reviewers/Staff	OIVD/DCTD	1172	07/22/00
Guidance for Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing (PDF Only)	OIVD/DCTD	1359	12/21/99
Guidance on Labeling for Laboratory Tests - Draft Guidance for Industry and for FDA Reviewers/ Staff	OIVD	1352	06/24/99
Document for Special Controls for Erythropoietin Assay Premarket Notifications [510(k)s]; Final Guidance for Industry	OIVD/DIHD	2241	04/28/99
In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Final Guidance for Industry and FDA Reviewers/Staff	OIVD/DIHD	2242	04/27/99
Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final Guidance for Industry	OIVD	1247	02/22/99
In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Final Guidance for Industry	OIVD/DCTD	1102	07/06/98
In Vitro Diagnostic Chloride Test System; Final Guidance for Industry	OIVD/DCTD	1103	07/06/98
In Vitro Diagnostic Potassium Test System; Final Guidance for Industry	OIVD/DCTD	1107	07/06/98
In Vitro Diagnostic Sodium Test System; Final Guidance for Industry	OIVD/DCTD	1109	07/06/98
In Vitro Diagnostic Urea Nitrogen Test System; Final Guidance for Industry	OIVD/DCTD	1110	07/06/98
In Vitro Diagnostic Glucose Test System; Final Guidance for Industry	OIVD/DCTD	1105	07/06/98
In Vitro Diagnostic Creatinine Test System; Final Guidance for Industry	OIVD/DCTD	1104	07/06/98
Guidance for Submission of Immunohistochemistry Applications to the FDA; Final Guidance for Industry	OIVD/DIHD	364	06/03/98
Review Criteria For Assessment Of Rheumatoid Factor (Rf) In Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay (Eia), Enzyme Linked Immunosorbent Assay (Elisa), Particle Agglutination Tests, And Laser And Rate Nephelometry	OIVD/DIHD	165	02/21/97
Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)	OIVD/DCTD	1345	11/06/96
Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs (PDF Only)	OIVD/DMD	1631	10/30/96
Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA	OIVD/DIHD	957	09/19/96
Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery (PDF Only)	OIVD/DCTD	122	02/20/96
Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic)	OIVD/DIHD	980	02/15/96
Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology	OIVD/DCTD	604	02/28/97
Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices/Cover Letter dated 3/14/1996 (PDF Only)	OIVD	553	03/14/96
Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use	OIVD/DCTD	605	07/13/95
Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance (PDF Only)	OIVD	95	09/26/94
Points to Consider for Cervical Cytology Devices (PDF Only)	OIVD/DIHD	968	07/25/94
Review Criteria for Assessment of Alpha-Fetoprotein (AFP) in vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies (PDF Only)	OIVD/DIHD	459	07/15/94

Title	Organization	Doc #	Date
Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoasay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA)	OIVD/DIHD	51	02/01/94
Guideline for the Manufacture of In Vitro Diagnostic Products (PDF only)	OIVD	918	01/10/94
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. [Tuberculosis (TB)] (PDF Only)	OIVD/DMD	862	07/06/93
Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter pylori (PDF Only)	OIVD/DMD	588	09/17/92
Draft Guidance Document for 510(k) Submission of Immunoglobulins A,G,M,D and E Immunoglobulin System In Vitro Devices (PDF Only)	OIVD/DIHD	785	09/01/92
Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents (PDF Only)	OIVD/DIHD	527	08/01/92
Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19 (PDF Only)	OIVD/DMD	770	05/15/92
Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe (PDF Only)	OIVD/DMD	554	12/30/91
Review Criteria for Assessment of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin In Vitro Diagnostic Devices (Text Only)	OIVD/DIHD	658	09/30/91
Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs using Monoclonal Antibodies (PDF Only)	OIVD/DIHD	475	09/26/91
Review Criteria for Blood Culture Systems (PDF Only)	OIVD/DIHD	82	08/12/91
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers (Text Only)	OIVD/DIHD	417	07/15/91
Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases (PDF Only)	OIVD/DMD	629	05/31/90
Assessing the Safety and Effectiveness of Home-Use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions (Text Only)	OIVD	272	10/05/88
Office of Surveillance and Biometrics Guidance Documents			
Draft Guidance for Industry, User Facilities and FDA Staff: eMDR - Electronic Medical Device Reporting	OSB/DPS	1679	08/21/09
Procedures for Handling Post-Approval Studies Imposed by PMA Order	OSB/DPS	1561	06/16/09
Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests	OSB/DB	1620	03/13/07
Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials	OSB/DB	1601	02/05/10
Postmarket Surveillance Under Section 522 of the Federal Food, Drug and Cosmetic Act	OSB	316	04/26/06
Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment	OSB/DPS OCER/DHC	1537	03/10/06
Needlesticks - Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers	OSB/DSS/ RSMB	250	11/12/02
Medical Device Reporting - Remedial Action Exemption; Guidance for FDA and Industry	OSB/DSS/ RSMB	188	09/26/01
Hospital Reprocessors: Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use	OSB/DSS/ RSMB	1334	04/24/01
MEDWATCH Medical Device Reporting Code Instructions	OSB/DSS	853	04/04/01
Medical Device Reporting - Alternative Summary Reporting (ASR) Program	OSB/DSS/ RSMB	315	10/19/00
Guidance for Industry and for FDA Reviewers/Staff - Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements	OSB/DPS	946	02/02/00
SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols	OSB/DPS	318	11/02/98
Instructions for Completing Form 3417 - Medical Device Reporting Baseline Report	OSB/DSS	1061	07/01/96
Variance from Manufacturer Report Number Format - No. 5	OSB/DSS		08/12/96
MDR Guidance Document No. 1 - IOL - E1996004	OSB/DSS	216	08/06/96
Variance from Manufacturer Report Number Format [MDR letter]	OSB/DSS	1059	07/16/96
Medical Device Reporting: An Overview	OSB/DSS	509	04/01/96
Statistical Guidance for Clinical Trials of Non Diagnostic Medical Devices	OSB	476	01/01/96
MedWatch: The FDA Safety Information and Adverse Event Reporting Program -			01/01/09
Common Problems: Baseline Reports and MedWatch Form 3500A (letter to manufacturers updated) (PDF version)	OSB/DSS	379	
Perspectives on Clinical Studies for Medical Device Submissions (PDF Only)	OSB	78	
PMA Review Statistical Checklist (PDF Only)	OSB	84	
Office of Science and Engineering Laboratories Guidance Documents			
Draft Guidance for Industry and FDA Staff: Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions	OSEL/DIAM	1698	10/21/09
Draft Guidance for Industry and FDA Staff: Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions	OSEL/DRARD/ RDB	1697	10/21/09
Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers	OSEL ODE/ DRARD	560	09/09/08
Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment	OSEL	1685	08/21/08
Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Bone Sonometers	OSEL ODE/ DRARD	1547	07/17/08

Title	Organization	Doc #	Date
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Full Field Digital Mammography System	OSEL ODE/ DRARD	1616	05/30/08
Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions	OSEL ODE/ DRARD	1617	05/30/08
CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition	OSEL	616	09/17/07
Frequently Asked Questions on Recognition of Consensus Standards	OSEL	109	09/17/07
Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards	OSEL	321	09/17/07
Radio-Frequency Wireless Technology in Medical Devices	OSEL/DPS/ EPB	1618	01/03/07
Dental Curing Lights - Premarket Notification [510(k)]	OSEL/DPS ODE/DAGID/ DEDB	1591	03/27/06
Immunotoxicity Testing Guidance	OSEL	635	05/06/99
Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problem	OSEL/DECS	2000	05/15/98
A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems	OSEL	952	02/07/97

V. Center for Food Safety and Applied Nutrition (CFSAN)

For information on a specific guidance document or to obtain a paper copy, call the contact number located on the title page of the guidance. You may access electronic versions of CFSAN's guidance documents at *http://www.fda.gov/FoodGuidances*, *http://www.fda.gov/CosmeticGuidances*, and *http://www.fda.gov/ColorAdditiveGuidances*.

The following is a list of CFSAN guidance documents that have been withdrawn:

Title of Document	Date of Issuance	Date of Withdrawal
Release of Task Force Report; Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Withdrawal of Guidance	July 10, 2003	January 16, 2009
Guidance for Industry; Importer's Guide for Low-Acid Canned and Acidified Food	1985	May 29, 2009
Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements; Withdrawal of Guidance	December 22, 1999	January 16, 2009
Guidance for Industry on the Food and Drug Administration Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Withdrawal of Guidance	January 22, 2001	April 25, 2008

The following is a list of current CFSAN guidance documents as of May 13, 2010:

Biotechnology Safety Assessments

- Statement of Policy & Guidance to Industry: Foods Derived from New Plant Varieties (57 FR 22984, May 29, 1992)
- Consultation Procedures under FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties (October 1997)
- Draft Guidance: Use of Antibiotic Resistance Marker Genes in Transgenic Plants (September 1998)
- Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (June 2006)

Chemical Contaminants and Pesticides

- Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed (2000)

Chemical Contaminants

- **Arsenic:** Bottled Water: Arsenic Small Entity Compliance Guide (April 2009)
- **Disinfectants:** Bottled Water: Residual Disinfectants and Disinfection Byproducts Small Entity Compliance Guide (May 2009)
- **Lead:** 1991 Letter to Bureau of Alcohol, Tobacco and Firearms Regarding Lead in Wine (March 2007)
- **Lead:** Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy (November 2006)
- **Lead:** Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers (June 13, 1995)
- **Uranium:** Bottled Water: Uranium Small Entity Compliance Guide (April 2009)

Pesticides

- **Pesticide Chemicals:** Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations (May 2005)
- **Methyl Parathion:** Channels of Trade Policy for Commodities with Methyl Parathion Residues (December 2000)
- **Vinclozolin:** Channels of Trade Policy for Commodities with Vinclozolin Residues (June 12, 2002)

Also see Natural Toxins

- Fumonisin Levels in Human Foods and Animal Feeds (November 9, 2001)

Dietary Supplements

- Liquid Dietary Supplements: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods (December 2009)

- Labeling: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (December 2007; Revised December 2008 and September 2009)
- A Dietary Supplement Labeling Guide (April 2005)
- Ephedrine Alkaloids: Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk (July 17, 2008)
- Label Warning Statements: Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide (October 17, 2003)
- Labeling: Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide (January 1999)
- Nutrient Content Claims: Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition for "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods Small Entity Compliance Guide (July 2008)
- Structure/Function Claims: Small Entity Compliance Guide (January 9, 2002)
- Substantiation for Claims: Substantiation for Dietary Supplement Claims Made Under Section 403(r) (6) of the Federal Food, Drug, and Cosmetic Act (November 2004)

Health Claims

- Evidence-Based Review System for the Scientific Evaluation of Health Claims (January 2009)
- Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (June 1998)

Qualified Health Claims

- Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003)

Adverse Events Reporting

- Adverse Event Reporting and Recordkeeping: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (June 2009)

Food Defense and Emergency Response

Emergency Response

- Guidance for Industry: Use of Water by Food Manufacturers in Areas Subject to a Boil-Water Advisory (May 2010)

Prior Notice of Food Imports

- Compliance Policy Guide - Guidance for FDA and CBP Staff: Prior Notice of Imported Food (May 2009)
- Entry Types and Entry Identifiers - Prior Notice of Imported Food (April 7, 2005)
- Prior Notice of Imported Food Contingency Plan for System Outages (August 12, 2004)
- Prior Notice of Imported Food Questions and Answers (Edition 2) (May 3, 2004)
- What You Need to Know About Prior Notice of Imported Food Shipments (November 25, 2003; Revised April 2009)
- Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators (August 26, 2004)

Registration of Food Facilities

- Questions and Answers Regarding Registration of Food Facilities (Edition 4) (August 6, 2004)
- Compliance Policy Guide - Guidance for FDA Staff: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (December 2003; Revised November 2004 and August 2006)
- Necessity of the Use of Food Product Categories in Registration of Food Facilities (July 17, 2003)
- What You Need to Know About Registration of Food Facilities (November 25, 2003)

Establishment and Maintenance of Records

- Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4) (September 21, 2006)
- Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (November 2005)
- What You Need to Know About Establishment and Maintenance of Records (December 2004)

Administrative Detention

- What You Need to Know About Administrative Detention of Foods (November 2004)

Food and Cosmetic Security Preventive Measures Guidance

- Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance (October 2007)
- Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance (October 2007)
- Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance (October 2007)
- Importers and Filers: Food Security Preventive Measures Guidance (October 2007)
- Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance (October 2007)

ALERT

- Letter to Industry, State and Local Food Regulators and Inspectors Regarding Web-based ALERT Training (February 22, 2007)

Food Ingredients and Packaging

Petition Process for Food and Color Additives

- Electronic Submissions
  - Regulatory Submissions: Providing Regulatory Submissions in Electronic Format or Paper Format to the Office of Food Additive Safety (Draft Guidance, March 2010).
  - Providing Regulatory Submissions in Electronic Format—General Considerations (Agency) (Draft Guidance, October 2003)
  - Providing Food and Color Additive Petitions in Electronic Format (Draft, July 2001)
  - Submission Form - FDA Form 3503 (PDF - 256KB)
- Preparing Petitions
  - Pre-Petition Consultations for Food Additives and Color Additives for the Preparation of Petition Submissions (April 2005)
  - Questions And Answers About the Food Additive Petition Process (September 2003; Revised April 2006)
- Food Additives
  - Guidance for Food Additive Petition Expedited Review (January 1999)

Preparation of Notifications for Food Contact Substances (Food Contact Notifications (FCN))

- Preparation of Food Contact Notifications: Administrative (June 2000; Revised May 2002)
  - FDA Form 3480 - Notification for New Use of a Food Contact Substance (PDF - 1031KB)
  - FDA Form 3479 - Notifications for Food Contact Formulation (PDF-583KB)

Threshold of Regulation (TOR) Guidance

- Guidance for Submitting Requests under 21 CFR 170.39, Threshold of Regulation for Substances Used in Food Contact Articles (March 1996; Revised April 2005)

GRAS Notices

- Frequently Asked Questions about GRAS (December 2004)

Scientific Guidance Documents

Chemistry Guidance Documents

- Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations (April 2002; Revised December 2007)
- Use of Recycled Plastics in Food Packaging: Chemistry Considerations (August 2006)
- Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions (March 2006; Revised March 2009)
- Estimating Dietary Intake of Substances in Food (September 1995; Revised August 2006)
- Enzyme Preparations: Chemistry Recommendations for Food Additive and GRAS Affirmation Petitions, January 1993.

Microbiology

- Guidance for Antimicrobial Food Additives (July 1999)
- Microbiological Considerations for Antimicrobial Food Additive Submissions (June 2008)

Toxicology Guidance Documents

- Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations (September 1999; April 2002)
- Summary Table of Recommended Toxicological Testing for Additives Used in Food (1983; Revised June 2006)
- Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food
  - Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as Redbook I), U.S. Food and Drug Administration, Bureau of Foods (now CFSAN), 1982. May be purchased from: National Technical Information Services (NTIS), 5285 Port Royal Road, Springfield, VA 22161, Telephone (703) 605-6000, NTIS Order Number PB83-170696.
  - Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives: 1993 Draft Redbook II. Sections of Draft Redbook II not yet finalized in Redbook 2000 are available.
  - Toxicological Principles for the Safety Assessment of Food Ingredients: Redbook 2000 (July 7, 2000; Revised October 2001, November 2003, April 2004, February 2006, and July 2007)
    (Redbook 2000 chapters now substitute for or supplement guidance available in the 1982 Redbook I and in the 1993 Draft Redbook II, which can be obtained from the Office of Food Additive Safety. Additional chapters of Redbook 2000 will become available electronically upon their completion.)
- Templates for reporting toxicology data (March 2004; April 2005)

Environmental Guidance Documents

- Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (May 2006)

When testing is necessary, consult the Environmental Assessment Technical Assistance Handbook for testing guidelines.

- Environmental Assessment Technical Assistance Handbook (September 2003; Revised May 2006)

Please contact the Environmental Review Group at *Premarkt@fda.hhs.gov* for assistance in preparing a claim of categorical exclusion or an EA and before doing environmental fate and effects testing.

Color Additives Guidance Documents

- Guidance for Industry: Color Additive Petitions - FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs, Cosmetics, or Medical Devices (January 1997; Revised July 2009)
- Guidance for Industry: Preparing a Color Additive Petition for Submission to the Center for Food Safety and Applied Nutrition for Color Additives Used in or on Contact Lenses (May 2006)

Food Labeling & Nutrition

General

- A Food Labeling Guide (April 2008)
- Retail Labeling: A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods (April 2008)
- Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Small Entity Compliance Guide (August 20, 2003)
- Guidelines for Determining Metric Equivalents of Household Measures (October 1, 1993)
- Food Allergens: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4) (October 2006)
- Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers (June 10, 1996)
- Guidance for Industry: Ingredients Declared as Evaporated Cane Juice; Draft Guidance (October 2009)

Nutrition Labeling

- Small Business Nutrition Labeling Exemption (October 1, 2004; Updated May 7, 2007)
- FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases (March 1998)

Label Claims

- Letter Regarding Point of Purchase Food Labeling (October 2009)
- Dear Manufacturer Letter Regarding Front-of-Package Symbols (December 2008)
- Dear Manufacturer Letter Regarding Food Labeling (January 2007)
- Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (July 1998)
- Structure/Function Claims: Small Entity Compliance Guide (January 9, 2002)
- Nutrient Content Claims: Dear Manufacturer Letter Regarding Sugar Free Claims (September 2007)
- Nutrient Content Definitions: Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition for "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods Small Entity Compliance Guide (July 2008)

Health Claims

- Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003)
- FDA's Implementation of "Qualified Health Claims": Questions and Answers (May 12, 2006)
- Evidence-Based Review System for the Scientific Evaluation of Health Claims (January 2009)
- Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (December 1999)
- Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis (May 2009)

Specific Products

- Beer: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration; Draft Guidance (August 2009)
- Juice: Exemptions from the Warning Label Requirement for Juice - Recommendations for Effectively Achieving a 5-Log Pathogen Reduction (October 7, 2002)
- Milk: Interim Guidance on the Voluntary Labeling of Milk and Milk Products that have not been treated with Recombinant Bovine Somatropin (59 FR 6279, February 10, 1994)

- Shell Eggs: Food Labeling - Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution Small Entity Compliance Guide (July 2001)
- Soy Lecithin: Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act (April 2006)
- White Chocolate: Standard of Identity for White Chocolate; Small Entity Compliance Guide (July 17, 2008)
- Whole Grain: Draft Guidance: Whole Grain Label Statements (February 2006)
- Biotechnology: Draft Guidance: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (January 2001)
- Irradiation: Implementation of Section 10809 of the Farm Security and Investment Act of 2002, Pub. L. No. 107-171, § 10809 (2002) regarding the Petition Process to Request Approval of Labeling for Foods that Have Been Treated by Irradiation. (October 2002)
- Label Warning Statements: Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide (October 17, 2003)
- Refrigeration: Guidance on Labeling of Foods that Need Refrigeration by Consumers (62 FR 8248, February 24, 1997)
- Serving Size: Food Labeling - Serving Sizes Reference Amount for Baking Powder, Baking Soda, Pectin; Small Entity Compliance Guide (July 2001)

Color Additive Guidance

- Guidance for Industry: Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products That Contain These Color Additives; Small Entity Compliance Guide (April 2009)

Food Processing & HACCP

- Food Processing: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods (February 2008)
- Juice
  - Juice HACCP Hazards and Control Guidance - First Edition (March 3, 2004)
  - Juice HACCP Small Entity Compliance Guide (April 4, 2003)
  - Standardized Training Curriculum for Application of HACCP Principles to Juice Processing (June 2003)
- Seafood
  - Fish and Fisheries Products Hazards and Control Guide 3rd Edition (June 2001)
  - Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products (July 2001)
  - Seafood HACCP Transition Policy (December 1999)

Food Safety

- Guidance for Industry: Sanitary Transportation of Food (April 2010)
- Guidance for Industry: Submitting a Report for Multiple Facilities to the Reportable Food Electronic Portal as Established by the Food and Drug Administration Amendments Act of 2007 March 2010
- Guidance for Industry Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 June 2009; Revised September 2009

Imports & Exports

- Establishing and Maintaining a List of U. S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile (June 22, 2005)
- Importers and Filers: Food Security Preventive Measures Guidance (October 2007)
- Draft Guidance: Regulatory Procedures Manual Chapter 9, Subchapter: Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned (November 5, 2002)
- Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers (June 13, 1995)

Prior Notice of Imported Foods

- Prior Notice of Imported Food Questions and Answers (Edition 2) (May 3, 2004)
- What You Need to Know About Prior Notice of Imported Food Shipments (November 25, 2003; Revised April 2009)

Infant Formula

Frequently Asked Questions about FDA's Regulation of Infant Formula (March 1, 2006)
Clinical Testing of Infant Formulas With Respect to Nutritional Suitability for Term Infants June 1988
Guidelines Concerning Notification and Testing of Infant Formulas 1985

Juice

- Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices (June 2007)
- Letter to State Regulatory Agencies and Firms That Produce Treated (but not Pasteurized) and Untreated Juice and Cider (September 22, 2005)
- Recommendations to Processors of Apple Juice or Cider on the Use of Ozone for Pathogen Reduction Purposes (November 2004)
- Juice HACCP Hazards and Control Guidance - First Edition (March 3, 2004)
- The Juice HACCP Regulation: Questions and Answers (September 4, 2003)
- Standardized Training Curriculum for Application of HACCP Principles to Juice Processing (June 2003)
- Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices (April 24, 2003)
- Juice HACCP Small Entity Compliance Guide (April 4, 2003)
- Exemptions from the Warning Label Requirement for Juice - Recommendations for Effectively Achieving a 5-Log Pathogen Reduction (October 7, 2002)
- The Juice HACCP Regulation: Questions & Answers (August 31, 2001)

Medical Foods

- Frequently Asked Questions About Medical Foods (May 1997; Revised May 2007)

Natural Toxins

- Letter to State Agricultural Directors, State Feed Control Officials, and Food, Feed, and Grain Trade Organizations (September 16, 1993)
- Fumonisin Levels in Human Foods and Animal Feeds (November 2001)

Related Guidance

- CPG Sec.510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products - Adulteration with Patulin*http://edocket.access.gpo.gov/2010/pdf/2010-12638.pdf*
  October 2001; Updated November 2005

Produce and Plant Products Guidance for Industry

Produce

- Guide to Minimize Microbial Food Safety Hazards of Tomatoes (July 2009)
- Guide to Minimize Microbial Food Safety Hazards of Melons (July 2009)
- Guide to Minimize Microbial Food Safety Hazards of Leafy Greens (July 2009)
- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (October 26, 1998)
  (Also available in French, Spanish, Portuguese and Arabic*)

- Final Guidance: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (February 2008)
- Reducing Microbial Food Safety Hazards For Sprouted Seeds (October 1999)
- Sampling And Microbial Testing Of Spent Irrigation Water During Sprout Production (October 1999)

Nuts

- Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Pistachio-Derived Product As An Ingredient (June 2009)
- Measures to Address the Risk for Contamination by *Salmonella* Species in Food Containing a Peanut-Derived Product as an Ingredient (March 2009)

Retail Food Protection

- Decontamination of Transport Vehicles: A Notice from the Food and Drug Administration to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products on Decontamination of Transport Vehicles (October 7, 2005; Revised August 2006)
- Food Defense: Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance (December 2003; Revised October 2007)
- Labeling of Shell Eggs: Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution, Small Entity Compliance Guide (July 2001)

Sanitation

- Defect Action Levels (DALS) (1995; Revised March 1997 and May 1998)

Booklet. This list is compiled from FDA's Compliance Policy Guides on established "current levels for natural or unavoidable defects in food for human use that present no health hazards."

- Action Levels for Poisonous or Deleterious Substances in Human Food and Feed (2000)

Seafood

- 1991 Letter to Seafood Manufacturers Regarding the Fraudulent Practice of Including Glaze (ice) as Part of the Weight of Frozen Seafood (February 2009)
- Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association (January 2009; Revised February 2009)
- Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products (July 2001)
- Fish and Fisheries Products Hazards and Control Guide *3rd Edition* (June 2001)
  - Updated Information: Letter to Seafood Processors that Purchase Grouper, Amberjack, and Related Predatory Reef Species Captured in the Northern Gulf of Mexico (February 2008)
- HACCP Regulation for Fish and Fishery Products; Questions and Answers for Guidance to Facilitate the Implementation of a HACCP System in Seafood Processing (Issue Three, January 1999)
- Seafood HACCP Transition Policy (December 1999)
- Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association (November 2004)
- Implementation of Section 403(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(t)) Regarding the Use of the Term "Catfish" (December 2002)
- Guidance and Protocol: Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association (January 2008)

Small Entity Compliance Guides

- Submission of Comments for CFSAN Rulemaking (October 2002)
- Booklets Available on Bioterrorism Act of 2002 Legislation
  - What You Need to Know About Registration of Food Facilities (November 2003)
  - What You Need to Know About Prior Notice of Imported Food Shipments (November 2003; Revised April 2009)
  - What You Need to Know About Establishment and Maintenance of Records (December 2004)
  - What You Need to Know About Administrative Detention of Foods (November 2004)
- Food Labeling
  - *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims (August 20, 2003)
  - Small Business Nutrition Labeling Exemption (October 2004; Revised May 2007)
  - Food Labeling - Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution (July 2001)
  - Food Labeling - Serving Sizes Reference Amount for Baking Powder, Baking Soda, Pectin (July 2001)
  - Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition for "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods (July 2008)
  - Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis (May 2009)
- Food Standards: Standard of Identity for White Chocolate (July 17, 2008)
- Dietary Supplements
  - Iron-Containing Supplements and Drugs: Label Warning Statements (October 17, 2003)
  - Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk (July 17, 2008)
  - Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements (January 1999)
  - Structure/Function Claims (January 9, 2002)
- Shell Eggs: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Transportation, and Storage (April 2010)
- Juice: Juice HACCP (April 4, 2003)
- Bottled Water
  - Bottled Water: Total Coliform and *E. coli* (March 2010)
  - Bottled Water: Residual Disinfectants and Disinfection Byproducts (May 2009)
  - Bottled Water: Arsenic (April 2009)
  - Bottled Water: Uranium (April 2009)

Color Additive Guidance

- Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products That Contain These Color Additives (April 2009)
- Petitions
  - Preparing a Color Additive Petition for Submission to the Center for Food Safety and Applied Nutrition for Color Additives Used in or on Contact Lenses (May 2006)

- Color Additive Petitions - FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs, Cosmetics, or Medical Devices (January 1997; Revised July 2009)

Cosmetic Guidance

- Guidance: Labeling for Cosmetics Containing Alpha Hydroxy Acids (January 10, 2005)
- Guidance for Industry: Cosmetics Processors and Transporters of Cosmetics Security Preventive Measures Guidance (November 2003; Revised October 2007)
- Cosmetic Labeling Manual (October 1991)

VI. Center for Tobacco Products (CTP)

For information on a specific guidance document or to obtain a paper copy contact:

Document Control Center, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, e-mail: *TobaccoIndustryQuestions@fda.hhs.gov*, *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

The following list of current CTP guidance documents was obtained from FDA's Web site on April 22, 2010:

- Final Guidance for Industry: Tobacco Health Document Submission
- Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments
- Draft Guidance: The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act
- Final Guidance for Industry: Listing of Ingredients in Tobacco Products
- Draft Guidance for Industry: Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act
- Guidance for Industry: Timeframe for Submission of Tobacco Health Documents
- Guidance to Industry and FDA Staff: General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)

VII. Center for Veterinary Medicine (CVM)

For information on a specific guidance document or to obtain a paper copy, contact:

Communications Staff, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9300, e-mail: *AskCVM@fda.hhs.gov*, *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm*.

The following list of CVM guidance documents that have been withdrawn was obtained from FDA's Web site on April 22, 2010:

WITHDRAWN/REPLACED GUIDANCES

No.	Title	Date
1	Anticoccidial Guidelines	*Replaced by Guideline #40*
2	Anthelmintics	*Withdrawn 12/22/2004*
4	Guidelines for Efficacy Studies for Systemic Sustained Release Sulfonamide Boluses for Cattle	*Withdrawn 12/22/2004*
8	Guidelines for Toxicological Investigations	*Replaced by Guideline # 3*
9	Preclearance Guidelines for Production Drugs	*Withdrawn pending revisions*
14	Guideline and Format for Reporting the Details of Clinical Trials Using An Investigational New Animal Drug in Food Producing Animals	*Withdrawn 12/22/2004*
15	Guideline and Format for Reporting the Details of Clinical Trials Using An Investigational New Animal Drug in Non-Food Producing Animals (2277)	*Withdrawn 12/22/2*
17	Working Guidelines for Assigning Residue Tolerances	*Replaced by Guideline # 3*
18	Antibacterial Drugs in Animal Feeds: *Human* Health Safety Criteria	*Withdrawn 12/22/2004*
19	Antibacterial Drugs in Animal Feeds: *Animal* Health Safety Criteria	*Withdrawn 12/22/2004*
20	Antibacterial Drugs in Animal Feeds: Antibacterial Effectiveness Criteria	*Withdrawn 12/22/2004*
21	Nutritional Ingredients in Animal Drugs and Feeds	*Withdrawn 9/17/2009*
25	Guidelines for the Efficacy Evaluation of Equine Anthelmintics	*Replaced by Guidance 109*
26	Guidelines for the Preparation of Data to Satisfy the Requirements of Section 512 of the Act Regarding Animal Safety, Effectiveness, Human Food Safety and Environmental Considerations for Minor Use of New Animal Drugs	*(superceded by Guidance #61) 04/86;*
27	New Animal Drug Determinations	*Withdrawn 9/17/2009*

WITHDRAWN/REPLACED GUIDANCES—Continued

No.	Title	Date
28	Animal Drug Applications Expedited Review Guideline	*Withdrawn 10/14/2009*
29	Guidelines for the Effectiveness Evaluation of Swine Anthelmintics	*Replaced by Guidance 110*
30	Guidelines for Anti-infective Bovine Mastitis Product Development	*Replaced by guideline #49*
31	Guideline for the Evaluation of Bovine Anthelmintics	*Replaced by guideline #95*
32	Guideline for Threshold Assessment	*Replaced by Guideline # 3*
33	Target Animal Safety Guidelines for New Animal Drugs	*Withdrawn, superceded by #85 4/24/09*
34	Biomass Guideline - Guideline for New Animal Drugs and Food Additives Derived From a Fermentation; Human Food Safety Evaluation	*Replaced by Guideline # 3*
36	Guidelines for Efficacy Evaluation of Canine/Feline Anthelmintics	*Replaced by Guidance # 111*
39	Guideline on the Conduct of Clinical Investigations: Responsibilities of Clinical Investigators and Monitors for Investigational New Animal Drug Studies	*replaced by Guidance # 85*
41	Draft Guideline: Formatting, Assembling, and Submitting New Animal Drug Applications	*Withdrawn 3/2002*
43	Draft Guideline for Generic Animal Drug Products Containing Fermentation-Derived Drug Substances	*Withdrawn 05/24/06*
51	Points to Consider Guideline - Development of a Pharmacokinetic Guideline Enabling Flexible Labeling of Therapeutic Antimicrobials	"*Please see Guidance 66 for updated information.*"
52	Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora, February 18, 2004	*Replaced by Guidance 159*
54	Draft Guideline for Utility Studies for Anti-Salmonella Chemical Food Additives in Animal Feeds	*06/94 See Final Guidance #80*
58	Guidance for Industry for Good Target Animal Study Practices: Clinical Investigators and Monitors	*Withdrawn 12/22/2004; superseded by guidance #85*
60	Guidance For Industry: Animal Proteins Prohibited From Animal Feed; Small Entity Compliance Guide	*Replaced by Guidance 67, 68, 69, and 70*
66	Withdrawal of Guidance Document on Professional Flexible Labeling of Antimicrobial Drugs	*Withdrawn 01/30/200*
77	Guidance for Industry: Interpretation of On-Farm Feed Manufacturing and Mixing Operations:	*Withdrawn 06/12/03*
78	Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals	*Replaced by Guidance 152*
154	Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records	*Withdrawn 02/25/03*
155	Draft Guidance for Industry: 21 CFR Part 11: Electronic Records; Electronic Signatures; Electronic Copies of Electronic Records	*Withdrawn 02/04/03*
172	Guidance for Industry #172 - Use of unapproved hormone implants in veal calves, April 2, 2004	*Withdrawn 07/15/04*

The following list of current CVM guidance documents was obtained from FDA's Web site on April 22, 2010:

3	CVM GFI #3 General Principles for Evaluating the Safety of Compounds Used in Food Producing Animals	07/27/06
5	CVM GFI #5 Stability Guidelines	12/01/90
6	CVM GFI #6 Submitting NADA's for Generic Drugs Reviewed by NAS/NR	03/19/76
10	CVM GFI #10 Amendment of Section II(G)(1)(b)(4) of the Preclearance Guidelines	10/01/75
13	CVM GFI #13 Evaluation of Effectiveness of New Animal Drugs for Use in Free-Choice Feeds-Medicated Block	01/01/85
22	CVM GFI #22 Guideline Labeling of Arecoline Base Drugs Intended for Animal Use	
23	CVM GFI #23 Medicated Free Choice Feeds—Manufacturing Control	07/01/85
24	CVM GFI #24 Drug Combinations for Use in Animals	10/01/83
35	CVM GFI #35 Bioequivalence Guidance	11/08/06
37	CVM GFI #37 Evaluation of Effectiveness of New Animal Drugs for Use in Poultry Feed for Pigmentation	03/01/84

38	CVM GFI #38 Guideline for Effectiveness Evaluation of Topical/Otic Animal Drugs	03/01/84
40	CVM GFI #40 Draft Guideline for the Evaluation of the Efficacy of Anticoccidial Drug Combinations in Poultry	04/01/92
42	CVM GFI #42 Animal Drug Manufacturing Guidelines- Series of Four Guidelines	01/01/94
45	CVM GFI #45 Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle	08/01/93
48	CVM GFI #48 Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products	11/01/94
49	CVM GFI #49 Target Animal Safety And Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products (Lactating and Non-Lactating Cow Products)	04/01/96
50	CVM GFI #50 Target Animal and Human Food Safety,Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products	02/01/93
53	CVM GFI #53 Evaluation of the Utility of Food Additives in Diet Fed to Aquatic Animals	05/01/94
55	CVM GFI #55 Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH Claims: Protocol Development	06/01/94
56	CVM GFI #56 Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials	07/10/01
57	CVM GFI #57 Preparation and Submission of Veterinary Master Files	01/01/95
59	CVM GFI #59 How to Submit a Notice of Claimed Investigational Exemption in Electronic Format to CVM	06/15/09
61	CVM GFI #61 FDA Approval of New Animal Drugs for MUMS	05/29/08
62	Consumer-Directed Broadcast Advertisements	
63	VICH GL1 - Validation of Analytical Procedures: Definition and Terminology	07/01/99
64	VICH GL2 - Validation of Analytical Procedures: Methodology: Final Guidance	07/01/99
	Industry-Supported Scientific and Educational Activites	
67	CVM GFI #67 Small Entities Compliance Guide for Renderers	02/01/98
68	CVM GFI #68 Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors	02/01/98
69	CVM GFI #69 Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Feed Mixing Operations	02/01/98
70	CVM GFI #70 Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations	07/13/09
72	CVM GFI #72 GMP'S For Medicated Feed Manufacturers Not Required to Register and be Licensed with FDA	05/01/98
73	VICH GL3(R) - Stability Testing Of New Veterinary Drug Substances	11/21/07
74	VICH GL4 - Stability Testing of New Veterinary Dosage Forms	05/01/99
75	VICH GL5 -Stability Testing-Photostability Testing of New Veterinary Drug Substances and Medicinal Products	05/01/99
76	CVM GFI #76 Questions and Answers BSE Feed Regulations	01/01/98
79	CVM GFI #79 Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by CVM	07/01/05
80	CVM GFI #80 Evaluation the Utility of Anti-Salmonella Chemical Food Additives	11/21/02
82	CVM GFI #82 Development of Supplemental Applications for Approved New Animal Drugs	10/28/02
83	CVM GFI #83 Chemistry, Manufacturing and Controls Changes to Approved NADA/ANADA	05/30/07
84	GFI #84- Product Name Placement, Size, and Prominence in	
85	VICH GL9 - Good Clinical Practices	05/09/01
86	CVM GFI #86 How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format to CVM	06/15/09
87	CVM GFI #87 How to Submit a Notice of Intent to Slaughter for Human Food Purpose in Electronic Format to CVM	06/15/09
88	CVM GFI #88 How to Submit a Request for a Meeting or Teleconference in Electronic Format to CVM	06/15/09
89	VICH GL6 - EIA's for Veterinary Medicinal Products - Phase I	03/07/01
90	VICH GL7 - Effectiveness of Anthelmintics: General Recommendations	10/11/01
91	VICH GL8 - Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products on Stability Testing for Medicated Premixes	03/01/00
92	VICH GL10(R) - Impurities In New Veterinary Drug Substances	11/21/07
93	VICH GL11(R) - Impurities in New Veterinary Medicinal Products	11/21/07
95	VICH GL12 - Efficacy of Anthelmintics: Specific Recommendations for Bovines	03/26/01
96	VICH GL13 - Efficacy of Anthelmintics: Specific Recommendations for Ovines	03/26/01
97	VICH GL14 - Efficacy of Anthelmintics: Specific Recommendations for Caprines	03/26/01
98	CVM GFI #98 Dioxin In Anti-Caking Agents In Animal Feed And Feed Ingredients	04/12/00
99	VICH GL17 - Testing of New Biotechnological/Biological Products	03/26/01
100	VICH GL18 Residual Solvents in New Veterinary Medicinal Products	05/15/01
102	CVM GFI #102 Manufacture and Distribution of Unapproved Piperazine Products	08/27/99
103	GFI #103 - Possible Dioxin/PCB Contamination of Drug and Biological Products	
104	CVM GFI #104 Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports For Submission	07/10/01
105	GFI #105 - Computerized Systems Used in Clinical Investigations	
106	CVM GFI #106 Published Literature in Support of New Animal Drug Approval	08/31/00
107	CVM GFI #107 How to Submit a Protocol without Data in Electronic Format to CVM	06/15/09
108	CVM GFI #108 Submit Information using the FDA Electronic Submission Gateway	06/15/09
109	VICH GL15 - Specific Recommendations for Equine	06/27/02
110	VICH GL16 - Specific Recommendations for Porcine	06/27/02
111	VICH GL19- Specific Recommendations for Canine	06/27/02
112	GFI #112 - Fumonisin Levels in Human Foods and Animal Feeds; Final Guidance	
113	VICH GL20 - Specific Recommendations for Feline	06/19/02
114	VICH GL21 - Specific Recommendations for Poultry-Gallus Gallus	06/19/02
115	VICH GL22 -Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies	07/27/06
116	VICH GL23 - Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing	07/27/06
117	VICH GL24 - Management of Adverse Event Reports (AER's)	05/01/06
118	CVM GFI #118 Mass Spectrometry for Confirmation of Identity of Animal Drug Resides	05/01/03
119	CVM GFI #119 How CVM Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug	08/29/02
120	CVM GFI #120 Veterinary Feed Directive Regulation	03/26/09
121	CVM GFI #121 Expedited Review for NADA for Human Pathogen Reduction Claims	03/06/01
122	CVM GFI #122 Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores	11/09/04
123	CVM GFI #123 Development of Data Supporting Approval of NSAIDS for Use in Animal	01/05/06

124	GFI #124 - Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering	
126	CVM GFI #126 BACPAC I-Intermediates in Drug Substance Synthesis Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation	06/01/06
132	CVM GFI #132 The Administrative New Animal Drug Application Process	11/06/02
135	CVM GFI #135 Validation of Analytical Procedures for Type C Medicated Feeds	11/07/05
136	CVM GFI #136 Method Transfer Studies for Type C Medicated Feed Assay Methods	04/26/07
137	CVM GFI #137 Analytical Methods Description for Type C Medicated Feeds	05/08/07
141	VICH GL28 - Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing,	07/27/06
142	VICH GL29 - Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)	12/12/01
143	VICH GL30 - Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms	06/20/07
144	VICH GL27 - Pre-Approval for Registration of New VMPs for Food-Producing Animals to Antimicrobial Resistance	04/27/04
145	GFI #145 -Bioanalytical Method Validation	
147	VICH GL31 - Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food Repeat Dose (90 Day) Toxicity Testing	11/12/03
148	VICH GL32 - Developmental Toxicity Testing	07/27/06
149	VICH GL33 - Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing	03/17/09
150	CVM GFI #150 Concerns Related to the use of Clove Oil as an Anesthetic for Fish	04/24/07
151	GFI #151 - FDA Export Certificates	
152	CVM GFI #152 Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern	10/23/03
153	CVM GFI #153 Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals	09/01/02
156	CVM GFI #156 Comparability Protocols-Chemistry, Manufacturing, and Controls Information	02/01/03
157	GFI #157 -Part 11, Electronic Records;Electronic Signatures-Scope and Application	
158	CVM GFI #158 Use of Material from Deer and Elk in Animal Feed	09/15/03
159	VICH GL36 - Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI	08/30/06
160	VICH GL37 - Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing	07/27/06
162	GFI #162 - Comparability Protocols -Protein Drug Products and Biological Products CMC	
163	CVM GFI #163 Scientific and Technical Issues Related to Pharmaceutical CGMP	08/25/03
164	GFI #164 - PAT -Framework for Innovative Pharmaceutical Development, Manufacturing,and Quality Assurance	
165	CVM GFI #165 Providing Regulatory Submissions in Electronic Format	10/01/03
166	VICH GL38 - EIA's for Veterinary Medicinal Products, Phase II	01/09/06
167	GFI #167 - Prior Notice of Imported Food; Q&A's	
168	GFI #168 -Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators	
169	CVM GFI #169 Drug Substance: Chemistry, Manufacturing, and Controls Information	06/01/06
170	CVM GFI #170 Animal Drug User Fees and Fee Waivers and Reductions	10/01/08
171	CVM GFI #171 Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles	10/06/08
173	CVM GFI #173 Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA)	02/07/05
173	CVM GFI #173 Appendix for the Animal Drug Sponsor Fees Under the (ADUFA)	02/07/05
174	CVM GFI #174 Use of Material from BSE Positive Cattle in Animal Feed	09/30/04
176	VICH GL39 - Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances	06/14/06
177	VICH GL40 - Test Procedures/Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Product	06/14/06
178	CVM GFI #178 Design/Evaluation of Effectiveness Studies - Swine Respiratory Disease Claims	10/01/07
179	CVM GFI #179 Use of Animal Clones and Clone Progeny for Human Food/Animal Feed	01/15/08
181	CVM GFI #181 Blue Bird Medicated Feed Labels	04/10/08
182	VICH GL42 - Pharmacovigilance of Veterinary Medicinal Products: Data Elements for Submission of Adverse Event Reports	05/01/06
183	CVM GFI #183 ADUFA- Animal Drug User Fees: Fees Exceed Costs Waiver/Reduction	03/09/07
185	VICH GL43 - Target Animal Safety for Veterinary Pharmaceutical Products	04/24/09
187	CVM GFI #187 Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs	01/15/09
190	GFI #190 -Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products	
191	CVM GFI #191 New NADAs vs. Category II Supplemental NADAs	11/19/09
192	CVM GFI #192 Anesthetics for Companion Animals	03/25/10
193	GFI #193 -Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing	
194	GFI #194 -Submission of Documentation in Applications for Parametric Release of Human and Veterinary Drug Products Terminally Sterilized by Moist Heat Processes	
196	CVM GFI #196 Process Validation: General Principles and Practices	11/08/08
195	CVM GFI #195 Small Entities Compliance Guide For Renderers—Substances Prohibited From Use In Animal Food Or Feed	05/06/09
197	CVM GFI #197 Documenting Statistical Analysis Programs and Data Files	04/30/09
198	VICH GL45 - Bracketing and Matrixing Designs For Stability Testing of New Veterinary Drug Substances and Medicinal Products	07/21/09
199	CVM GFI #199 - Animal Generic Drug User Fees and Fee Waivers and Reductions	05/13/09
205	VICH GL46 - Metabolism Study to Determine the Quantity and Identify the Nature of Residues	04/09/10
206	VICH GL47 - Comparative Metabolism Studies In Laboratory Animals	04/09/10
207	VICH GL48 - Marker Residue Depletion Studies to Establish Product Withdrawal Periods	04/09/10
208	VICH GL49 - Validation of Analytical Methods Used in Residue Depletion Studies	04/09/10

Sub Chapter 600 - Veterinary Drugs

- CPG Sec. 605.100 - Use of Statements Regarding NADA Approval by FDA in Labeling and Advertising of New Animal Drugs
- CPG Sec. 607.100 - Adequate Directions for Use (Species Designation) - Animal Drugs and Veterinary Devices

- CPG Sec. 608.100 Human-Labeled Drugs Distributed and Used in Animal Medicine (Withdrawn 7/7/2006)
- CPG Sec. 608.200 Over-The-Counter Sale of Injectable Animal Drugs
- CPG Sec. 608.300 Lay Use of *Animal Capture and Euthanasia* Drugs
- CPG Sec. 608.400 Compounding of Drugs for Use in Animals
- CPG Sec. 608.500 Illegal Sales of Veterinary Prescription Drugs Direct Reference Authority for *Warning* Letter Issuance
- CPG Sec. 615.100 Extra Label Use of New Animal Drugs in Food Producing Animals - Revoked on 09/24/1998 (63 FR 51074)
- CPG Sec 615.115 Extra-Label Use of Medicated Feeds for Minor Species
- CPG Sec. 615.200 Proper Drug Use and Residue Avoidance by Non-Veterinarians
- CPG Sec. 615.300 Responsibility for Illegal Drug Residues in Meat, Milk and Eggs
- CPG Sec. 616.100 Streptomycin Residues in Cattle Tissues (Withdrawn 7/7/2006)
- CPG Sec. 625.200 Availability of Bulk Chemicals for Animal Drug Use
- CPG Sec. 625.300 Unapproved New Animal Drugs - Follow-up Action to Approved Warning Letter - Direct Reference Seizure Authority
- CPG Sec.625.400 Reconditioning of New Animal Drugs Seized Under Section 501 (a)(5)
- CPG Sec. 625.500 Failure to Register *and/or Drug List*
- CPG Sec. 625.600 Orders for Post-Approval Record Reviews
- CPG Sec. 634.100 Drugs Packaged for Infusion or Injection of Food-Producing Animals
- CPG Sec. 635.100 Large Volume Parenterals (LVP's) for Animal Use
- CPG Sec. 637.100 Plastic Containers for Injectable Animal Drugs
- CPG Sec. 638.100 Process Validation Requirements for Drug Products Subject to Pre-Market Approval
- CPG Sec. 640.100 Anthelmintics
- CPG Sec. 641.100 *Products for Control of Fleas and Ticks* Containing a Pesticide
- CPG Sec. 642.100 *Drugs for Odor Control and Conception in Pet Animals*
- CPG Sec. 643.100 Oral Iron Products for Baby Pigs
- CPG Sec. 645.100 Biological Drugs for Animal Use
- CPG Sec. 650.100 Animal Drugs for Euthanasia
- CPG Sec. 651.100 Ethylenediamine Dihydroiodide (EDDI) (Revised 05/01/2000)
- CPG Sec. 653.100 Animal Grooming Aids
- CPG Sec. 654.100 Dimethyl Sulfoxide (DMSO) for Animal Use
- CPG Sec. 654.200 Teat Dips and Udder Washes for Dairy Cows and Goats
- CPG Sec. 654.300 Chloramphenicol as an Unapproved New Animal Drug - Direct Reference Seizure Authority
- CPG Sec. 655.100 Devices for Use in Animals
- CPG Sec. 655.200 Adequate Directions for Use - Animal Drugs & Veterinary Devices
- CPG Sec. 655.300 Barking Dog Collar
- CPG Sec. 655.400 The Status of Syringes and Needles for Animal Use

Sub Chapter 660 - Animal Feed

- CPG Sec. 660.100 Failure to Register
- CPG Sec. 665.100 Common or Usual Names for Animal Feed Ingredients
- CPG Sec. 665.200 Checklist Labeling for Custom Mixed Medicated Feeds
- CPG Sec. 665.300 Use of Type A Medicated Article Brand Names in Feed Labels
- CPG Sec. 666.100 Alternate Feeding of Different Medicated Feeds
- CPG Sec. 670.100 Refusals of Formula Information During Inspection of Feed Mills Manufacturing Feeds Requiring Approved Medicated Feed Applications
- CPG Sec. 670.200 Status of Vitamins and Minerals in Type B and C Medicated Feed and in Non-Medicated Feed
- CPG Sec. 670.500 Ammoniated Cottonseed Meal - Interpretation of 21 CFR
- CPG Sec. 675.100 Diversion of Contaminated Food for Animal Use
- CPG Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use
- CPG Sec. 675.300 Moisture Damaged Grain
- CPG Sec. 675.400 Rendered Animal Feed Ingredients
- CPG Sec. 680.100 Tracers in Animal Feed
- CPG Sec. 680.200 CGMP Regulations for Medicated Feeds - Daily Inventory Requirements
- CPG Sec. 680.400 Medicated Feeds—Combined Batches
- CPG Sec. 680.500 Unsafe Contamination of Animal Feed from Drug Carryover
- CPG Sec. 680.600 Sequencing as a Means to Prevent Unsafe Drug Contamination in the Production, Storage, and Distribution of Feeds
- CPG Sec. 681.100 Order for Post-Approval Record Reviews
- CPG Sec. 682.100 Use of Drug-Contaminated Products in Animal Feed
- CPG Sec. 682.200 The Use of Antibiotic Drug Residue By-Products in Animal Feed Feed
- CPG Sec. 683.100 Action Levels for Aflatoxins in Animal Feeds
- CPG Sec. 685.100 Recycled Animal Waste
- CPG Sec. 687.500 Silage Ingredients
- CPG Sec. 688.100 Unapproved Additives for Exported Grains
- CPG Sec. 689.100 Direct-Fed Microbial Products
- CPG Sec. 690.100 Nutritional Supplements for Companion Animals
- CPG Sec. 690.200 Pet Food Labeling
- CPG Sec. 690.300 Canned Pet Food
- CPG Sec. 690.400 Water and Gravy in Pet Food
- CPG Sec. 690.500 Uncooked Meat for Animal Food
- CPG Sec. 690.600 Rodent Contaminated Pet Foods - *Direct Reference Seizure Authority*
- CPG Sec. 690.700 Salmonella Contamination of Dry Dog Food

VII. Office of the Commissioner

For information on a specific guidance document or to obtain a paper copy, please go to FDA's Web site: *http://www.fda.gov/RegulatoryInformation/Guidances/Default.htm.*

The following list of current OC guidance documents was obtained from FDA's Web site on April 26, 2010:

FDA Guidance Documents: General and Cross-Cutting Topics

- 03/2001 Acceptance of Foreign Clinical Studies
- 01/2009 Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007
- 12/2006 Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration
- 08/1999 Consumer-Directed Broadcast Advertisements
- 02/2008 Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products
- 11/1997 Direct Final Rule Procedures
- 08/2003 Part 11, Electronic Records; Electronic Signatures—Scope and Application
- 11/2002 Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records (PDF - 143KB)
- 09/2001 (247) 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms; Draft Guidance for Industry (PDF - 117KB)
- 09/2001 (246) 21 CFR Part 11; Electronic Records; Electronic Signatures,Validation; Draft Guidance for Industry (PDF - 202KB)
- 07/2007 Emergency Use Authorization of Medical Products
- 03/2003 FDA Issues Food and Cosmetic Security Preventive Measures Guidance
- 05/2004 Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV
- 01/2009 Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices
- 11/1997 Industry Supported Scientific and Educational Activities (PDF - 428KB)
- 10/2003 Guidance for Industry - Providing Regulatory Submissions in Electronic Format—General Considerations
- 03/2010 Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages
- 01/2009 Submission Of Laboratory Packages By Accredited Laboratories
- 09/1997 The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use
- 03/2006 Using Electronic Means to Distribute Certain Product Information
- 01/2009 Voluntary Third-Party Certification Programs for Foods and Feeds

Advisory Committee Guidance Documents

- 03/2010 Public Availability of Advisory Committee Members' Financial Interest Information and Waivers - Draft Guidance (PDF - 59KB)
- 08/2008 Preparation and Public Availability of Information Given to Advisory Committee Members - Final Guidance - August 1, 2008 (PDF - 169KB)
- 08/2008 Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees - Final Guidance - August 1, 2008 (PDF - 106KB)
- 08/2008 Public Availability of Advisory Committee Members' Financial Interest Information and Waivers - Final Guidance - August 1, 2008 (PDF - 55KB)
- 08/2008 Voting Procedures at Advisory Committee Meetings - Final Guidance - August 1, 2008 (PDF - 37KB)
- 08/2008 When FDA Convenes an Advisory Committee - Draft Guidance - August 1, 2008 (PDF - 40KB)
- 02/2005 The Open Public Hearing - FDA Advisory Committee Meetings - Draft Guidance

Clinical Trials Guidance Documents

- 01/2010 IRB Continuing Review After Clinical Investigation Approval - Draft Guidance (PDF - 125KB)
- 07/2009 Frequently Asked Questions - IRB Registration (PDF - 48KB)
- 09/2005 Collection of Race and Ethnicity Data in Clinical Trials
- 01/1988 Monitoring Clinical Investigations
- 04/1999 Computerized Systems Used in Clinical Trials
- 01/2006 Significant Risk and Nonsignificant Risk Medical Device Studies - Information Sheet (PDF - 121KB)
- 01/1998 Institutional Review Boards Frequently Asked Questions - Information Sheet
- 01/1998 Cooperative Research - Information Sheet
- 01/1998 Non-local IRB Review - Information Sheet
- 01/1998 Continuing Review After Study Approval - Information Sheet
- 01/1998 Sponsor - Investigator - IRB Interrelationship - Information Sheet
- 01/1998 Acceptance of Foreign Clinical Studies - Information Sheet
- 01/1998 Charging for Investigational Products - Information Sheet
- 01/1998 Recruiting Study Subjects - Information Sheet
- 01/1998 Payment to Research Subjects - Information Sheet
- 01/1998 Screening Tests Prior to Study Enrollment - Information Sheet
- 01/1998 A Guide to Informed Consent - Information Sheet
- 01/1998 Use of Investigational Products When Subjects Enter a Second Institution - Information Sheet
- 01/1998 Exception from Informed Consent for Studies Conducted in Emergency Settings: Regulatory Language and Excerpts from Preamble - Information Sheet
- 01/1998 "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet
- 09/2008 Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials - Information Sheet (PDF - 71KB)
- 01/1998 Emergency Use of an Investigation Drug or Biologic - Information Sheet
- 01/1998 Treatment Use of Investigational Drugs - Information Sheet
- Waiver of IRB Requirements for Drug and Biological Product Studies - Information Sheet (PDF - 35KB)
- 01/1998 Drug Study Designs - Information Sheet
- 01/1998 Evaluation of Gender Differences in Clinical Investigations - Information Sheet
- 01/2006 FDA Inspections of Clinical Investigators - Information Sheet (PDF - 48KB)
- 01/2006 FDA Institutional Review Board Inspections - Information Sheet (PDF - 45KB)
- 01/2007 FDA/NCI MOU Regarding Common Standards-based Data Repository (PDF - 312KB)
- Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection
- 01/2009 Adverse Event Reporting to IRBs - Improving Human Subject Protection (PDF - 79KB)
- 12/2006 Process for Handling Referrals to FDA under 21 CFR 50.54 (PDF - 76KB)
- 03/2006 Establishment and Operation of Clinical Trial Data Monitoring Committees (PDF - 194KB)
- 07/2004 Available Therapy
- 03/2005 Development and Use of Risk Minimization Action Plans (PDF - 84KB)
- 03/2001 Financial Disclosure by Clinical Investigators
- 12/2002 Food-Effect Bioavailability and Fed Bioequivalence Studies (PDF - 166KB)

- 03/2005 Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (PDF - 220KB)
- 07/1993 Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (PDF - 1875KB)
- 05/2004 Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability (PDF - 166KB)
- 01/2004 IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (PDF - 188KB)
- 03/2002 Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (PDF - 34KB)
- 10/2003 IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations (PDF - 614KB)
- 08/2003 Electronic Records; Electronic Signatures - Part 11, Scope and Application (PDF - 215KB)
- 01/2002 General Principles of Software Validation
- 03/2005 Pharmacogenomic Data Submissions (PDF - 96KB)
- 03/2005 Premarketing Risk Assessment (PDF - 91KB)
- 10/2005 Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
- 09/2004 The Use of Clinical Holds Following Clinical Investigator Misconduct (PDF - 33KB)
- 03/2006 Using a Centralized IRB Review Process in Multicenter Clinical Trials
- 04/2006 Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable
- 01/2006 Frequently Asked Questions About Medical Devices - Information Sheet (PDF - 105KB)
- 03/2006 The Establishment and Operation of Clinical Trial Data Monitoring Committees for Clinical Trial Sponsors
- 08/2004 Independent Consultants for Biotechnology Clinical Trial Protocols
- 04/2007 Adverse Event Reporting - Improving Human Subject Protection
- 02/2005 Clinical Lactation Studies - Study Design, Data Analysis, and Recommendations for Labeling
- 01/2006 Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products - Content and Format
- 10/2000 Submitting and Reviewing Complete Responses to Clinical Holds
- 12/2006 Process for Handling Referrals to FDA Under 21 CFR 50.54 - Additional Safeguards for Children in Clinical Investigations
- 07/2006 Exception from Informed Consent Requirements for Emergency Research
- 10/2009 Investigator Responsibilities—Protecting the Rights, Safety and Welfare of Study Subjects,
- 05/2010 Information Sheet Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors—Clinical Investigator Administrative Actions—Disqualifications

Combination Products Guidance Documents

- 12/2009 Guidance for Industry - New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products (PDF - 159KB)
- 04/2009 Technical Considerations for Pen, Jet, and Related Injectors Intended for Use with Drugs and Biological Products (PDF - 112KB)
- 07/2007 Devices Used to Process Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)
- 09/2006 Minimal Manipulation of Structural Tissue (Jurisdictional Update)
- 09/2006 Early Development Considerations for Innovative Combination Products
- 08/2005 How to Write a Request for Designation (RFD)
- 04/2005 Application User Fees for Combination Products
- 09/2004 Current Good Manufacturing Practice for Combination Products (Draft Guidance)
- 05/2004 Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product

Import and Export Guidance Documents

- 07/12/2004 FDA Export Certificates
- 07/23/2007 Exports Under the FDA Export Reform and Enhancement Act of 1996
- 05/01/2001 E 10 Choice of Control Group and Related Issues in Clinical Trials
- 01/01/2009 Good Importer Practices (Draft Guidance)

IX. Office of Regulatory Affairs (ORA)

For information on a specific guidance document or to obtain a paper copy, please go to FDA's Web site: *http://www.fda.gov/RegulatoryInformation/Guidances/Default.htm.*

The following is a list of ORA guidance documents that have been withdrawn:

Title of document	Date of	
	Issuance	Withdrawal
Compliance Policy Guide Sec. 608.100 Human-Labeled Drugs Distributed and Used in Animal Medicine (CPG 7125.35)	March 19, 1991	July 7, 2006
Compliance Policy Guide Sec. 616.100 Streptomycin Residues in Cattle Tissues (CPG 7125.22)	October 1, 1980	July 7, 2006
Compliance Policy Guide Sec. 555.700 Revocation of Tolerances for Cancelled Pesticides (CPG 7120.29)	February 1, 1983	January 8, 2008
Compliance Policy Guide Sec. 560.700 Processing of Imported Frozen Products of Multiple Sizes (e.g., Shrimp, Prawns, Etc.) (CPG 7119.10)	October 1, 1980	June 6, 2008
Compliance Policy Guide Sec. 540.575 Fish—Fresh and Frozen—Adulteration Involving Decomposition (CPG 7108.05)	October 1, 1980	July 18, 2008
Compliance Policy Guide Sec. 540.375 Canned Salmon—Adulteration Involving Decomposition (CPG 7108.10)	October 1, 1980	March 22, 2010

The following is a list of current ORA guidance documents:

Title of Document	Date of Issuance
Compliance Policy Guides Manual	
Application Integrity Policy Procedures	March 5, 1998 (Edited for format March 4, 2004)
Points to Consider for Internal Reviews and Corrective Action Operating Plans	June 1991
Guidance for Industry and FDA Staff: Reduction of Civil Money Penalties for Small Entities	March 20, 2001 (Effective: April 19, 2001) (This document supersedes the Draft Civil Money Penalty Reduction Policy for Small Entities released on May 18, and June 15, 1999.)
Guidance for Industry: Good Laboratory Practice Regulations Management Briefings Post Conference Report	August 1979 (Minor editorial and formatting changes made November 1998)
Guidance for Industry: Good Laboratory Practices Questions and Answers	June 1981 (Minor editorial and formatting changes made December 1999, September 2000, & July 2007)
Guidance for Industry: Product Recalls, Including Removals and Corrections	November 3, 2003

Dated: July 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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