• ''E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs'' (69 FR 55163; Docket No. 2004D–0377) provides recommendations to sponsors concerning clinical studies to assess the potential of a new drug to cause cardiac arrhythmias, focusing on the assessment of changes in the QT/QTc interval on the electrocardiogram as a predictor of risk.

• ''S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals'' (69 FR 55164; Docket No. 2004D–0378) describes a nonclinical testing strategy for assessing the potential of a test substance to delay ventricular repolarization and includes information concerning nonclinical assays and an integrated risk assessment.

Interested persons were given until December 13, 2004, to submit comments on the draft guidances.

On December 13, 2004, FDA received letters from Wyeth Pharmaceuticals requesting that the agency extend the comment periods for the draft guidances.

In response to these requests, FDA has decided to reopen the comment period on the draft guidances until February 18, 2005, to allow the public more time to review and comment on the contents.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidances on or before February 18, 2005. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the corresponding docket number of the draft guidance as follows: Docket No. 2004D–0377 ''E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs'' and Docket No. 2004D–0378 ''S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals.'' The draft guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the draft guidance documents at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: December 28, 2004.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 05–110 Filed 1–4–05; 8:45 am]

**BILLING CODE 4160–01–S**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 1998N–0046]**

### Annual 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 its annual comprehensive list of all guidance documents currently in use at the agency. This list is being published under FDA's good guidance practices (GGPs) regulations. 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 year.

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

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. We have provided information in the tables in the **SUPPLEMENTARY INFORMATION** section of this document on where to obtain a single copy of any of the guidance documents listed.

**FOR FURTHER INFORMATION CONTACT:** *Regarding GGPs*: Lisa Helmanis, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

**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 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 (§ 10.115 (21 CFR 10.115)). In § 10.115(n)(2), FDA stated that it intended to publish an annual comprehensive list of guidance documents. The list in this document updates a comprehensive list that published October 24, 2001 (66 FR 53836).

The following comprehensive list identifies all guidances that have been issued and are in use, and all draft guidances that have been distributed for comment and not for implementation. Any guidances that have been withdrawn since the last publication of this comprehensive list are also identified. These withdrawn guidances include some final and draft guidances that had been withdrawn prior to the date of publication of this list, and some that are being withdrawn as of this date. 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. Please note that although we have stated that the ''Guidance for Industry on Qualified Health Claims in Labeling of Conventional Foods and Dietary Supplements'' (December 2002) has been ''replaced'' by subsequent guidance, the agency has not abandoned the position in the 2002 guidance regarding reasonable consumer standard.

We have organized the documents by the issuing center or office within FDA, and have identified the pertinent intended users or regulatory activities. 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 information in the tables in this document.

The following most frequently used Internet sites for agency guidances are provided for future reference:

• Center for Biologics Evaluation and Research (CBER): *http://www.fda.gov/cber/guidelines.htm*

• Center for Drug Evaluation and Research (CDER): *http://www.fda.gov/cder/guidance/index.htm*

• Center for Devices and Radiological Health (CDRH): *http://www.fda.gov/cdrh/guidance.html*

• Center for Food Safety and Applied Nutrition (CFSAN): *http://www.cfsan.fda.gov/dms/guidance.html*

• Center for Veterinary Medicine (CVM): *http://www.fda.gov/cvm/guidance/published.htm*

• Office of Regulatory Affairs (ORA) and Office of the Commissioner: *http:/*

*/www.fda.gov/opacom/morechoices/industry/guidance.htm*

GUIDANCE DOCUMENTS ISSUED BY CBER

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| Guidelines for Immunization of Source Plasma (Human) Donors With Blood Substances | June 1980 | FDA regulated industry | Office of Communication, Training, and Manufacturers Assistance (HFM–40), 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 | *http://www.fda.gov/cber/guidelines.htm* |
| Collection of Human Leukocytes for Further Manufacturing (Source Leukocytes) | January 28, 1981 | Ditto (Do) | Do. | *http://www.fda.gov/cber/memo.htm* |
| Interferon Test Procedures: Draft Points to Consider (PTC) in the Production and Testing of Interferon Intended for Investigational Use in Humans | July 28, 1983 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Deferral of Blood Donors Who Have Received the Drug Accutane (isotretinoin/Roche; 13-cis-retinoic acid) | February 28, 1984 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Equivalent Methods for Compatibility Testing | December 14, 1984 | Do. | Do. | Do. |
| Plasma Derived From Therapeutic Plasma Exchange | December 14, 1984 | Do. | Do. | Do. |
| Draft PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology | April 10, 1985 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Reduction of the Maximum Platelet Storage Period to 5 Days in an Approved Container | June 2, 1986 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| To In Vitro Diagnostic Reagent Manufacturers: Guidance on the Labeling of Human Blood Derived In Vitro Diagnostic Devices in Regard to Labeling for HTLV–III/LAV Antibody Testing | December 6, 1986 | Do. | Do. | Do. |
| Guideline on General Principles of Process Validation | May 1987 | Do. | Do. | *http://www.fda.gov/cber/guidelines/htm* |
| Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone | November 25, 1987 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| 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 | December 1987 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Recommendations for the Management of Donors and Units That Are Initially Reactive for Hepatitis B Surface Antigen (HbsAg) | December 2, 1987 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Extension of Dating Period for Storage of Red Blood Cells, Frozen | December 4, 1987 | Do. | Do. | Do. |
| To Licensed In Vitro Diagnostic Manufacturers: Handling of Human Blood Source Materials | December 23, 1987 | Do. | Do. | Do. |
| Recommendations for Implementation of Computerization in Blood Establishments | April 6, 1988 | Do. | Do. | Do. |
| Control of Unsuitable Blood and Blood Components | April 6, 1988 | Do. | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| Discontinuance of Prelicensing Inspection for Immunization Using Licensed Tetanus Toxoid and Hepatitis B and Rabies Vaccines | July 7, 1988 | Do. | Do. | Do. |
| Physician Substitutes | August 15, 1988 | Do. | Do. | Do. |
| To Licensed Manufacturers of Blood Grouping Reagents: Criteria for Exemption of Lot Release | August 26, 1988 | Do. | Do. | Do. |
| Revised Guideline for the Collection of Platelets, Pheresis | October 7, 1988 | Do. | Do. | Do. |
| To Manufacturers of HTLV–I Antibody Test Kits: Antibody to Human T-Cell Lymphotropic Virus, Type I (HTLV–I) Release Panel I | October 18, 1988 | Do. | Do. | Do. |
| HTLV–1 Antibody Testing | November 29, 1988 | Do. | Do. | Do. |
| Use of Recombigen HIV–1 LA Test | February 1, 1989 | Do. | Do. | Do. |
| Guidance for Autologous Blood and Blood Components | March 15, 1989 | Do. | Do. | Do. |
| Use of Recombigen HIV–1 Latex Agglutination (LA) Test | August 1, 1989 | Do. | Do. | Do. |
| Draft PTC in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus, Type 1 | August 8, 1989 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| PTC in the Collection, Processing, and Testing of Ex Vivo Activated Mononuclear Leukocytes for Administration to Humans | August 22, 1989 | Do. | Do. | Do. |
| Requirements for Computerization of Blood Establishments | September 8, 1989 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Abbott Laboratories' HIVAG–1 Test for HIV–1 Antigen(s) Not Recommended for Use as a Donor Screen | October 4, 1989 | Do. | Do. | Do. |
| Guideline for Collection of Blood or Blood Products From Donors With Positive Tests for Infectious Disease Markers (''High Risk'' Donors) | October 26, 1989 | Do. | Do. | Do. |
| Guideline for the Determination of Residual Moisture in Dried Biological Products | January 1990 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Autologous Blood Collection and Processing Procedures | February 12, 1990 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Use of Genetic Systems HIV–2 EIA | June 21, 1990 | Do. | Do. | Do. |
| FDA Request for Information on Blood Storage Patterns and Red Cell Contamination by *Yersinia Enterocolitica* | March 15, 1991 | Do. | Do. | Do. |
| Revision to October 26, 1989, Guideline for Collection of Blood or Blood Products From Donors With Positive Tests for Infectious Disease Markers (''High Risk'' Donors) | April 17, 1991 | Do. | Do. | Do. |
| Deficiencies Relating to the Manufacture of Blood and Blood Components | March 20, 1991 | Do. | Do. | Do. |
| Responsibilities of Blood Establishments Related to Errors and Accidents in the Manufacture of Blood and Blood Components | March 20, 1991 | Do. | Do. | Do. |
| FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc) | September 10, 1991 | Do. | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| Disposition of Blood Products Intended for Autologous Use That Test Repeatedly Reactive for Anti-HCV | September 11, 1991 | Do. | Do. | Do. |
| Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing | December 12, 1991 | Do. | Do. | Do. |
| Supplement to the PTC in the Production and Testing of New Drugs and Biologics Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability | April 6, 1992 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products | April 23, 1992 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Use of Fluorognost HIV–1 Immunofluorescent Assay (IFA) | April 23, 1992 | Do. | Do. | Do. |
| Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV) | April 23, 1992 | Do. | Do. | Do. |
| Exemptions to Permit Persons With a History of Viral Hepatitis Before the Age of Eleven Years to Serve as Donors of Whole Blood and Plasma: Alternative Procedures, 21 CFR 640.120 | April 23, 1992 | Do. | Do. | Do. |
| Changes in Equipment for Processing Blood Donor Samples | July 21, 1992 | Do. | Do. | Do. |
| Nomenclature for Monoclonal Blood Grouping Reagents | September 28, 1992 | Do. | Do. | Do. |
| Volume Limits for Automated Collection of Source Plasma | November 4, 1992 | Do. | Do. | Do. |
| FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics | November 25, 1992 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Revision of October 7, 1988, Memo Concerning Red Blood Cell Immunization Programs | December 16, 1992 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Draft PTC in the Characterization of Cell Lines Used to Produce Biologicals | July 12, 1993 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Guidance on Alternatives to Lot Release for Licensed Biological Products | July 20, 1993 | Do. | Do. | Do. |
| Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products | July 22, 1993 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Deferral of Blood and Plasma Donors Based on Medications | July 28, 1993 | Do. | Do. | Do. |
| Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV) | August 5, 1993 | Do. | Do. | Do. |
| Clarification of the Use of Unlicensed Anti-HCV Supplemental Test Results in Regard to Donor Notification | August 19, 1993 | Do. | Do. | Do. |
| Draft Guideline for the Validation of Blood Establishment Computer Systems | September 28, 1993 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Guidance Regarding Post Donation Information Reports | December 10, 1993 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a History of Viral Hepatitis | December 22, 1993 | Do. | Do. | Do. |
| Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors | January 3, 1994 | Do. | Do. | Do. |
| Recommendations for Deferral of Donors for Malaria Risk | July 26, 1994 | Do. | Do. | Do. |
| Office of Establishment Licensing and Product Surveillance (OELPS), Advertising and Promotional Labeling Staff, Procedural Guidance Document (Draft) | August 1994 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances | November 1994 | Do. | Do. | Do. |
| Recommendations to Users of Medical Devices That Test for Infectious Disease Markers by Enzyme Immunoassay (EIA) Test Systems | December 20, 1994 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Timeframe for Licensing Irradiated Blood Products | February 3, 1995 | Do. | Do. | Do. |
| Revision of August 27, 1982, FDA Memo: Requirements for Infrequent Plasmapheresis Donors | March 10, 1995 | Do. | Do. | Do. |
| To All Licensed Establishments Performing Red Blood Cell Immunizations: Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma Donors | March 14, 1995 | Do. | Do. | Do. |
| Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes, and Source Plasma | June 8, 1995 | Do. | Do. | Do. |
| Guideline for Quality Assurance in Blood Establishments | July 11, 1995 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products | July 11, 1995 | Do. | Do. | Do. |
| Recommendations for Labeling and Use of Units of Whole Blood, Blood Components, Source Plasma, Recovered Plasma, or Source Leukocytes Obtained From Donors With Elevated Levels of Alanine Aminotransferase (ALT) | August 8, 1995 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen | August 8, 1995 | Do. | Do. | Do. |
| PTC in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals | 1995 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Draft Reviewers' Guide: Informed Consent for Plasmapheresis/Immunization | October 1, 1995 | FDA personnel | Do. | Do. |
| Draft Reviewers' Guide: Disease Associated Antibody Collection Program | October 1, 1995 | Do. | Do. | Do. |
| Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Stem Cell Products Intended for Transplantation or Further Manufacturing Into Injectable Products | December 1995 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis | December 4, 1995 | FDA regulated industry | Do. | Do. |
| Draft Document Concerning the Regulation of Peripheral Blood Hematopoietic Stem Cell Products Intended for Transplantation or Further Manufacturing Into Injectable Products | February 1996 | Do. | Do. | Do. |
| International Conference on Harmonisation (ICH) Final Guideline on Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products | February 23, 1996 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| ICH Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals | March 1, 1996 | Do. | Do. | Do. |
| Additional Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen | March 14, 1996 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products | April 1996 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Additional Recommendations for Testing Whole Blood, Blood Components, Source Plasma, and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV) | May 16, 1996 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| Guidance for Industry—The Content and Format for Pediatric Use Supplements | May 1996 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair or Reconstruction | May 1996 | Do. | Do. | Do. |
| Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products | May 29, 1996 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| ICH Final Guidelines on Stablity Testing of Biotechnological/Biological Products | July 10, 1996 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Recommendations for the Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human T-Lymphotropic Virus Type I (HTLV–I) | July 19, 1996 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| 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 | August 1996 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection | December 11, 1996 | Do. | Do. | *http://www.fda.gov/cber/memo.htm* |
| PTC on Plasmid DNA Vaccines for Preventive Infectious Disease Indications | December 1996 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products | January 1997 | Do. | Do. | Do. |
| Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software | January 13, 1997 | FDA personnel | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| PTC in the Manufacture and Testing of Monoclonal Antibody Products for Human Use | February 28, 1997 | FDA regulated industry | Do. | Do. |
| Proposed Approach to Regulation of Cellular and Tissue-Based Products | February 28, 1997 | Do. | Do. | Do. |
| Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing, and Clinical Studies | April 1997 | Do. | Do. | Do. |
| ICH Guidelines for the Photostability Testing of New Drug Substances and Products | May 16, 1997 | Do. | Do. | Do. |
| Guidance for Industry: Changes to an Approved Application: Biological Products | July 1997 | Do. | Do. | Do. |
| Guidance for Industry: Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products | July 1997 | Do. | Do. | Do. |
| Guidance for Industry: Screening and Testing of Donors of Human Tissue Intended for Transplantation | July 1997 | Do. | Do. | Do. |
| Guidance for Industry: Donor Screening for Antibodies to HTLV–II | August 1997 | Do. | Do. | Do. |
| Guidance for Industry: Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report | August 1997 | Do. | Do. | Do. |
| Guidance for Industry: The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use | September 1997 | Do. | Do. | Do. |
| Guidance for FDA and Industry: Direct Final Rule Procedures | November 21, 1997 | FDA personnel and regulated industry | Do. | Do. |
| Draft Guidance for Industry: Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs) | December 1997 | FDA regulated industry | Do. | Do. |
| Guidance for Industry: Industry-Supported Scientific and Educational Activities | November 1997 | Do. | Do. | Do. |
| Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products | January 1998 | Do. | Do. | Do. |
| Draft Guidance for Industry: Container and Closure Integrity Testing In Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products | January 28, 1998 | Do. | Do. | Do. |
| Draft Guidance for Industry: Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients | March 1998 | Do. | Do. | Do. |
| Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy | March 1998 | Do. | Do. | Do. |
| Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to CBER | May 1998 | Do. | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| Guidance for Industry: Classifying Resubmissions in Response to Action Letters | May 14, 1998 | Do. | Do. | Do. |
| Guidance for Industry: Pharmacokinetics in Patients With Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling | May 1998 | Do. | Do. | Do. |
| Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements | May 15, 1998 | Do. | Do. | Do. |
| Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products | May 1998 | Do. | Do. | Do. |
| Draft Guidance for Industry: Stability Testing of Drug Substances and Drug Products | June 1998 | Do. | Do. | Do. |
| Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing | June 1998 | Do. | Do. | Do. |
| ICH Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data | June 10, 1998 | Do. | Do. | Do. |
| Draft Guidance for Industry: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996 | June 12, 1998 | Do. | Do. | Do. |
| Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements | July 1998 | Do. | Do. | Do. |
| Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications | July 1998 | Do. | Do. | Do. |
| Draft Guidance for Industry: Submitting Debarment Certification Statements | September 1998 | Do. | Do. | Do. |
| Guidance for Industry: How to Complete the Vaccine Adverse Event Reporting System Form (VAERS–1) | September 1998 | Do. | Do. | Do. |
| Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review | July 2004 | Do. | Do. | Do. |
| ICH Guidance on Statistical Principles for Clinical Trials | September 16, 1998 | Do. | Do. | Do. |
| ICH Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products | September 21, 1998 | Do. | Do. | Do. |
| ICH Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin | September 24, 1998 | Do. | Do. | Do. |
| Draft Guidance for Industry: General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products | November 1998 | Do. | Do. | Do. |
| Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products | December 1998 | Do. | Do. | Do. |
| Draft Guidance for Industry: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling | January 1999 | Do. | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| Guidance for Industry: Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for a Vaccine or Related Product | January 1999 | Do. | Do. | Do. |
| Guidance on Amended Procedures for Advisory Panel Meetings | January 26, 1999 | Do. | Do. | Do. |
| Draft Guidance for Industry; Providing Regulatory Submissions in Electronic Format—General Considerations | October 2003 | Do. | Do. | *http://www.fda.gov/cber/esub/esubguid.htm* |
| Guidance for Industry: Population Pharmacokinetics | February 1999 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) | February 1999 | Do. | Do. | Do. |
| 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 | February 1999 | Do. | Do. | Do. |
| Draft Guidance for Industry: Accelerated Approval Products—Submission of Promotional Materials | March 1999 | Do. | Do. | Do. |
| Guidance for Industry: Content and Format of Chemistry, Manufacturing, and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product | March 1999 | Do. | Do. | Do. |
| Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans | April 1999 | Do. | Do. | Do. |
| 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 | April 1999 | Do. | Do. | Do. |
| 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'' | May 1999 | Do. | Do. | Do. |
| Draft Guidance for Industry for Platelet Testing and Evaluation of Platelet Substitute Products | May 1999 | Do. | Do. | Do. |
| Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use | May 1999 | Do. | Do. | Do. |
| Draft Reviewer Guidance: Evaluation of Human Pregnancy Outcome Data | June 1999 | FDA personnel | Do. | Do. |
| Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections From Donors With Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV) | June 1999 | FDA regulated industry | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| | | | Mailing Address | Internet Address |
| ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) | June 25, 1999 | Do. | Do. | Do. |
| Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA) | July 1999 | Do. | Do. | Do. |
| Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations | July 1999 | Do. | Do. | Do. |
| Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics | August 1999 | Do. | Do. | Do. |
| Guidance for Industry: Consumer-Directed Broadcast Advertisements | August 1999 | Do. | Do. | Do. |
| Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products | August 1999 | Do. | Do. | Do. |
| Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications | August 1999 | Do. | Do. | Do. |
| ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products | August 18, 1999 | Do. | Do. | Do. |
| Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act | September 1999 | Do. | Do. | Do. |
| Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Biologics Marketing Applications (Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA), and New Drug Application (NDA)); revised | November 1999 | Do. | Do. | Do. |
| Guidance for Industry: In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling | November 1999 | Do. | Do. | Do. |
| ICH of Technical Requirements for Registration of Pharmaceuticals for Human Use; M4: Common Technical Document | November 8, 1999 | Do. | Do. | Do. |
| 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 | December 1999 | Do. | Do. | Do. |
| Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol | November 2000 | FDA personnel | Do. | Do. |
| Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products | February 2000 | FDA regulated industry | Do. | Do. |
| Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level | February 2000 | Do. | Do. | Do. |
| Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing | February 2000 | Do. | Do. | Do. |

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| | | | Mailing Address | Internet Address |
| Draft Guidance for Industry: Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics | May 2000 | Do. | Do. | Do. |
| Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components | June 2000 | Do. | Do. | Do. |
| Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria | June 2000 | Do. | Do. | Do. |
| Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request | June 2000 | Do. | Do. | Do. |
| Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use With Cadaveric Blood Specimens | June 2000 | Do. | Do. | Do. |
| Draft Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment | June 2000 | Do. | Do. | Do. |
| Draft Guidance for Industry: Analytical Procedures and Methods Validation—Chemistry, Manufacturing, and Controls Documentation | August 2000 | Do. | Do. | Do. |
| Draft Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications | August 2000 | Do. | Do. | Do. |
| Guidance for Industry: Q & A Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products | October 2000 | Do. | Do. | Do. |
| Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Followup of Patients in Clinical Trials Using Retroviral Vectors | October 2000 | Do. | Do. | Do. |
| Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds | October 2000 | Do. | Do. | Do. |
| Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts | November 2000 | Do. | Do. | Do. |
| Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices | November 2000 | Do. | Do. | Do. |
| Draft Guidance for Industry: Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)) | November 2000 | Do. | Do. | Do. |
| ICH Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population | December 2000 | Do. | Do. | Do. |
| Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees | December 2000 | Do. | Do. | Do. |
| ICH Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances | December 29, 2000 | Do. | Do. | Do. |
| PHS Guideline on Infectious Disease Issues in Xenotransplantation | January 19, 2001 | Do. | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| | | | Mailing Address | Internet Address |
| Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion | January 2001 | Do. | Do. | Do. |
| Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods | January 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling | January 2001 | Do. | Do. | Do. |
| Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods—Technical Correction | February 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research | February 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines | March 2001 | Do. | Do. | Do. |
| Guidance for Industry: Acceptance of Foreign Clinical Studies | March 2001 | Do. | Do. | Do. |
| Guidance for Industry: Financial Disclosure by Clinical Investigators | March 2001 | Do. | Do. | Do. |
| Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing | March 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 | April 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports | May 2001 | Do. | Do. | Do. |
| Guidance for Industry: E10 Choice of Control Group and Related Issues in Clinical Trials | May 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information | May 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format | July 2001 | Do. | Do. | Do. |
| Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained From an Outside Supplier | July 2001 | Do. | Do. | Do. |
| Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors | July 2001 | Do. | Do. | Do. |
| ICH Guidance for Industry: S7A Safety Pharmacology Studies for Human Pharmaceuticals | July 2001 | Do. | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| Guidance for FDA Reviewers: Premarket Notification Submissions for Empty Containers for the Collection and Processing of Blood and Blood Components | July 2001 | Do. | Do. | Do. |
| Guidance for FDA Reviewers: Premarket Notification Submissions for Transfer Sets (Excluding Sterile Connecting Devices) | July 2001 | Do. | Do. | Do. |
| Guidance for FDA Reviewers: Premarket Notification Submissions for Blood and Plasma Warmers | July 2001 | Do. | Do. | Do. |
| Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture | July 2001 | Do. | Do. | Do. |
| Draft Guidance for FDA Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments | August 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components | August 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments | August 2001 | Do. | Do. | Do. |
| Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis | August 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Submitting Type V Drug Master Files to the CBER | August 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Premarket Notifications (510(k)s) for In Vitro HIV Drug Resistance Genotype Assays: Special Controls | August 2001 | Do. | Do. | Do. |
| Draft Guidance for Industry: Submitting Marketing Applications According to the ICH-CTD Format—General Considerations | August 2001 | Do. | Do. | Do. |
| ICH Guidance: Q7A Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients | August 2001 | Do. | Do. | Do. |
| ICH Guidance on M4 Common Technical Document | August 2001 | Do. | Do. | Do. |
| Guidance for Industry: Cancer Drug and Biological Products—Clinical Data in Marketing Applications | October 2001 | Do. | Do. | Do. |
| Guidance for Industry: Content and Format of Geriatric Labeling | October 2001 | Do. | Do. | Do. |
| Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax | October 2001 | Do. | Do. | Do. |
| Draft Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees | November 2001 | Do. | Do. | Do. |
| Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act | November 2001 | Do. | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CBER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| 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 | January 2002 | Do. | Do. | Do. |
| Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff | January 2002 | Do. | Do. | Do. |
| 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 | February 2002 | Do. | Do. | Do. |
| Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation | March 2002 | Do. | Do. | Do. |
| Guidance for Industry; Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions | March 2002 | Do. | Do. | *http://www.fda.gov/cber/gdlns/clintrial031802.pdf* |
| Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs) | March 2002 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Guidance for Industry: E2BM Data Elements for Transmission of Individual Case Safety Reports | April 2002 | Do. | Do. | Do. |
| Draft Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations | April 2002 | Do. | Do. | Do. |
| Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation | May 1999 | Do. | Do. | Do. |
| Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Questions and Answers | May 2002 | Do. | Do. | Do. |
| Draft Guidelines for Ensuring the Quality of Information Disseminated to the Public (HHS Guideline) | May 2002 | Do. | Do. | Do. |
| Guidance for Industry: Special Protocol Assessment | May 2002 | Do. | Do. | Do. |
| Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) | June 2002 | Do. | Do. | Do. |
| Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records | August 2002 | Do. | Do. | Do. |
| Guidance for Industry: Establishing Pregnancy Exposure Registries | August 2002 | Do. | Do. | Do. |
| Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals | September 2002 | Do. | Do. | Do. |
| Draft Guidance for Industry: Nonclinical Studies for Development of Pharmaceutical Excipients | September 2002 | Do. | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry | October 2002 | Do. | Do. | Do. |
| Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Human Dura Mater | December 18, 2003 | Do. | Do. | *http://www.fda.gov/cber/gdlns/humduramat.pdf* |
| 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 | December 2002 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Draft Guidance for Industry and Reviewers on Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers | December 2002 | Do. | Do. | Do. |
| ICH Guidance for Industry; Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products | January 2003 | Do. | Do. | Do. |
| Draft Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials | January 2003 | Do. | Do. | Do. |
| Draft Guidance for Industry: Drug Product: Chemistry, Manufacturing, and Controls Information | January 2003 | Do. | Do. | Do. |
| ICH Guidance for Industry: M4 CTD—Safety: Questions and Answers | February 2003 | Do. | Do. | Do. |
| Guidance for Industry and FDA Staff: Quality System Information for Certain Premarket Application Reviews | February 2003 | Do. | Do. | Do. |
| ICH Guidance for Industry: Q3A Impurities in New Drug Substances | February 2003 | Do. | Do. | Do. |
| Draft Guidance for Industry; Comparability Protocols—Chemistry, Manufacturing, and Controls Information | February 2003 | Do. | Do. | Do. |
| 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; Guidance for Industry and FDA | February 25, 2003 | Do. | Do. | *http://www.fda.gov/cber/dap/devpubs.htm* |
| Guidance for Industry and FDA: FY 2003 MDUFMA Small Business Qualification Worksheet and Certification | March 2003 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| ICH Guidance for Industry: M2 eCTD: Electronic Common Technical Document Specification | April 2003 | Do. | Do. | Do. |
| Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans | April 2003 | Do. | Do. | Do. |
| 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 | April 2003 | Do. | Do. | Do. |
| Guidance for Industry, FDA Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria | October 4, 2004 | Do. | Do. | *http://www.fda.gov/cber/dap/devpubs.htm* |

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| Guidance for Industry: Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications | April 2003 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection | May 2003 | Do. | Do. | Do. |
| Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling | May 2003 | Do. | Do. | Do. |
| Draft Guidance for Industry and FDA Staff: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices | June 2003 | Do. | Do. | Do. |
| Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations | June 2003 | Do. | Do. | Do. |
| Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports | June 2003 | Do. | Do. | Do. |
| Draft Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis | June 2003 | Do. | Do. | Do. |
| 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 | July 2003 | Do. | Do. | Do. |
| Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires | July 2003 | Do. | Do. | Do. |
| Draft Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices | July 2003 | Do. | Do. | Do. |
| Draft Guidance for Review Staff and Industry: Good Review Management Principles for PDUFA Products | July 2003 | Do. | Do. | Do. |
| Compliance Program Guidance Manual (drugs and biologics) | Dates vary—Individual issue dates | Do. | Do. | *http://www.fda.gov/cber/cpg/cpg.htm* |
| ICH Guidance for Industry: Q3C—Tables and List | November 2003 | Do. | Do. | *http://www.fda.gov/cber/guidelines.htm* |
| ICH Guidance for Industry: Q3B(R) Impurities in New Drug Products | November 2003 | Do. | Do. | Do. |
| ICH Guidance for Industry: Q1A(R2) Stability Testing of New Drug Substances and Products | November 2003 | Do. | Do. | Do. |
| WITHDRAWN GUIDANCES | | | | |
| Draft Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma | November 1999 | Do. | N/A | |
| Draft Document Concerning the Regulation of Placental/Umbilical Cord Blood Hematopoietic Stem Cell Products Intended for Transplantation or Further Manufacturing Into Injectable Products | December 1995 | Do. | Do. | |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| Draft Document Concerning the Regulation of Peripheral Blood Hematopoietic Stem Cell Products Intended for Transplantation or Further Manufacturing into Injectable Products | February 1996 | Do. | Do. | |
| Draft Advertising and Promotional Labeling Staff Procedural Guidance | August 1994 | Do. | Do. | |
| Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures; Validation | August 2001 | Do. | Do. | |
| Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures; Glossary of Terms | August 2001 | Do. | Do. | |
| Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures; Time Stamps | February 2002 | Do. | Do. | |
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| Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling | January 12, 1998 | Advertising | Division of Drug Information (HFD–200), Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573 | *http://www.fda.gov/cder/guidance/index.htm* |
| Consumer-Directed Broadcast Advertisements | August 9, 1999 | Do. | Do. | Do. |
| Industry-Supported Scientific and Educational Activities | December 3, 1997 | Do. | Do. | Do. |
| Accelerated Approval Products—Submission of Promotional Materials | March 26, 1999 | Advertising draft | Do. | Do. |
| Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements | February 10, 2004 | Do. | Do. | Do. |
| ''Help-Seeking'' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms | February 10, 2004 | Do. | Do. | Do. |
| Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling | March 12, 1999 | Do. | Do. | Do. |
| Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs) | January 5, 1998 | Do. | Do. | Do. |
| Bioanalytical Method Validation | May 23, 2001 | Biopharmaceutics | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| | | | Mailing Address | Internet Address |
| Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations | March 19, 2003 | Do. | Do. | Do. |
| Cholestyramine Powder In Vitro Bioequivalence | July 15, 1993 | Do. | Do. | Do. |
| Clozapine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing | November 15, 1996 | Do. | Do. | Do. |
| Corticosteroids, Dermatologic (topical) In Vivo | June 2, 1995 | Do. | Do. | Do. |
| Dissolution Testing of Immediate Release Solid Oral Dosage Forms | August 25, 1997 | Do. | Do. | Do. |
| Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations | September 26, 1997 | Do. | Do. | Do. |
| Food-Effect Bioavailability and Fed Bioequivalence Studies | December 2002 | Do. | Do. | Do. |
| Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro | June 27, 1989 | Do. | Do. | Do. |
| Phenytoin/Phenytion Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing | March 4, 1994 | Do. | Do. | Do. |
| Statistical Approaches to Establishing Bioequivalence | February 2, 2001 | Do. | Do. | Do. |
| Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System | August 31, 2000 | Do. | Do. | Do. |
| Antifungal (topical) | February 24, 1990 | Biopharmaceutics draft | Do. | N/A |
| Antifungal (vaginal) | February 24, 1990 | Do. | Do. | Do. |
| Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action | April 2003 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing | December 2003 | Do. | Do. | Do. |
| Conjugated Estrogens, USP–LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence | March 2000 | Do. | Do. | Do. |
| BACPAC I: Intermediates in Drug Substance Synthesis: Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation | February 16, 2001 | Chemistry | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products | July 24, 1997 | Do. | Do. | Do. |
| Changes to an Approved NDA or ANDA | April 2004 | Do. | Do. | Do. |
| Changes to an Approved NDA or ANDA: Questions and Answers | January 22, 2001 | Do. | Do. | Do. |
| Container Closure Systems for Packaging Human Drugs and Biologics | May 1999 | Do. | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| | | | Mailing Address | Internet Address |
| Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products | April 1996 | Do. | Do. | Do. |
| Development of New Stereoisomeric Drugs | May 1, 1992 | Do. | Do. | Do. |
| Drug Master Files | September 1, 1989 | Do. | Do. | Do. |
| Drug Master Files for Bulk Antibiotic Drug Substances | November 29, 1999 | Do. | Do. | Do. |
| Environmental Assessment of Human Drug and Biologics Applications | July 27, 1998 | Do. | Do. | Do. |
| Format and Content for the CMC Section of an Annual Report | September 1, 1994 | Do. | Do. | Do. |
| Format and Content of the Chemistry, Manufacturing, and Controls Section of an Application | February 1, 1987 | Do. | Do. | Do. |
| Format and Content of the Microbiology Section of an Application | February 1, 1987 | Do. | Do. | Do. |
| IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information | May 25, 2001 | Do. | Do. | Do. |
| INDs for Phase 2 and 3 Studies; Chemistry, Manufacturing, and Controls Information | May 20, 2003 | Do. | Do. | Do. |
| Monoclonal Antibodies Used as Reagents in Drug Manufacturing | March 29, 2001 | Do. | Do. | Do. |
| Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Chemistry, Manufacturing, and Controls Documentation | July 5, 2002 | Do. | Do. | Do. |
| NDAs: Impurities in Drug Substances | February 25, 2000 | Do. | Do. | Do. |
| PAC–ALTS: Postapproval Changes—Analytical Testing Laboratory Sites | April 28, 1998 | Do. | Do. | Do. |
| Reviewer Guidance: Validation of Chromatographic Methods | November 1994 | Do. | Do. | Do. |
| Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products | November 1, 1994 | Do. | Do. | Do. |
| Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances | November 1994 | Do. | Do. | Do. |
| Submitting Documentation for the Manufacturing of, and Controls for, Drug Products | February 1, 1987 | Do. | Do. | Do. |
| Submitting Documentation for the Stability of Human Drugs and Biologics | February 1, 1987 | Do. | Do. | Do. |
| Submitting Samples and Analytical Data for Methods Validation | February 1987 | Do. | Do. | Do. |
| Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Products | February 1, 1987 | Do. | Do. | N/A |
| Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances | February 1987 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| SUPAC IR—Immediate-Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation | November 1995 | Do. | Do. | Do. |
| SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum | January 1999 | Do. | Do. | Do. |
| SUPAC–IR Questions and Answers About SUPAC–IR Guidance | February 18, 1997 | Do. | Do. | Do. |
| 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 | October 6, 1997 | Do. | Do. | Do. |
| SUPAC–SS—Nonsterile Semisolid Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation | May 1997 | Do. | Do. | Do. |
| The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) | December 20, 2000 | Do. | Do. | Do. |
| Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation | August 30, 2000 | Chemistry draft | Do. | Do. |
| Botanical Drug Products | June 9, 2004 | Do. | Do. | Do. |
| Comparability Protocols—Chemistry, Manufacturing, and Controls Information | February 25, 2003 | Do. | Do. | Do. |
| Drug Product: Chemistry, Manufacturing, and Controls Information | January 28, 2003 | Do. | Do. | Do. |
| Drug Substance: Chemistry, Manufacturing, and Controls Information | January 7, 2004 | Do. | Do. | Do. |
| Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals | September 2002 | Do. | Do. | Do. |
| Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations | July 1999 | Do. | | Do. |
| Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation | August 2002 | Do. | Do. | Do. |
| Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation | November 19, 1998 | Do. | Do. | Do. |
| Stability Testing of Drug Substances and Drug Products | June 8, 1998 | Do. | Do. | Do. |
| Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications | November 1, 1991 | Do. | Do. | N/A |
| SUPAC–SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum | January 5, 1999 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval | October 2002 | Clinical antimicrobial | Do. | Do. |
| Clinical Development and Labeling of Anti-Infective Drug Products | October 26, 1992 | Do. | Do. | Do. |
| Clinical Evaluation of Anti-Infective Drugs (Systemic) | September 1, 1977 | Do. | Do. | Do. |
| Preclinical Development of Antiviral Drugs | November 1990 | Do. | Do. | Do. |
| Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Clinical antimicrobial draft | Do. | Do. |
| Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Acute or Chronic Bacterial Prostatitis; Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Acute Otitis Media; Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment | October 18, 1999 | Do. | Do. | Do. |
| Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Complicated Urinary Tract Infections and Pylonephritis—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Developing Antimicrobial Drugs—General Considerations for Clinical Trials | July 22, 1998 | Do. | Do. | Do. |
| Developing Drugs to Treat Inhalational Anthrax (Post-Exposure) | March 18, 2002 | Do. | Do. | Do. |
| Empiric Therapy of Febrile Neutropenia—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products | February 1997 | Do. | Do. | Do. |
| Lyme Disease—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Nosocomial Pneumonia—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Secondary Bacterial Infections of Acute Bronchitis—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Streptococcal Pharyngitis and Tonsillitis—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Uncomplicated and Complicated Skin and Skin Structure Infections—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| Uncomplicated Gonorrhea—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Uncomplicated Urinary Tract Infections—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Vaccinia Virus—Developing Drugs to Mitigate Complications From Smallpox Vaccination | March 2004 | Do. | Do. | Do. |
| Vuvlovaginal Candidiasis—Developing Antimicrobial Drugs for Treatment | July 22, 1998 | Do. | Do. | Do. |
| Acceptance of Foreign Clinical Studies | March 2001 | Clinical medical | Do. | Do. |
| Calcium DTPA and Zinc DTPA Drug Products—Submitting a New Drug Application | August 2004 | Do. | Do. | Do. |
| Cancer Drug and Biological Products—Clinical Data in Marketing Applications | October 2001 | Do. | Do. | Do. |
| Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) | February 1999 | Do. | Do. | Do. |
| Clinical Development Programs for MDI and DPI Drug Products | September 19, 1994 | Do. | Do. | Do. |
| Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children) | April 1988 | Do. | Do. | Do. |
| Clinical Evaluation of Antianxiety Drugs | September 1, 1977 | Do. | Do. | Do. |
| Clinical Evaluation of Antidepressant Drugs | September 1, 1977 | Do. | Do. | Do. |
| Clinical Evaluation of Antiepileptic Drugs (adults and children) | January 1, 1981 | Do. | Do. | Do. |
| Clinical Evaluation of General Anesthetics | May 1, 1982 | Do. | Do. | Do. |
| Clinical Evaluation of Hypnotic Drugs | September 1, 1977 | Do. | Do. | Do. |
| Clinical Evaluation of Local Anesthetics | May 1982 | Do. | Do. | Do. |
| Clinical Evaluation of Psychoactive Drugs in Infants and Children | July 1979 | Do. | Do. | Do. |
| Content and Format for Pediatric Use Supplements | May 1996 | Do. | Do. | Do. |
| Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products | November 1995 | Do. | Do. | Do. |
| Establishing Pregnancy Exposure Registries | August 2002 | Do. | Do. | Do. |
| FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products | February 2, 1999 | Do. | Do. | Do. |
| FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer | January 1991 | Do. | Do. | Do. |
| Format and Content of the Clinical and Statistical Sections of an Application | July 1, 1988 | Do. | Do. | Do. |
| Format and Content of the Summary for New Drug and Antibiotic Applications | February 1, 1987 | Do. | Do. | Do. |
| Formatting, Assembling and Submitting New Drug and Antiobiotic Applications | February 1, 1987 | Do. | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| General Considerations for the Clinical Evaluation of Drugs | December 1, 1978 | Do. | Do. | Do. |
| General Considerations for the Clinical Evaluation of Drugs in Infants and Children | September 1, 1977 | Do. | Do. | Do. |
| Guidance for the Development of Vaginal Contraceptive Drugs (NDA) | April 1995 | Do. | Do. | Do. |
| IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer | January 15, 2004 | Do. | Do. | Do. |
| Integration of Dose-Counting Mechanisms Into MDI Drug Products | March 2003 | Do. | Do. | Do. |
| Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing | March 8, 2001 | Do. | Do. | Do. |
| Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Colon and Rectal Cancer | April 19, 1988 | Do. | Do. | Do. |
| Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer | April 1988 | Do. | Do. | Do. |
| Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report | August 27, 1997 | Do. | Do. | Do. |
| Postmarketing Reporting of Adverse Drug Experiences | March 1, 1992 | Do. | Do. | Do. |
| Preclinical Development of Immunomodulatory Drugs for Treatment of HIV Infection and Associated Disorders | September 1992 | Do. | Do. | Do. |
| Preparation of Investigational New Drug Products (Human and Animal) | November 1, 1992 | Do. | Do. | Do. |
| Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products | May 1998 | Do. | Do. | Do. |
| Prussian Blue Drug Products—Submitting a New Drug Application | February 4, 2003 | Do. | Do. | Do. |
| Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs | July 22, 1993 | Do. | Do. | Do. |
| Study of Drugs Likely to be Used in the Elderly | November 1, 1989 | Do. | Do. | Do. |
| Submission of Abbreviated Reports and Synopses in Support of Marketing Applications | September 13, 1999 | Do. | Do. | Do. |
| Abuse Liability Assessment | July 1, 1990 | Clinical medical draft | Do. | N/A |
| Allergic Rhinitis: Clinical Development Programs for Drug Products | June 21, 2000 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Available Therapy | July 22, 2004 | Do. | Do. | Do. |
| Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment | June 28, 2000 | Do. | Do. | Do. |

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| Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA) | July 1999 | Do. | Do. | Do. |
| Clinical Evaluation of Anti-Anginal Drugs | January 1, 1989 | Do. | Do. | N/A |
| Clinical Evaluation of Anti-Arrhythmic Drugs | July 1, 1985 | Do. | Do. | Do. |
| Clinical Evaluation of Antihypertensive Drugs | May 1, 1988 | Do. | Do. | Do. |
| Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure | December 1, 1987 | Do. | Do. | Do. |
| Clinical Evaluation of Lipid-Altering Agents in Adults and Children | September 1990 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Clinical Evaluation of Weight-Control Drugs | September 24, 1996 | Do. | Do. | Do. |
| Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees | November 2001 | Do. | Do. | Do. |
| Collection of Race and Ethnicity Data in Clinical Trials for FDA-Regulated Products | January 30, 2003 | Do. | Do. | Do. |
| Developing Medical Imaging Drug and Biological Products—2nd draft | May 19, 2003 | Do. | Do. | Do. |
| Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders | February 12, 1992 | Do. | Do. | N/A |
| Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis | May 2000 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals | September 2002 | Do. | Do. | Do. |
| Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommendations for Clinical Evaluation | January 2003 | Do. | Do. | Do. |
| Evaluation of Human Pregnancy Outcome Data | June 1999 | Do. | Do. | Do. |
| Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children | November 6, 2001 | Do. | Do. | Do. |
| Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB | February 20, 2002 | Do. | Do. | Do. |
| Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment | May 19, 2000 | Do. | Do. | Do. |
| Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research | March 2000 | Do. | Do. | Do. |
| Inhalation Drug Products Packaged in Semipermeable Container Closure Systems | July 26, 2002 | Do. | Do. | Do. |
| OTC Treatment of Herpes Labialis with Antiviral Agents | March 8, 2000 | Do. | Do. | Do. |
| Pediatric Oncology Studies in Response to a Written Request | June 21, 2000 | Do. | Do. | Do. |

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| Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis | April 1, 1994 | Do. | Do. | Do. |
| Preparation of IND Applications for New Drugs Intended for the Treatment of HIV-Infected Individuals | September 1, 1991 | Do. | Do. | N/A |
| Recommendations for Complying With the Pediatric Rule | November 2000 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro | April 7, 1997 | Clinical pharmacology | Do. | Do. |
| Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications | April 2003 | Do. | Do. | Do. |
| Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application | February 1, 1987 | Do. | Do. | Do. |
| In Vivo Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling | November 24, 1999 | Do. | Do. | Do. |
| Pharmacokinetics in Patients With Impaired Hepatic Function; Study Design, Data Analysis, and Impact on Dosing and Labeling | May 30, 2003 | Do. | Do. | Do. |
| Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis, and Impact on Dosing and Labeling | May 1998 | Do. | Do. | Do. |
| Population Pharmacokinetics | February 10, 1999 | Do. | Do. | Do. |
| General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products | November 30, 1998 | Clinical pharmacology draft | Do. | Do. |
| A Review of FDA's Implementation of the Drug Export Amendments of 1986 | May 1990 | Compliance | Do. | Do. |
| Compressed Medical Gases | February 1989 | Do. | Do. | Do. |
| Computerized Systems Used in Clinical Trials | April 1999 | Do. | Do. | Do. |
| Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron | June 27, 1997 | Do. | Do. | Do. |
| General Principles of Process Validation | May 1987 | Do. | Do. | Do. |
| Good Laboratory Practice Regulations Questions and Answers | June 1981 | Do. | Do. | Do. |
| Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities—FDA Public Health Advisory | March 2001 | Do. | Do. | Do. |
| 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 | December 1987 | Do. | Do. | Do. |
| Monitoring of Clinical Investigations | January 1988 | Do. | Do. | Do. |
| Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment | May 1984 | Do. | Do. | Do. |
| Pharmacy Compounding: Compliance Policy Guide | May 2002 | Do. | Do. | Do. |

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| Possible Dioxin/PCB Contamination of Drug and Biological Products | August 23, 1999 | Do. | Do. | Do. |
| Sterile Drug Products Produced by Aseptic Processing | June 1987 | Do. | Do. | Do. |
| Street Drug Alternatives | March 2000 | Do. | Do. | Do. |
| Current Good Manufacturing Practices for Medical Gases | May 6, 2003 | Compliance draft | Do. | Do. |
| Good Manufacturing Practice for Positron Emission Tomography Drug Products | April 1, 2002 | Do. | Do. | Do. |
| Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research | May 12, 2000 | Do. | Do. | Do. |
| Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production | September 30, 1998 | Do. | Do. | Do. |
| Manufacture, Processing, or Holding of Active Pharmaceutical Ingredients | April 17, 1998 | Do. | Do. | Do. |
| Marketed Unapproved Drugs—Compliance Policy Guide | October 2003 | Do. | | Do. |
| Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics | June 27, 2002 | Do. | Do. | Do. |
| Repackaging of Solid Oral Dosage Form Drug Products | February 1, 1992 | Do. | Do. | N/A |
| Part 11, Electronic Records; Electronic Signatures—Scope and Application | August 2003 | Current good manufacturing practices (CGMPs) | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information | September 2003 | CGMPs draft | Do. | Do. |
| Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practices | August 2003 | Do. | Do. | Do. |
| Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment | November 7, 2003 | Do. | Do. | Do. |
| Process Analytical Technology—A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance | October 4, 2004 | Do. | Do. | Do. |
| Sterile Drug Products Produced by Aseptic Processing | October 4, 2004 | Do. | Do. | Do. |
| Providing Electronic Submissions in Electronic Format—ANDAs | June 27, 2002 | Electronic submissions | Do. | Do. |
| Regulatory Submissions in Electronic Format; General Considerations | January 28, 1999 | Do. | Do. | Do. |
| Regulatory Submissions in Electronic Format; New Drug Applications | January 28, 1999 | Do. | Do. | Do. |
| Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs | August 2003 | Electronic submissions draft | Do. | Do. |

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| Providing Regulatory Submissions in Electronic Format—Content of Labeling | February 2004 | Do. | Do. | Do. |
| Providing Regulatory Submissions in Electronic Format—General Considerations | October 22, 2003 | Do. | Do. | Do. |
| Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions | August 29, 2003 | Do. | Do. | Do. |
| Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports | May 4, 2001 | Do. | Do. | Do. |
| Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports | June 2003 | Do. | Do. | Do. |
| Providing Regulatory Submissions in Electronic Format, Prescription Drug Advertising and Promotional Labeling | January 31, 2001 | Do. | Do. | Do. |
| 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day | July 2003 | Generics | Do. | |
| Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs | December 12, 2000 | Do. | Do. | Do. |
| ANDAs: Impurities in Drug Substances | November 1999 | Do. | Do. | Do. |
| Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act | March 2000 | Do. | Do. | Do. |
| Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past | August 1995 | Do. | Do. | Do. |
| Letter describing efforts by the CDER & the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new & abbreviated drug approval process in order to reduce duplication or redundancy in the process | October 1994 | Do. | Do. | Do. |
| 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 | April 1994 | Do. | Do. | Do. |
| Letter on the provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters | July 1992 | Do. | Do. | Do. |
| Letter on the provision of new procedures and policies affecting the generic drug review process | March 1989 | Do. | Do. | Do. |
| 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 | November 1991 | Do. | Do. | Do. |
| Letter on the response to 12/20/84 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act | March 1985 | Do. | Do. | Do. |

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| 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 | January 1993 | Do. | Do. | Do. |
| Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria, and bioequivalence requirements | August 1993 | Do. | Do. | Do. |
| Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications | December 2001 | Do. | Do. | Do. |
| Organization of an ANDA | March 2, 1999 | Do. | Do. | Do. |
| Revising ANDA Labeling Following Revision of the RLD Labeling | May 2000 | Do. | Do. | Do. |
| Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products | February 3, 2000 | Do. | Do. | Do. |
| Variations in Drug Products that May Be Included in a Single ANDA | December 1998 | Do. | Do. | Do. |
| ANDAs: Impurities in Drug Products | January 5, 1999 | Generics draft | Do. | Do. |
| Handling and Retention of Bioavailability and Bioequivalence Testing Samples | May 26, 2004 | Do. | Do. | Do. |
| Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing (revised) | August 7, 2002 | Do. | Do. | Do. |
| Pharmacology/Toxicology Review Format | May 2001 | Good review practices (GRP) | Do. | Do. |
| Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review | November 22, 1996 | GRP draft | Do. | Do. |
| Good Review Management Principles for Prescription Drug User Fee Act Products | July 28, 2003 | Do. | Do. | Do. |
| E10—Choice of Control Group and Related Issues in Clinical Trials | May 14, 2001 | ICH, efficacy | Do. | Do. |
| E11—Clinical Investigation of Medicinal Products in the Pediatric Population | December 15, 2000 | Do. | Do. | Do. |
| E1A—The Extent of Population Exposure to Assess Clinical Safety: for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions | March 1995 | Do. | Do. | Do. |
| E2A—Clinical Safety Data Management: Definitions and Standards for Expedited Reporting | March 1995 | Do. | Do. | Do. |
| E2B—Data Elements for Transmission of Individual Case Safety Reports | January 15, 1998 | Do. | Do. | Do. |
| E2BM—Data Elements for Transmission of Individual Case Safety Reports (revised) | April 3, 2002 | Do. | Do. | Do. |
| E2BM—Data Elements for Transmission of Individual Case Safety Reports—Questions and Answers | May 2004 | Do. | Do. | Do. |
| E2C—Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs | May 19, 1997 | Do. | Do. | Do. |

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| E2C Addendum—Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs | February 5, 2004 | Do. | Do. | Do. |
| E3—Structure and Content of Clinical Study Reports | July 1996 | Do. | Do. | Do. |
| E4—Dose-Response Information to Support Drug Registration | November 1994 | Do. | Do. | Do. |
| E5—Ethnic Factors in the Acceptability of Foreign Clinical Data | June 1998 | Do. | Do. | Do. |
| E6—Good Clinical Practice: Consolidated Guideline | May 9, 1997 | Do. | Do. | Do. |
| E7—Studies in Support of Special Populations: Geriatrics | August 1994 | Do. | Do. | Do. |
| E8—General Considerations for Clinical Trials | December 24, 1997 | Do. | Do. | Do. |
| E9—Statistical Principles for Clinical Trials | September 1998 | Do. | Do. | Do. |
| M2 eCTD: Electronic Common Technical Document Specification | April 2, 2003 | ICH, joint safety/efficacy (multidisciplinary) | Do. | Do. |
| M3—Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals | November 25, 1997 | Do. | Do. | Do. |
| M4—Organization of the CTD | August 2004 | Do. | Do. | Do. |
| M4—The CTD—Efficacy Questions and Answers | May 2004 | Do. | Do. | Do. |
| M4—The CTD—General Questions and Answers | May 2004 | Do. | Do. | Do. |
| M4—The CTD—Safety Questions and Answers | February 4, 2003 | Do. | Do. | Do. |
| Q1A(R2)—Stability Testing of New Drug Substances and Products | November 21, 2003 | ICH, quality | Do. | Do. |
| Q1B—Photostability Testing of New Drug Substances and Products | November 1996 | Do. | Do. | Do. |
| Q1C—Stability Testing for New Dosage Forms | May 9, 1997 | Do. | Do. | Do. |
| Q1D—Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products | January 16, 2003 | Do. | Do. | Do. |
| Q1F—Stability Data Package for the Registration in Climatic Zones III and IV | June 2004 | Do. | Do. | Do. |
| Q2A—Text on Validation of Analytical Procedures | March 1995 | Do. | Do. | Do. |
| Q2B—Validation of Analytical Procedures: Methodology | May 19, 1997 | Do. | Do. | Do. |
| Q3A—Impurities in New Drug Substances | February 2003 | Do. | Do. | Do. |
| Q3B(R)—Impurities in Drug Products | November 14, 2003 | Do. | Do. | Do. |
| Q3C—Impurities: Residual Solvents | December 24, 1997 | Do. | Do. | Do. |
| Q3C—Tables and List (revised recommendations for N-Methylpyrrolidone and Tetrahydrofuran) | November 2003 | Do. | Do. | Do. |
| Q5A—Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin | September 24, 1998 | Do. | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| | | | Mailing Address | Internet Address |
| Q5B—Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products | February 1996 | Do. | Do. | Do. |
| Q5C—Quality of Biotechnological Products: Stability Testing of Biotechnology/Biological Products | July 1996 | Do. | Do. | Do. |
| Q5D—Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products | September 21, 1998 | Do. | Do. | Do. |
| Q6A—Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances | December 29, 2000 | Do. | Do. | Do. |
| Q6B—Test Procedures and Acceptance Criteria for Biotechnological/Biological Products | August 18, 1999 | Do. | Do. | Do. |
| Q7A—Good Manufacturing Practice for Active Pharmaceutical Ingredients | August 2001 | Do. | Do. | Do. |
| S1A—The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals | March 1996 | ICH, safety | Do. | Do. |
| S1B—Testing for Carcinogenicity of Pharmaceuticals | July 1997 | Do. | Do. | Do. |
| S1C—Dose Selection for Carcinogenicity Studies of Pharmaceuticals | March 1995 | Do. | Do. | Do. |
| S1C(R)—Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes | December 4, 1997 | Do. | Do. | Do. |
| S2A—Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals | April 1996 | Do. | Do. | Do. |
| S2B—Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals | November 21, 1997 | Do. | Do. | Do. |
| S3A—Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies | March 1995 | Do. | Do. | Do. |
| S3B—Pharmacokinetics: Repeated Dose Tissue Distribution Studies | March 1995 | Do. | Do. | Do. |
| S4A—Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) | June 25, 1999 | Do. | Do. | Do. |
| S5A—Detection of Toxicity to Reproduction for Medicinal Products | September 22, 1994 | Do. | Do. | Do. |
| S5B—Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility | April 1996 | Do. | Do. | Do. |
| S6—Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals | November 18, 1997 | Do. | Do. | Do. |
| S7A—Safety Pharmacology Studies for Human Pharmaceuticals | July 13, 2001 | Do. | Do. | Do. |
| E2D—Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting | July 2003 | ICH draft, efficacy | Do. | Do. |
| E12A—Principles for Clinical Evaluation of New Antihypertensive Drugs | August 9, 2000 | Do. | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDER—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| | | | Mailing Address | Internet Address |
| M4—Common Technical Document—Quality: Questions and Answers/Location Issues | December 30, 2002 | ICH draft, joint safety/efficacy (multidisciplinary) | Do. | Do. |
| Submitting Marketing Appilcations According to the ICH–CTD Format—General Considerations | September 5, 2001 | Do. | Do. | Do. |
| Q1E—Evaluation of Stability Data | June 14, 2002 | ICH draft, quality | Do. | Do. |
| S7B—The Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals | June 2004 | ICH draft, safety | Do. | Do. |
| Content and Format of INDs for Phase 1 Studies of Drugs; Including Well-Characterized, Therapeutic, Biotechnology-Derived Products | November 1995 | IND | Do. | Do. |
| A Revision in Sample Collection Under the Compliance Program Pertaining to Preapproval Inspections | July 15, 1996 | Industry letters | Do. | N/A |
| Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program | March 2, 1998 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required | April 1987 | Do. | Do. | Do. |
| Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I | October 1986 | Do. | Do. | Do. |
| Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance | October 1984 | Do. | Do. | Do. |
| Implementation Plan USP injection nomenclature | October 1995 | Do. | Do. | Do. |
| Instructions for Filing Supplements Under the Provisions of SUPAC–IR | April 11, 1996 | Do. | Do. | N/A |
| Seventh of a series of letters about the Act providing guidance on the "180-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C Act | July 1988 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act | April 1988 | Do. | Do. | Do. |
| Streamlining Initiatives | December 24, 1996 | Do. | Do. | N/A |
| Supplement to 10/11/84 letter about policies, procedures and implementation of the Act (Q & A format) | November 1984 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Third of a series of letters regarding the implementation of the Act | May 1985 | Do. | Do. | Do. |
| Year 2000 Letter from Dr. Janet Woodcock | October 19, 1998 | Do. | Do. | Do. |
| Barbiturate, Single Entity-Class Labeling | March 1, 1981 | Labeling | Do. | N/A |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
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| Content and Format for Geriatric Labeling | October 5, 2001 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Hypoglycemic Oral Agents | April 1, 1984 | Do. | Do. | N/A |
| Labeling Over-the-Counter Human Drug Products; Updating Labeling in Reference Listed Drugs and Abbreviated New Drug Applications | October 18, 2002 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Local Anesthetics—Class Labeling | September 1, 1982 | Do. | Do. | N/A |
| Clinical Studies Section of Labeling for Prescription Drugs and Biologics—Content and Format | July 9, 2001 | Labeling draft | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics | March 5, 2004 | Do. | Do. | Do. |
| Labeling for Combined Oral Contraceptives | March 2004 | Do. | Do. | Do. |
| Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling | February 2004 | Do. | Do. | Do. |
| OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis) | June 1998 | Do. | Do. | Do. |
| Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications | October 26, 2000 | Do. | Do. | Do. |
| Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16) | May 1984 | OTC | Do. | Do. |
| General Guidelines for OTC Combination Products | September 1978 | Do. | Do. | Do. |
| Labeling OTC Human Drug Products Using a Column Format | December 19, 2000 | Do. | Do. | Do. |
| Upgrading Category III Antiperspirants to Category I (43 FR 46728–46731) | October 1978 | Do. | Do. | Do. |
| Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals | December 19, 2000 | OTC draft | Do. | Do. |
| Labeling OTC Human Drug Products Updating Labeling in ANDAs | February 2001 | Do. | Do. | Do. |
| OTC Actual Use Studies | July 22, 1994 | Do. | Do. | N/A |
| OTC Nicotine Substitutes | March 1, 1994 | Do. | Do. | Do. |
| Time and Extent Applications | February 10, 2004 | Do. | Do. | *http://www.fda.gov/cder/guidance/index.htm* |
| Carcinogenicity Study Protocol Submissions | May 2002 | Pharmacology/Toxicology | Do. | Do. |
| Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application | February 1987 | Do. | Do. | Do. |
| Immunotoxicology Evaluation of Investigational New Drugs | October 2002 | Do. | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| 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 | October 1996 | Do. | Do. | Do. |
| Photosafety Testing | May 7, 2003 | Do. | Do. | Do. |
| Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies | February 1989 | Do. | Do. | Do. |
| Single Dose Acute Toxicity Testing for Pharmaceuticals | August 1996 | Do. | Do. | Do. |
| Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers | January 16, 2003 | Pharmacology/ Toxicology draft | Do. | Do. |
| Integration of Study Results to Access Concerns About Human Reproductive and Developmental Toxicities | November 13, 2001 | Do. | Do. | Do. |
| Nonclinical Safety Evaluation of Pediatric Drug Products | February 2003 | Do. | Do. | Do. |
| Nonclinical Studies for Development of Pharmaceutical Excipients | October 2, 2002 | Do. | Do. | Do. |
| Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals | May 8, 2001 | Do. | Do. | Do. |
| 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act | June 1998 | Procedural | Do. | Do. |
| Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under the PDUFA | October 2003 | Do. | Do. | Do. |
| Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Drug Development of Fast Track Products Under the PDUFA | October 2003 | Do. | Do. | Do. |
| Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act | March 27, 2000 | Do. | Do. | Do. |
| 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 | November 30, 1999 | Do. | Do. | Do. |
| Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy | June 3, 2003 | Do. | Do. | Do. |
| Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act | November 23, 1998 | Do. | Do. | Do. |
| Fast Track Drug Development Programs—Designation, Development, and Application Review | July 2004 | Do. | Do. | Do. |
| Financial Disclosure by Clinical Investigators | March 2001 | Do. | Do. | Do. |
| Formal Dispute Resolution: Appeals Above the Division Level | February 2000 | Do. | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| Formal Meetings With Sponsors and Applicants For PDUFA Products | February 2003 | Do. | Do. | Do. |
| Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997—Advisory Committees | November 2, 1998 | Do. | Do. | Do. |
| Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements | July 21, 1998 | Do. | Do. | Do. |
| Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions | January 27, 2004 | Do. | Do. | Do. |
| Potassium Iodide in Radiation Emergencies—Questions and Answers | December 23, 2002 | Do. | Do. | Do. |
| Potassium Iodide Tablets for Shelf Life Extension for Federal Agencies and State and Local Governments | March 8, 2004 | Do. | Do. | Do. |
| Levothyroxine Sodium Products Enforcement of August 14, 2001, Compliance Date and Submission of New Applications | July 13, 2001 | Do. | Do. | Do. |
| National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs | April 9, 1998 | Do. | Do. | Do. |
| Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies | December 11, 2001 | Do. | Do. | Do. |
| Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act (revised) | September 1999 | Do. | Do. | Do. |
| Refusal to File | July 12, 1993 | Do. | Do. | Do. |
| Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act | May 1998 | Do. | Do. | Do. |
| Special Protocol Assessment | May 17, 2002 | Do. | Do. | Do. |
| Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements | May 15, 1998 | Do. | Do. | Do. |
| Guidance for FDA Staff: The Leveraging Handbook; an Agency Resource for Effective Collaborations | June 19, 2003 | Do. | Do. | Do. |
| Women and Minorities Guidance Requirements | July 20, 1998 | Do. | Do. | Do. |
| Applications Covered by Section 505(b)(2) | October 1999 | Procedural draft | Do. | Do. |
| Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees | November 2001 | Do. | Do. | Do. |
| PET Drug Applications—Content and Format for NDAs and ANDAs | March 2000 | Do. | Do. | Do. |
| Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by CDER, Beginning January 1, 2000 | December 22, 1999 | Do. | Do. | Do. |
| Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees | February 14, 2002 | Do. | Do. | Do. |

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| Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution | April 2001 | Do. | Do. | Do. |
| Good Review Management Principles for PDUFA Products | July 28, 2003 | Do. | Do. | Do. |
| Independent Consultants for Biotechnology Clinical Trial Protocols | May 7, 2003 | Do. | Do. | Do. |
| Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions | January 27, 2004 | Do. | Do. | Do. |
| Pharmacogenomic Data Submissions | January 27, 2004 | Do. | Do. | Do. |
| Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines | March 12, 2001 | Do. | Do. | Do. |
| Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 | April 4, 2001 | Do. | Do. | Do. |
| Submitting Debarment Certification Statements | October 2, 1998 | Do. | Do. | Do. |
| Submitting Marketing Applications According to the ICH/CTD Format—General Considerations | September 5, 2001 | Do. | Do. | Do. |
| The Use of Clinical Holds Following Clinical Investigator Misconduct | April 2002 | Do. | Do. | Do. |
| Sterility Requirements for Aqueous-Based Drug Products for Oral Inhalation—Small Entity Compliance Guide | November 7, 2001 | Small entity compliance guides | Do. | Do. |
| Applicability of User Fees to (1) Applications Withdrawn Before Filing, or (2) Applications the Agency Has Refused to File and That Are Resubmitted or Filed Over Protest (Attachment F) | July 12, 1993 | User fee | Do. | Do. |
| Application, Product, and Establishment Fees: Common Issues and Their Resolution (revised) (attachment D) (I) | December 16, 1994 | Do. | Do. | Do. |
| Classifying Resubmissions in Response to Action Letters | May 14, 1998 | Do. | Do. | Do. |
| Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act | June 1999 | Do. | Do. | Do. |
| Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act | November 21, 2001 | Do. | Do. | Do. |
| Submitting and Reviewing Complete Responses to Clinical Holds (revised) | October 26, 2000 | Do. | Do. | Do. |
| Document for Waivers of and Reductions in User Fees (attachment G) | July 16, 1993 | User fees draft | Do. | Do. |
| Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees | December 2000 | Do. | Do. | Do. |
| WITHDRAWALS | | | | |
| In Vivo Bioequivalence Studies on Population and Individual Bioequivalence Studies | December 30, 1987 | Do. | Do. | |
| Clinical Evaluation of Antacid Drugs | April 1, 1978 | N/A | N/A | |
| Clinical Evaluation of Antidiarrheal Drugs | September 1, 1977 | Do. | Do. | |

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| Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs | September 1, 1977 | Do. | Do. | |
| Clinical Evaluation of Laxative Drugs | April 1, 1978 | Do. | Do. | |
| Clinical Evaluation of Radiopharmaceutical Drugs | October 1, 1981 | Do. | Do. | |
| FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer | June 20, 1989 | Do. | Do. | |
| ANDAs: Blend Uniformity Analysis | August 27, 1999 | Do. | Do. | |
| Topical Dermatological Drug Products NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release, and Associated Studies | June 18, 1998 | Do. | Do. | |
| Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women | March 1, 1995 | Do. | Do. | |
| Noncontraceptive Estrogen Drug Products—Prescribing Information for Healthcare Providers and Patient Labeling | September 27, 1999 | Do. | Do. | |
| Chlordiazepoxide Hydrochloride Capsules | January 1, 1988 | Do. | Do. | |
| Clorazepate Dipotassium Capsules/Tablets | March 1, 1993 | Do. | Do. | |
| Cyproheptadine Hydrochloride Tablets/Syrup | December 1, 1986 | Do. | Do. | |
| Dipivefrin Hydrochloride Ophthalmic Solution, 0.1% | November 2, 1998 | Do. | Do. | |
| Ergoloid Mesylate Tablets | January 1, 1988 | Do. | Do. | |
| Hydroxyzine Hydrochloride Injection | December 1, 1989 | Do. | Do. | |
| Isoetharine Inhalation Solution | March 1, 1989 | Do. | Do. | |
| Meclofenamate Sodium Capsules | July 1, 1992 | Do. | Do. | |
| Naphazoline Hydrochloride Ophthalmic Solution | March 1, 1989 | Do. | Do. | |
| Niacin Tablets | July 1, 1992 | Do. | Do. | |
| Phendimetrazine Tartrate Capsules/Tablets and Extended-Release Capsules | February 1, 1991 | Do. | Do. | |
| Phentermine Hydrochloride Capsules/Tablets | August 1, 1988 | Do. | Do. | |
| Promethazine Hydrochloride Tablets | March 1, 1990 | Do. | Do. | |
| Propantheline Bromide Tablets | August 1, 1988 | Do. | Do. | |
| Pyridoxine Hydrochloride Injection | June 1, 1984 | Do. | Do. | |
| Quinidine Sulfate Capsules USP | October 1, 1995 | Do. | Do. | |
| Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets | February 1, 1992 | Do. | Do. | |
| Theophylline Immediate Release Oral Dosage Forms | February 1, 1995 | Do. | Do. | |
| Thiamine Hydrochloride Injection | February 1, 1988 | Do. | Do. | |
| Vitamin A Capsules | February 1, 1992 | Do. | Do. | |
| Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records | November 12, 2002 | Do. | Do. | |

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| Clinical Evaluation of Analgesic Drugs | December 1, 1992 | Do. | Do. | |
| Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements | April 23, 2001 | Do. | Do. | |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance for Industry, FDA Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria | October 4, 2004 | FDA, regulated industry, and third parties | Division of Small Manufacturers, International and Consumer Assistance, 1–800–638–2041 or 301–443–6597; or Facts-on-Demand,[1] 301–827–0111; or Internet at *http://www.fda.gov/cdrh/guidance.html* |
| Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties | February 2, 2001 | Do. | Do. |
| Mutual Recognition Agreement Between the European Union and the United States of America: Confidence Building Programme: Overview and Procedure; Medical Device Annex, Version 7, June 29, 2000; Draft | June 29, 2000 | FDA and regulated industry | Do. |
| Draft Guidance for Industry and FDA; Medical Glove Guidance Manual | July 30, 1999 | Do. | Do. |
| Guidance for Industry and FDA; Regulation of Medical Devices; Background Information for International Officials (entire document available on disk) | April 14, 1999 | Do. | Do. |
| Guidance for Staff, Industry, and Third Parties; Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA) | January 6, 1999 | Do. | Do. |
| Medical Device Appeals and Complaints: Guidance on Dispute Resolution | February 1998 | Do. | Do. |
| Overview of FDA Modernization Act of 1997 Medical Device Provisions | February 19, 1998 | Do. | Do. |
| Medical Device Reporting for Manufacturers | March 1997 | Do. | Do. |
| In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (FDA 97–4224) | January 1997 | Do. | Do. |
| Medical Device Quality Systems Manual: A Small Entity Compliance Guide | April 14, 1999 | Do. | Do. |
| Comparison Chart: 1996 Quality System Regulation vs. 1978 Good Manufacturing Practices Regulation vs. ANSI/ISO/ASQC Q9001–1994 and ISO/DIS 13485:1996 | November 29, 1996 | Do. | Do. |
| Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices (FDA 95–4158) | August 1995 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Labeling—Regulatory Requirements for Medical Devices | September 1, 1989 | Do. | Do. |
| Impact Resistant Lenses: Questions and Answers (FDA 87–4002) | September 1987 | Do. | Do. |
| CDRH Manual for the GGP Regulations; Final Guidance for FDA Staff | February 9, 2001 | FDA | Do. |
| Human Factors Principles for Medical Device Labeling | September 1, 1993 | FDA, regulated industry | Do. |
| Human Factors PTC for IDE Devices | January 17, 1997 | Do. | Do. |
| Write It Right | August 1993 | Do. | Do. |
| Do It By Design—An Introduction to Human Factors in Medical Devices | December 1996 | Do. | Do. |
| Guidance for Industry and FDA Premarket and Design Control Reviewers; Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management | July 18, 2000 | Do. | Do. |
| Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers | April 19, 2001 | Do. | Do. |
| Medical Device Reporting for User Facilities | April 1996 | FDA and user facilities | Do. |
| 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 | July 6, 2001 | FDA, regulated industry, third party, and hospital reprocessors | Do. |
| Frequently-Asked Questions About the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors; Three Additional Questions | July 16, 2003 | Do. | Do. |
| Continuing Education Credit for Reading/Writing Articles/Papers and Presenting Courses/Lectures (incorporated into the Policy Guidance Help System (PGHS)) | March 17, 1998 | FDA, accreditation bodies, and mammography facilities | Do. |
| Guidance for Submission of Request for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Acts, 42 U.S.C. 263(b)/4/8, 1998 (incorporated into PGHS) | March 26, 1998 | Do. | Do. |
| Guidance for Review of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S.C. 263(b)/4/8, 1998 (incorporated into PGHS) | March 26, 1998 | Do. | Do. |
| Policy and Standard Operating Procedures When Mammography Facilities in States That Have Accreditation Bodies Intend to Change Accreditation Bodies (incorporated into PGHS) | April 15, 1998 | Do. | Do. |
| Guidance for Industry; Requalification for Interpreting Physician's Continuing Experience Requirement (incorporated into PGHS) | May 28, 1998 | Do. | Do. |
| Guidance; The Mammography Quality Standards Act Final Regulations; Document #1 (incorporated into PGHS) | March 19, 1999 | Do. | Do. |

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|---|---|---|---|
| Compliance Guidance; The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly (incorporated into PGHS) | March 23, 1999 | Do. | Do. |
| Guidance for Request and Issuance of Interim Notice Letters for Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S.C. Section 263(b) (incorporated into PGHS) | May 4, 1999 | Do. | Do. |
| Compliance Guidance; The Mammography Quality Standards Act Final Regulations Quality Assurance Documentation (incorporated into PGHS) | December 7, 1999 | Do. | Do. |
| Compliance Guidance; The Mammography Quality Standards Act Final Regulations; Document #2 (incorporated into PGHS) | February 25, 2000 | Do. | Do. |
| The Mammography Quality Standards Act Final Regulations Modifications to the Policy Guidance Help System #1; Guidance for Industry and FDA (incorporated into PGHS) | July 5, 2000 | Do. | Do. |
| Compliance Guidance; The Mammography Quality Standards Act Final Regulations; Document #3 (incorporated into PGHS) | July 18, 2000 | Do. | Do. |
| Compliance Guidance; Mammography Facility Survey, Equipment Evaluation, and Medical Physicist Qualification Requirements Under MQSA; Final (incorporated into PGHS) | November 6, 2000 | Do. | Do. |
| The Mammography Quality Standards Act Final Regulations; Modifications and Additions to Policy Guidance Help System #2; Final Guidance for Industry and FDA (incorporated into PGHS) | January 24, 2001 | Do. | Do. |
| The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #4; Guidance for Industry and FDA (incorporated into PGHS) | May 23, 2001 | Do. | Do. |
| The Mammography Quality Standards Act Final Regulations Modifications to the Policy Guidance Help System Due to the September 11, 2002, Terrorist Attacks; Final Guidance for Industry and FDA (incorporated into PGHS) | October 5, 2001 | Do. | Do. |
| The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #3; Guidance for Industry and FDA (incorporated into PGHS) | November 5, 2001 | Do. | Do. |
| Compliance Guidance; The Mammography Quality Standards Act Final Regulations—Preparing for MQSA Inspections (incorporated into PGHS) | November 5, 2001 | Do. | Do. |
| The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #4; Guidance for Industry and FDA (incorporated into PGHS) | March 25, 2002 | Do. | Do. |
| The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #5; Guidance for Industry and FDA (incorporated into PGHS) | July 8, 2002 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #7; Guidance for Industry and FDA (incorporated into PGHS) | January 28, 2003 | Do. | Do. |
| The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6 (incorporated into PGHS) | August 19, 2003 | Do. | Do. |
| Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations to State and Local Agencies | August 13, 1998 | FDA, State and local agencies | Do. |
| Office of Device Evaluation | | | |
| FY 2004 MDUFMA Small Business Qualification Worksheet and Certification; Guidance for Industry and FDA | August 1, 2003 | Office of Device Evaluation | Do. |
| Premarket Assessment of Pediatric Medical Devices; Draft Guidance for Industry and FDA Staff | July 24, 2003 | Do. | Do. |
| Pediatric Expertise for Advisory Panels; Guidance for Industry and FDA Staff | June 3, 2003 | Do. | Do. |
| Premarket Approval Application Filing Review; Guidance for Industry and FDA Staff | May 1, 2003 | Do. | Do. |
| Guidance for Industry and FDA; FY 2003 MDUFMA Small Business Qualification Worksheet and Certification | March 27, 2003 | Do. | Do. |
| 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 | February 21, 2003 | Do. | Do. |
| Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff | December 3, 2002 | Do. | Do. |
| The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry | October 4, 2002 | Do. | Do. |
| Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA | September 6, 2002 | Do. | Do. |
| Updated 510(k) Sterility Review Guidance K90–1; Final Guidance for Industry and FDA | August 30, 2002 | Do. | Do. |
| Availability of Information Given to Advisory Committee Members in Connection With CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff | July 18, 2001 | Do. | Do. |
| Humanitarian Device Exemptions (HDE) Regulation: Questions and Answers; Final Guidance for Industry | July 12, 2001 | Do. | Do. |
| Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and CDRH Staff | May 29, 2001 | Do. | Do. |
| Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff | February 28, 2001 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Deciding When To Submit a 510(k) for a Change to an Existing Wireless Telemetry Medical Device; Final Guidance for FDA Reviewers and Industry | November 30, 2000 | Do. | Do. |
| Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997 | August 9, 2000 | Do. | Do. |
| Guidance on Amended Procedures for Advisory Panel Meetings; Final | July 22, 2000 | Do. | Do. |
| Guidance on the Use of Standards in Substantial Equivalence Determinations; Final | March 12, 2000 | Do. | Do. |
| Guidance for Off-the-Shelf Software Use in Medical Devices; Final | September 9, 1999 | Do. | Do. |
| Draft Guidance on Evidence Models for the Least Burdensome Means to Market | September 1, 1999 | Do. | Do. |
| Medical Devices Containing Materials Derived from Animal Sources (Except In Vitro Diagnostic Devices); Final Guidance for FDA Reviewers and Industry | November 16, 1998 | Do. | Do. |
| Guidance for the Medical Device Industry on PMA Shell Development and Modular Review; Final | November 6, 1998 | Do. | Do. |
| Guidance for Industry; General/Specific Intended Use; Final | November 4, 1998 | Do. | Do. |
| Frequently Asked Questions on the New 510(k) Paradigm; Final | October 22, 1998 | Do. | Do. |
| Modifications to Devices Subject to Premarket Approval—The PMA Supplement Decision Making Process; Draft | August 6, 1998 | Do. | Do. |
| Guidance for Industry; Contents of a Product Development Protocol; Draft | July 27, 1998 | Do. | Do. |
| New Model Medical Device Development Process; Final | July 21, 1998 | Do. | Do. |
| Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final | May 29, 1998 | Do. | Do. |
| Guidance to Industry Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review; Final | May 20, 1998 | Do. | Do. |
| A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications | March 20, 1998 | Do. | Do. |
| PMA/510(k) Expedited Review; Guidance for Industry and CDRH Staff; Final | March 20, 1998 | Do. | Do. |
| PMA/510(k) Expedited Review G94–4 (blue book memo) | March 20, 1998 | Do. | Do. |
| 30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes; Guidance for Industry and CDRH (Docket No. 98D–0080); Final | February 19, 1998 | Do. | Do. |
| Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—for Use by CDRH and Industry; Final | February 19, 1998 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| New section 513(f)(2)—Evaluation of Automatic Class III Designation; Guidance for Industry and CDRH Staff; Final | February 19, 1998 | Do. | Do. |
| Procedures for Class II Device Exemptions from Premarket Notification Guidance for Industry and CDRH Staff; Final | February 19, 1998 | Do. | Do. |
| Guidance on IDE Policies and Procedures; Final | January 20, 1998 | Do. | Do. |
| Distribution and Public Availability of PMA Summary of Safety and Effectiveness Data Packages | October 10, 1997 | Do. | Do. |
| Kit Certification for 510(k)s | July 1, 1997 | Do. | Do. |
| Convenience Kits Interim Regulatory Guidance | May 20, 1997 | Do. | Do. |
| Real-Time Review Program for Premarket Aproval Application (PMA) Supplements | April 22, 1997 | Do. | Do. |
| Deciding When to Submit a 510(k) for a Change to an Existing Device (K97–1) | January 10, 1997 | Do. | Do. |
| Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities | September 3, 1996 | Do. | Do. |
| Memorandum of Understanding Regarding Patient Labeling Review (blue book memo #G96–3) | August 9, 1996 | Do. | Do. |
| Continued Access to Investigational Devices During PMA Preparation and Review (blue book memo #D96–1) | July 15, 1996 | Do. | Do. |
| Document Review by the Office of the Chief Counsel (blue book memo G96–1) | June 6, 1996 | Do. | Do. |
| Format for IDE Progress Reports | June 1, 1996 | Do. | Do. |
| Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance | April 1, 1996 | Do. | Do. |
| 510(k) Quality Review Program (blue book memo) | March 29, 1996 | Do. | Do. |
| Suggested Content for Original IDE Application Cover Letter | February 27, 1996 | Do. | Do. |
| Indications for Use Statement | January 2, 1996 | Do. | Do. |
| Letter—Vascular Graft Industry (Philip Phillips) | November 22, 1995 | Do. | Do. |
| 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) | November 21, 1995 | Do. | Do. |
| Color Additives for Medical Devices (Snesko) | November 15, 1995 | Do. | Do. |
| #D95–2, Attachment A (Interagency Agreement between FDA and HCFA) | September 15, 1995 | Do. | Do. |
| #D95–2, Attachment B (Criteria for Categorization of Investigational Devices (HCFA)) | September 15, 1995 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| HCFA Reimbursement Categorization Determinations for FDA-Approved IDEs | September 15, 1995 | Do. | Do. |
| Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Attachment A Interagency Agreement, Attachment B Criteria for Catergorization of Investigational Devices, and Attachment C—List (blue book memo #D95–2) | September 15, 1995 | Do. | Do. |
| Goals and Initiatives for the IDE Program (blue book memo #D95–1) | July 12, 1995 | Do. | Do. |
| Memorandum: Electromagnetic Compatibility for Medical Devices: Issues and Solutions | June 13, 1995 | Do. | Do. |
| Use of International Standard ISO–10993, ''Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'' (replaces #G87–1 #8294) (blue book memo) | May 1, 1995 | Do. | Do. |
| Premarket Approval Application (PMA) Closure (blue book memo #P94–2) | July 8, 1994 | Do. | Do. |
| 510(k) Sign-Off Procedures (blue book memo #K94–2) | June 3, 1994 | Do. | Do. |
| Letter to Industry, Powered Wheelchair/Scooter or Accessory/Component Manufacturer from Susan Alpert, Ph.D., M.D. | May 26, 1994 | Do. | Do. |
| 510(k) Refuse to Accept Procedures (blue book memo #K94–1) | May 20, 1994 | Do. | Do. |
| IDE Refuse to Accept Procedures (blue book memo #D94–1) | May 20, 1994 | Do. | Do. |
| PMA/510(k) Triage Review Procedures (blue book memo #G94–1) | May 20, 1994 | Do. | Do. |
| Preamendments Class III Strategy | April 19, 1994 | Do. | Do. |
| Premarket Notification (510(k)) Status Request Form | March 7, 1994 | Do. | Do. |
| Documentation and Resolution of Differences of Opinion on Product Evaluations (blue book memo #G93–1) | December 23, 1993 | Do. | Do. |
| 510(k) Additional Information Procedures (blue book memo #K93–1) | July 23, 1993 | Do. | Do. |
| CDRH's Investigational Device Exemption (IDE) Refuse to Accept Policy | June 30, 1993 | Do. | Do. |
| CDRH's Premarket Notification (510(k)) Refuse to Accept Policy (updated checklist March 14, 1995) | June 30, 1993 | Do. | Do. |
| Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assesment and Allocating Review Resources | June 30, 1993 | Do. | Do. |
| Classified Convenience Kits | April 30, 1993 | Do. | Do. |
| Telephone Communications Between ODE Staff and Manufacturers (blue book memo #I93–1) | January 29, 1993 | Do. | Do. |
| Preamendment Class III Devices | March 11, 1992 | Do. | Do. |
| Nondisclosure of Financially Sensitive Information (blue book memo #I92–1) | March 5, 1992 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Document Review Processing (blue book memo #I91–1) | February 12, 1992 | Do. | Do. |
| 4-of-a-Kind PMAs | October 1, 1991 | Do. | Do. |
| Review of 510(k)s for Computer Controlled Medical Devices (blue book memo #K91–1) | August 29, 1991 | Do. | Do. |
| Review of Final Draft Medical Device Labeling (blue book memo #P91–4) | August 29, 1991 | Do. | Do. |
| Integrity of Data and Information Submitted to ODE (blue book memo #I91–2) | May 29, 1991 | Do. | Do. |
| Clinical Utility and Premarket Approval (blue book memo #P91–1) | May 3, 1991 | Do. | Do. |
| Panel Review of Premarket Approval Applications (blue book memo #P91–2) | May 3, 1991 | Do. | Do. |
| PMA Compliance Program (blue book memo #P91–3) | May 3, 1991 | Do. | Do. |
| Shelf Life of Medical Devices | April 1, 1991 | Do. | Do. |
| Device Labeling Guidance (blue book memo #G91–1) | March 8, 1991 | Do. | Do. |
| Review and Approval of PMAs of Licensees (blue book memo #P86–4) | October 22, 1990 | Do. | Do. |
| Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices (blue book memo #G90–2) | October 19, 1990 | Do. | Do. |
| Consolidated Review of Submissions for Lasers and Accessories (blue book memo #G90–1) | October 19, 1990 | Do. | Do. |
| Assignment of Review Documents (blue book memo #I90–2) | August 24, 1990 | Do. | Do. |
| PMA Supplements: ODEs Letter to Manufacturers; Identifies Situations Which May Require the Submission of a PMA Supplement (When PMA Supplements Are Required) (blue book memo #P90–1) | April 24, 1990 | Do. | Do. |
| Policy Development and Review Procedures (blue book memo #I90–1) | February 15, 1990 | Do. | Do. |
| Substantial Equivalence (SE) Decision Making Documentation Attached: ''SE'' Decision Making Process (detailed); i.e., The Decision Making Tree | January 1, 1990 | Do. | Do. |
| Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical Devices Marketed Prior to May 28, 1976 | January 1, 1990 | Do. | Do. |
| Meetings with the Regulated Industry (blue book memo #I89–3) | November 20, 1989 | Do. | Do. |
| FDA Policy for The Regulation of Computer Products; Draft | November 13, 1989 | Do. | Do. |
| Toxicology Risk Assessment Committee (blue book memo #G89–1) | August 9, 1989 | Do. | Do. |
| Review of IDEs for Feasibility Studies (blue book memo #D89–1) | May 17, 1989 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Premarket Notification—Consistency of Reviews (blue book memo #K89–1) | February 28, 1989 | Do. | Do. |
| Review of Laser Submissions (blue book memo #G88–1) | April 15, 1988 | Do. | Do. |
| PMA Review Schedules (P87–1); replaced by P94–2 | March 31, 1988 | Do. | Do. |
| Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test | December 1, 1987 | Do. | Do. |
| Necessary Information for Diagnostic Ultrasound 510(k); Draft | November 24, 1987 | Do. | Do. |
| Limulus Amebocute Lysate; Reduction of Samples for Testing | October 23, 1987 | Do. | Do. |
| ODE Executive Secretary Guidance Manual G87–3 | August 7, 1987 | Do. | Do. |
| Guideline on Sterile Drug Products Produced by Aseptic Processing | June 1, 1987 | Do. | Do. |
| Master Files Part III; Guidance on Scientific and Technical Information | June 1, 1987 | Do. | Do. |
| ODE Regulatory Information for the Office of Compliance—Information Sharing Procedures (blue book memo #G87–2) | May 15, 1987 | Do. | Do. |
| Guideline on General Principles of Process Validation | May 1, 1987 | Do. | Do. |
| Industry Representatives on Scientific Panel | March 27, 1987 | Do. | Do. |
| Panel Review of ''Me-Too'' Devices (blue book memo #P86–6) | July 1, 1986 | Do. | Do. |
| Guidance on CDRH's Premarket Notification Review Program (blue book memo #K86–3) | June 30, 1986 | Do. | Do. |
| Panel Report and Recommendations on PMA Approvals (blue book memo #P86–5) | April 18, 1986 | Do. | Do. |
| Criteria for Panel Review of PMA Supplements (blue book memo #P86–3) | January 30, 1986 | Do. | Do. |
| PMAs—Early Review and Preparation of Summaries of Safety and Effectiveness (blue book memo #P86–1) | January 27, 1986 | Do. | Do. |
| PTC in the Characterization of Cell Lines Used to Produce Biological Products | June 1, 1984 | Do. | Do. |
| Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices | December 1, 1983 | Do. | Do. |
| Methods for Conducting Recall Effectiveness Checks | June 16, 1978 | Do. | Do. |
| Guidance for Submitting Reclassification Petition | 1997 | Do. | Do. |
| Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; Draft | February 8, 2000 | Do. | Do. |
| Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA | July 17, 2002 | Do. | Do. |
| Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCo2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA | December 13, 2002 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA | October 5, 2001 | Do. | Do. |
| Heated Humidifier Review Guidance | August 30, 1991 | Do. | Do. |
| 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 | April 22, 2003 | Do. | Do. |
| Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA | November 12, 2002 | Do. | Do. |
| Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers | August 14, 2002 | Do. | Do. |
| Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA | May 14, 2002 | Do. | Do. |
| Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Draft Guidance for Industry and FDA | February 20, 2002 | Do. | Do. |
| Overview of Information Necessary for Premarket Notification Submissions for Endosseous Implants; Final | April 21, 1999 | Do. | Do. |
| Guidance for the Preparation of Premarket Notifications for Dental Composites | November 27, 1998 | Do. | Do. |
| Dental Cements—Premarket Notification; Final | August 18, 1998 | Do. | Do. |
| Dental Impression Materials—Premarket Notification; Final | August 17, 1998 | Do. | Do. |
| OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits; Final | August 17, 1998 | Do. | Do. |
| Draft Guidance Document for the Preparation of Premarket Notification 510(k)s for Dental Alloys | March 3, 1997 | Do. | Do. |
| Information Necessary for Premarket Notification Submissions for Screw-Type Endosseous Implants | December 9, 1996 | Do. | Do. |
| Guidance Document on Dental Handpieces | July 1, 1995 | Do. | Do. |
| Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for an Endosseous Implant for Prosthetic Attachment | May 16, 1989 | Do. | Do. |
| Supplementary Guidance on Premarket Notifications for Medical Devices With Sharps Injury Prevention Features; Guidance for Industry and FDA | December 31, 2002 | Do. | Do. |
| Guidance on Premarket Notifications for Intravascular Administration Sets | October 12, 2000 | Do. | Do. |
| Neonatal and Neonatal Transport Incubators—Premarket Notifications; Final | September 18, 1998 | Do. | Do. |
| Guidance on the Content of Premarket Notification (510(k)) Submissions for Protective Restraints | December 1, 1995 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance on Premarket Notification (510(k)) Submissions for Short-Term and Long-Term Intravascular Catheters | March 16, 1995 | Do. | Do. |
| Guidance on the Content of Premarket Notification (510(k)) Submissions for Hypodermic Single Lumen Needles | April 1, 1993 | Do. | Do. |
| Guidance on the Content of Premarket Notification (510(k)) Submissions for Piston Syringes | April 1, 1993 | Do. | Do. |
| Guidance on the Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers | March 1, 1993 | Do. | Do. |
| Guidance on the Content of Premarket Notification (510(k)) Submissions for External Infusion Pumps | March 1, 1993 | Do. | Do. |
| Guidance on 510(k) Submissions for Implanted Infusion Ports | October 1, 1990 | Do. | Do. |
| Surgical Masks—Premarket Notification (510(k)) Submissions; Draft Guidance | May 15, 2003 | Do. | Do. |
| Regulatory Status of Disinfectants Used to Process Dialysate Delivery Systems and Water Purification Systems for Hemodialysis; Guidance for Industry and FDA | August 30, 2002 | Do. | Do. |
| Premarket Notification (510(k)) Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA | March 7, 2002 | Do. | Do. |
| Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff | February 7, 2002 | Do. | Do. |
| Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance for Industry and FDA Staff | June 1, 2001 | Do. | Do. |
| Premarket Notifications (510(k)) for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers | May 21, 2001 | Do. | Do. |
| Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA | March 2, 2001 | Do. | Do. |
| Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Sterilants and High Level Disinfectants; Final | January 3, 2000 | Do. | Do. |
| Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Draft | November 16, 1999 | Do. | Do. |
| Premarket Notification (510(k)) Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products; Final | January 13, 1999 | Do. | Do. |
| CDRH Regulatory Guidance for Washers and Washer-Disinfectors Intended for Use in Processing Reusable Medical Devices | June 2, 1998 | Do. | Do. |
| Testing for Sensitizing Chemicals in Natural Rubber Latex Medical Devices (addendum to 944) | July 28, 1997 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Addendum to Guidance on Premarket Notification (510(k)) Submissions for Sterilizers Intended for Use in Health Care Facilities | September 19, 1995 | Do. | Do. |
| Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Sharps Containers | October 1, 1993 | Do. | Do. |
| Guidance on Premarket Notification (510(k)) Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities | August 1, 1993 | Do. | Do. |
| Guidance on Premarket Notification (510(k)) Submissions for Surgical Gowns and Surgical Drapes | August 1, 1993 | Do. | Do. |
| Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities | March 1, 1993 | Do. | Do. |
| Battery Guidance | January 1, 1994 | Do. | Do. |
| Policy for Expiration Dating (DCRND RB92–G) | October 30, 1992 | Do. | Do. |
| Balloon Valvuloplasty Guidance for the Submission of an IDE Application and a PMA Application | January 1, 1989 | Do. | Do. |
| Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry | July 1, 2002 | Do. | Do. |
| Investigational Device Exemption (IDE) Study Enrollment for Cardiac Ablation of Typical Atrial Flutter; Final Guidance for Industry and FDA Reviewers | November 8, 2000 | Do. | Do. |
| Recommended Clinical Study Design for Ventricular Tachycardia Ablation | May 7, 1999 | Do. | Do. |
| Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1; Final | November 19, 1998 | Do. | Do. |
| Non-Invasive Blood Pressure (NIBP) Monitor Guidance | March 10, 1997 | Do. | Do. |
| Electrocardiograph (ECG) Electrode | February 11, 1997 | Do. | Do. |
| Electrocardiograph (ECG) Lead Switching Adapter | February 11, 1997 | Do. | Do. |
| Electrocardiograph (ECG) Surface Electrode Tester | February 11, 1997 | Do. | Do. |
| Draft Version Cardiac Ablation Preliminary Guidance (Data To Be Submitted to the FDA in Support Investigation Device Exemption Application) | March 1, 1995 | Do. | Do. |
| Draft Version Electrode Recording Catheter Preliminary Guidance (Data To Be Submitted to the FDA in Support of Premarket Notifications) | March 1, 1995 | Do. | Do. |
| Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff | January 31, 2001 | Do. | Do. |
| Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA | November 29, 2000 | Do. | Do. |
| Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA | November 29, 2000 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff | November 13, 2000 | Do. | Do. |
| Draft Replacement Heart Valve Guidance | October 14, 1994 | Do. | Do. |
| Draft Guidance; Human Heart Valve Allografts | June 21, 1991 | Do. | Do. |
| Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses | April 1, 1990 | Do. | Do. |
| Draft Intravascular Brachytherapy—Guidance for Data To Be Submitted to FDA in Support of Investigational Device Exemption (IDE) Applications | May 24, 1996 | Do. | Do. |
| Draft Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents | May 1, 1995 | Do. | Do. |
| Draft Percutaneous Transluminal Coronary Angioplasty Package Insert Template | February 7, 1995 | Do. | Do. |
| Coronary and Cerebrovascular Guidewire Guidance | January 1, 1995 | Do. | Do. |
| Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions | November 1, 2000 | Do. | Do. |
| Draft Guidance for Implantable Cardioverter-Defibrillators | June 19, 1996 | Do. | Do. |
| Implantable Pacemaker Testing Guidance | January 12, 1990 | Do. | Do. |
| Guidance Document for Vascular Prostheses 510(k) Submissions | November 1, 2000 | Do. | Do. |
| Guidance for Cardiovascular Intravascular Filter 510(k) Submissions; Final | November 26, 1999 | Do. | Do. |
| Carotid Stent—Suggestions for Content of Submissions to FDA in Support of Investigational Devices Exemption (IDE) Applications | October 26, 1996 | Do. | Do. |
| Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses | August 1, 1993 | Do. | Do. |
| Guidance Document for Powered Suction Pump 510(k)s | September 30, 1998 | Do. | Do. |
| Guidance Document for Surgical Lamp 510(k)s; Final | July 13, 1998 | Do. | Do. |
| Electroencephalograph Devices Draft Guidance for 510(k) Content | November 3, 1997 | Do. | Do. |
| Guidelines for Reviewing Premarket Notifications That Claim Substantial Equivalence to Evoked Response Stimulators | February 1, 1997 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Electromyograph Needle Electrodes | July 26, 1995 | Do. | Do. |
| Guidance on the Content and Organization of a Premarket Notification for a Medical Laser | June 1, 1995 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Draft 510(k) Guideline for General Surgical Electrosurgical Devices | May 10, 1995 | Do. | Do. |
| Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices | August 30, 1994 | Do. | Do. |
| Galvanic Skin Response Measurement Devices; Draft Guidance for 510(k) Content | August 23, 1994 | Do. | Do. |
| Draft Version 1; Biofeedback Devices; Draft Guidance for 510(k) Content | August 1, 1994 | Do. | Do. |
| Draft Version Cranial Perforator Guidance | July 13, 1994 | Do. | Do. |
| Draft Version Neuro Endoscope Guidance | July 7, 1994 | Do. | Do. |
| Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators | June 1, 1994 | Do. | Do. |
| Draft Guidance for Arthroscope and Accessory 510(k)s | May 1, 1994 | Do. | Do. |
| Class II Special Controls Guidance Document; Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA | January 16, 2003 | Do. | Do. |
| Class II Special Controls Guidance Document; Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA | July 17, 2002 | Do. | Do. |
| Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis | April 30, 2002 | Do. | Do. |
| Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semiconstrained Porous-Coated Uncemented Prosthesis | October 31, 2000 | Do. | Do. |
| Guidance for Spinal System 510(k)s | September 27, 2000 | Do. | Do. |
| Guidance Document for the Preparation of IDEs for Spinal Systems | January 13, 2000 | Do. | Do. |
| Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices; Draft | March 18, 1998 | Do. | Do. |
| Draft Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices—The Basic Elements | July 16, 1997 | Do. | Do. |
| ORDB 510(k) Sterility Review Guidance | July 3, 1997 | Do. | Do. |
| Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants | February 21, 1997 | Do. | Do. |
| Reviewers Guidance Checklist for Intramedullary Rods | February 21, 1997 | Do. | Do. |
| Reviewers Guidance Checklist for Orthopedic External Fixation Devices | February 21, 1997 | Do. | Do. |
| 510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants | February 20, 1997 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance Document for Testing Biodegradable Polymer Implant Devices | April 20, 1996 | Do. | Do. |
| Guidance Document for Testing Bone Anchor Devices | April 20, 1996 | Do. | Do. |
| Draft Guidance Document for Femoral Stem Prostheses | August 1, 1995 | Do. | Do. |
| Draft Guidance Document for Testing Acetabular Cup Prostheses | May 1, 1995 | Do. | Do. |
| Guidance Document for Testing Non-Articulating, ''Mechanically Locked,'' Modular Implant Components | May 1, 1995 | Do. | Do. |
| Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices | March 28, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification for Ceramic Ball Hip Systems | January 10, 1995 | Do. | Do. |
| Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement | April 28, 1994 | Do. | Do. |
| Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semiconstrained Total Knee Prostheses | April 1, 1993 | Do. | Do. |
| Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prothetic Knee Ligament Devices | February 18, 1993 | Do. | Do. |
| Class II Special Controls Guidance Document; Surgical Sutures; Guidance for Industry and FDA | June 3, 2003 | Do. | Do. |
| Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA | February 11, 2003 | Do. | Do. |
| Class II Special Controls Guidance Document; Human Dura Mater; Draft Guidance for Industry and FDA | October 22, 2002 | Do. | Do. |
| Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Guidance for Industry | June 18, 2002 | Do. | Do. |
| Guidance Document for Dura Substitute Devices; Final Guidance for Industry | November 9, 2000 | Do. | Do. |
| Guidance for Neurological Embolization Devices | November 1, 2000 | Do. | Do. |
| Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater; Final | October 14, 1999 | Do. | Do. |
| Guidance for Dermabrasion Devices; Final | March 2, 1999 | Do. | Do. |
| Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Final | March 2, 1999 | Do. | Do. |
| Guidance for Content of Premarket Notifications for Esophageal and Tracheal Prostheses; Final | April 28, 1998 | Do. | Do. |
| Guidance for Testing MR Interaction With Aneurysm Clips | May 22, 1996 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Draft Guidance for the Preparation of IDE Submission for Interactive Wound and Burn Dressing | April 4, 1995 | Do. | Do. |
| Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing | March 31, 1995 | Do. | Do. |
| Draft Version; Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model | September 12, 1994 | Do. | Do. |
| Protocol for Dermal Toxicity Testing for Devices in Contact With Skin; Draft | January 1, 1985 | Do. | Do. |
| Class II Special Controls Guidance Document; Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA | June 2, 2003 | Do. | Do. |
| Guidance Document for Powered Muscle Stimulator 510(k)s; Final | June 9, 1999 | Do. | Do. |
| Guidance Document for the Preparation of Notification (510(k)) Applications for Therapeutic Massagers and Vibrators | July 26, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Beds | July 26, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Communications Systems (Powered and Nonpowered) and Powered Environmental Control Systems | July 26, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Exercise Equipment | July 26, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Heating and Cooling Devices | July 26, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Immersion Hydrobaths | July 26, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Powered Tables and Multifunctional Physical Therapy Tables | July 26, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Submerged (Underwater) Exercise Equipment | July 26, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles | July 26, 1995 | Do. | Do. |
| Guide for TENS 510(k) Content; Draft | August 1, 1994 | Do. | Do. |
| Draft Version Guidance for Clinical Data To Be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators | August 20, 1992 | Do. | Do. |
| Draft Guidance for Cortical Electrode 510(k) Content | August 10, 1992 | Do. | Do. |
| Guidance for Studies for Pain Therapy Devices—General Consideration in the Design of Clinical Studies for Pain-Alleviating Devices | May 12, 1988 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Accountability Analysis for Clinical Studies for Ophthalmic Devices; Draft | August 4, 1999 | Do. | Do. |
| Guidance Document for Nonprescription Sunglasses; Final | October 9, 1998 | Do. | Do. |
| Ophthalmoscope Guidance | July 8, 1998 | Do. | Do. |
| Retinoscope Guidance; Final | July 8, 1998 | Do. | Do. |
| Slit Lamp Guidance; Final | July 8, 1998 | Do. | Do. |
| Discussion Points for Expansion of the ''Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers;'' Draft Document | September 5, 1997 | Do. | Do. |
| Third Party Review Guidance for Phacofragmentation System Device Premarket Notification (510(k)) | January 31, 1997 | Do. | Do. |
| Third Party Review Guidance for Vitreous Aspiration and Cutting Device Premarket Notification (510(k)) | January 31, 1997 | Do. | Do. |
| Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers (excimer) | October 10, 1996 | Do. | Do. |
| Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers; Final | March 12, 2000 | Do. | Do. |
| Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification; Final | January 14, 1998 | Do. | Do. |
| Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Children Ages 2 through 17 Years | May 1, 1990 | Do. | Do. |
| Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Adults at Least 18 Years of Age | May 1, 1990 | Do. | Do. |
| Refractive Implants: Guidance for Investigational Device Exemptions (IDE) and Premarket Approval (PMA) Applications; Draft | August 1, 2000 | Do. | Do. |
| Intraocular Lens Guidance Document; Draft | October 14, 1999 | Do. | Do. |
| Guidance on 510(k) Submissions for Keratoprostheses; Final | March 3, 1999 | Do. | Do. |
| Aqueous Shunts—510(k) Submissions; Final | November 16, 1998 | Do. | Do. |
| FDA Guidelines for Multifocal Intraocular Lens IDE Studies and PMAs | May 29, 1997 | Do. | Do. |
| Important Information About Rophae Intraocular Lenses | August 20, 1992 | Do. | Do. |
| Guidance for Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses; Final | April 10, 2000 | Do. | Do. |
| Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear; Final | August 11, 1998 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Premarket Notification 510(k) Guidance for Contact Lens Care Products | May 1, 1997 | Do. | Do. |
| Premarket Notification (510(k)) Guidance Document for Class II Daily Wear Contact Lenses | June 28, 1994 | Do. | Do. |
| New FDA Recommendations and Results of Contact Lens Study (7-day letter) | May 30, 1989 | Do. | Do. |
| Class II Special Controls Guidance Document; Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA | November 28, 2001 | Do. | Do. |
| 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 | May 16, 2001 | Do. | Do. |
| Guidance for Investigational Device Exemptions for Solutions for Hypothermic Flushing, Transport, and Storage of Organs for Transplantation; Final Guidance for Industry and FDA Reviewers | January 16, 2001 | Do. | Do. |
| Guidance for Industry and CDRH Reviewers on the Content of Premarket Notifications for Hemodialysis Delivery Systems; Final | August 7, 1998 | Do. | Do. |
| Guidance for the Content of Premarket Notification for Conventional and High Permeability Hemodialyzers; Final | August 7, 1998 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; Final | February 5, 1998 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis | May 30, 1997 | Do. | Do. |
| Draft Guidance for Hemodialyzer Reuse Labeling | October 6, 1995 | Do. | Do. |
| Class II Special Controls Guidance Document; Breast Lesion Documentation System; Guidance for Industry and FDA Staff | July 28, 2003 | Do. | Do. |
| Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers | March 9, 2001 | Do. | Do. |
| Class II Special Controls Guidance Document for Clitoral Engorgement Devices | July 3, 2000 | Do. | Do. |
| Draft Guidance for Industry; Electro-optical Sensors for the In Vivo Detection of Cervical Cancer and Its Precursors: Submission Guidance for an IDE/PMA | August 25, 1999 | Do. | Do. |
| Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures; Draft | September 10, 1998 | Do. | Do. |
| Latex Condoms for Men—Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions | July 23, 1998 | Do. | Do. |
| Uniform Contraceptive Labeling; Final | July 23, 1998 | Do. | Do. |
| Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft Document | June 14, 1997 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Letter to Manufacturers of Prescription Home Monitors for Nonstress Tests | September 6, 1996 | Do. | Do. |
| Letter to Manufacturers of Falloposcopes | September 5, 1996 | Do. | Do. |
| Thermal Endometrial Ablation Devices (Submission Guidance for an IDE) | March 14, 1996 | Do. | Do. |
| Hysteroscopes and Gynecology Laparoscopes (Submission Guidance for a 510(k)) | March 7, 1996 | Do. | Do. |
| Hysteroscopes and Laparoscopic Insufflators (Submission Guidance for a 510(k)) | August 1, 1995 | Do. | Do. |
| Testing Guidance for Male Condoms Made From New Material (Nonlatex) | June 29, 1995 | Do. | Do. |
| Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons | May 25, 1995 | Do. | Do. |
| Information for a Latex Condom 510(k) Submission for Obstetrics-Gynecology Devices Branch; Draft | April 13, 1994 | Do. | Do. |
| Premarket Testing Guidelines for Falloposcopes | November 20, 1992 | Do. | Do. |
| Draft Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions | July 29, 1991 | Do. | Do. |
| Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases | April 4, 1990 | Do. | Do. |
| Guidance (‘‘Guidelines’’) for Evaluation of Hysteroscopic Sterilization Devices | May 10, 1978 | Do. | Do. |
| Guidance (‘‘Guidelines’’) for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories) | May 1, 1978 | Do. | Do. |
| Guidance (‘‘Guidelines’’) for Evaluation of Tubal Occlusion Devices | November 22, 1977 | Do. | Do. |
| Guidance (‘‘Guidelines’’) for Evaluation of Fetal Clip Electrode | March 8, 1977 | Do. | Do. |
| Guidelines for Evaluation of Nondrug IUDs | September 28, 1976 | Do. | Do. |
| Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices; Guidance for Industry and FDA Staff | July 14, 2003 | Do. | Do. |
| Bone Sonometer PMA Applications; Final Guidance for Industry and FDA | June 21, 2001 | Do. | Do. |
| Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA | February 16, 2001 | Do. | Do. |
| Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources | August 2, 2000 | Do. | Do. |
| Guidance for the Submission of Premarket Notifications for Medical Image Management Devices | July 27, 2000 | Do. | Do. |
| Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices; Final | August 6, 1999 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems; Final | December 3, 1998 | Do. | Do. |
| Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators; Final | November 20, 1998 | Do. | Do. |
| Harmonic Imaging With/Without Contrast—Premarket Notification; Final | November 16, 1998 | Do. | Do. |
| Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Final | November 14, 1998 | Do. | Do. |
| Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers | September 30, 1997 | Do. | Do. |
| Letter: Notice to Manufacturers of Bone Mineral Densitometers | September 25, 1997 | Do. | Do. |
| Simplified 510(k) Procedures for Certain Radiology Devices: 12/21/93 letter from L. Yin, ODE/DRAERD, to NEMA | December 21, 1993 | Do. | Do. |
| Draft Guidance for Review of Bone Densitometer 510(k) Submissions | November 9, 1992 | Do. | Do. |
| Reviewer Guidance for Automatic X-Ray Film Processor 510(k) | February 1, 1990 | Do. | Do. |
| Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi | August 9, 2000 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Penile Rigidity Implants; Final | January 16, 2000 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters; Final | November 30, 1998 | Do. | Do. |
| CDRH Interim Regulatory Policy for External Penile Rigidity Devices | September 10, 1997 | Do. | Do. |
| Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence | November 29, 1995 | Do. | Do. |
| Draft Guidance for the Clinical Investigation of Urethral Stents | November 2, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology | August 16, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Urological Irrigation System and Tubing Set | August 1, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology | June 22, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence | June 6, 1995 | Do. | Do. |
| Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter) | May 1, 1995 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology | March 17, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Condom Catheters | February 23, 1995 | Do. | Do. |
| Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) | November 11, 1994 | Do. | Do. |
| Checklist for Mechanical Lithotripters and Stone Dislodgers Used in Gastroenterology and Urology | November 1, 1994 | Do. | Do. |
| 510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments | September 19, 1994 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters | September 12, 1994 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems | July 29, 1994 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Urine Drainage Bags | June 7, 1994 | Do. | Do. |
| Draft Guidance Outline—PTC for Clinical Studies for Vasovasostomy Devices | November 30, 1993 | Do. | Do. |
| Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants | March 16, 1993 | Do. | Do. |
| Draft Guidance for Preparation of PMA Applications for Testicular Prostheses | March 16, 1993 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology | February 10, 1993 | Do. | Do. |
| Guidance for the Content of Premarket Notifications for Ureteral Stents | February 10, 1993 | Do. | Do. |
| Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Cathethers | January 24, 1992 | Do. | Do. |
| Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements | January 18, 1991 | Do. | Do. |
| Draft Guidance to Firms on Biliary Lithotripsy Studies | August 2, 1990 | Do. | Do. |
| Office of In Vitro Diagnostic Device Evaluation and Safety | | | |
| Analyte Specific Reagents; Small Entity Compliance Guidance; Guidance for Industry | February 26, 2003 | Do. | Do. |
| Assessing the Safety/Effectiveness of Home-Use In Vitro Diagnostic Devices (IVDs): Draft PTC Regarding Labeling and Premarket Submissions | October 1, 1988 | Do. | Do. |
| Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers | June 10, 1996 | Do. | Do. |
| Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff | December 3, 2002 | Do. | Do. |
| Guidance for Administrative Procedures for CLIA Categorization | August 14, 2000 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA | March 1, 2001 | Do. | Do. |
| Guidance for Industry; Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final | February 22, 1999 | Do. | Do. |
| Guidance on Labeling for Laboratory Tests; Draft | June 24, 1999 | Do. | Do. |
| Letter to IVD Manufacturers on Streamlined PMA; Final | December 22, 1997 | Do. | Do. |
| PTC for Collection of Data in Support of In Vitro Device Submissions for 510(k) Clearance | September 26, 1994 | Do. | Do. |
| PTC for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices (cover letter dated March 14, 1996) | February 1, 1996 | Do. | Do. |
| PTC Guidance Document on Assayed and Unassayed Quality Control Material; Draft | February 3, 1999 | Do. | Do. |
| Premarket Approval Application Filing Review; Guidance for Industry and FDA Staff | May 1, 2003 | Do. | Do. |
| Breath Nitric Oxide Test System; Class II Special Controls Guidance Document | July 7, 2003 | Do. | Do. |
| Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers | November 30, 2000 | Do. | Do. |
| Class II Special Controls Guidance Document; Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA | September 16, 2002 | Do. | Do. |
| Draft Guidance for Prescription Use of Drugs of Abuse Assays Premarket Notifications | November 14, 2000 | Do. | Do. |
| Draft Guidance on the Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing | December 21, 1999 | Do. | Do. |
| Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use | July 14, 1995 | Do. | Do. |
| Guidance for Industry In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Final | July 6, 1998 | Do. | Do. |
| Guidance for Industry In Vitro Diagnostic Chloride Test System; Final | July 6, 1998 | Do. | Do. |
| Guidance for Industry In Vitro Diagnostic Creatinine Test System; Final | July 2, 1998 | Do. | Do. |
| Guidance for Industry In Vitro Diagnostic Glucose Test System; Final | July 6, 1998 | Do. | Do. |
| Guidance for Industry In Vitro Diagnostic Potassium Test System; Final | July 6, 1998 | Do. | Do. |
| Guidance for Industry In Vitro Diagnostic Sodium Test System; Final | July 6, 1998 | Do. | Do. |
| Guidance for Industry In Vitro Diagnostic Urea Nitrogen Test System; Final | July 6, 1998 | Do. | Do. |
| Guidance for Industry; In Vitro Diagnostic C-Reactive Protein Immunological Test System | July 20, 1998 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s | July 22, 2000 | Do. | Do. |
| Guidance for Over-the-Counter (OTC) Ovulation Predictor 510(k)s | July 22, 2000 | Do. | Do. |
| Over-the-Counter (OTC) Screening Tests for Drugs of Abuse; Guidance for Premarket Notifications | November 14, 2000 | Do. | Do. |
| PTC for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery | February 20, 1996 | Do. | Do. |
| Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies | August 31, 1995 | Do. | Do. |
| Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology | February 14, 1996 | Do. | Do. |
| Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs) | November 6, 1996 | Do. | Do. |
| 510(k) Submissions for Coagulation Instruments; Guidance for Industry and FDA Staff | June 19, 2003 | Do. | Do. |
| Class II Special Control Guidance Document for Anti-*Saccharomyces cerevisia* (*S. cerevisiae*) Antibody (ASCA) Premarket Notifications | August 23, 2000 | Do. | Do. |
| 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 | December 4, 2001 | Do. | Do. |
| Document for Special Controls for Erythropoietin Assay Premarket Notifications (510(k)s); Final | April 28, 1999 | Do. | Do. |
| Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests | July 29, 1992 | Do. | Do. |
| Draft Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for IVDs | September 30, 1991 | Do. | Do. |
| Draft Guidance Document for 510(k) Submission of Immunoglobulins A, G, M, D and E Immunoglobulin System In Vitro Devices | September 1, 1992 | Do. | Do. |
| Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs Using Monoclonal Antibodies | September 26, 1991 | Do. | Do. |
| Draft; Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors In Vitro Diagnostic Devices Using Steroid Hormone Binding (SBA) with Dextran-Coated Charcoal (DCC) Separation, Histochemical Receptor Bind | September 10, 1992 | Do. | Do. |
| Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification (510(k)) to FDA | September 19, 1996 | Do. | Do. |
| Guidance for Submission of Immunohistochemistry Applications to the FDA; Final | June 3, 1998 | Do. | Do. |
| In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Final | April 27, 1999 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Multiplex Tests for Heritable DNA Markers, Mutations, and Expression Patterns; Draft Guidance for Industry and FDA Reviewers | February 27, 2003 | Do. | Do. |
| PTC for Cervical Cytology Devices | July 25, 1994 | Do. | Do. |
| PTC for Hematology Quality Control Materials | September 30, 1997 | Do. | Do. |
| Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k)s; Final Guidance for Industry and FDA | August 22, 2001 | Do. | Do. |
| Review Criteria for Assessment of Alpha-Fetoprotein (AFP) In Vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies | July 15, 1994 | Do. | Do. |
| Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers | July 15, 1991 | Do. | Do. |
| 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 | February 21, 1997 | Do. | Do. |
| Review Criteria for Blood Culture Systems | August 12, 1991 | Do. | Do. |
| Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Do Antibodies to Viral Agents | August 1, 1992 | Do. | Do. |
| 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) | February 1, 1994 | Do. | Do. |
| 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) | February 15, 1996 | Do. | Do. |
| Review Criteria for the Assessment of Anti-Nuclear Antibodies (ANA) In Vitro Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA), Immunodiffusion (IMD), and Enzyme Linked Immunosorbant Assay (ELISA) | September 1, 1992 | Do. | Do. |
| Class II Special Controls Guidance Document; Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA | February 5, 2003 | Do. | Do. |
| Draft Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms | June 14, 1993 | Do. | Do. |
| Premarket Approval Applications for In Vitro Diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, or Other HCV-Associated Disease; Draft Guidance for Industry and FDA | April 27, 2001 | Do. | Do. |
| Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs | October 30, 1996 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens | January 1, 1992 | Do. | Do. |
| Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of *Mycobacterium* Spp. (Tuberculosis (TB)) | July 6, 1993 | Do. | Do. |
| Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to *Helicobacter pylori* | September 17, 1992 | Do. | Do. |
| Review Criteria for Devices Assisting in the Diagnosis of *C. Difficile* Associated Diseases | May 31, 1990 | Do. | Do. |
| Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe | December 30, 1991 | Do. | Do. |
| Review Criteria for Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19 | May 15, 1992 | Do. | Do. |
| Office of Surveillance and Biometrics | | | |
| PMA Review Statistical Checklist | (no date available) | Do. | Do. |
| Statistical Aspects of Submissions to FDA: A Medical Device Perspective (also includes as appendix the article "Observed Uses and Abuses of Statistical Procedures in Medical Device Submissions") | June 1, 1984 | Do. | Do. |
| Statistical Guidance for Clinical Trials of Nondiagnostic Medical Devices | January 1, 1996 | Do. | Do. |
| MDR Guidance Document: Remedial Action Exemption; Final | September 26, 2001 | Industry and FDA | Do. |
| Guidance on Adverse Event Reporting for Hospitals That Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use | April 24, 2001 | Industry | Do. |
| MDR Guidance Document No. 1—IOL—E1996004; Final | August 7, 1996 | Do. | Do. |
| Common Problems: Baseline Reports and Medwatch Form 3500A | January 1, 1997 | Do. | Do. |
| Medical Device Reporting: An Overview; Final | April 1, 1996 | Do. | Do. |
| Instructions for Completing FDA Form 3500A With Coding Manual for Form 3500A (MEDWATCH) (MDR); Final | December 15, 1995 | Do. | Do. |
| MEDWATCH FDA Form 3500A for Use by User Facilities, Distributors and Manufacturers for Mandatory Reporting (MDR); Final | June 1, 1993 | Industry and user facilities | Do. |
| Variance from Manufacturer Report Number Format (MDR letter); Final | July 16, 1996 | Industry | Do. |
| Instructions for Completing Form 3417: Medical Device Reporting Baseline Report (MDR); Final | March 31, 1997 | Do. | Do. |
| Medical Device Reporting—Alternative Summary Reporting (ASR) Program; Guidance for Industry | October 19, 2000 | Do. | Do. |
| Addendum to the Instructions for Completing FDA Form 3500A With Coding Manual (MEDWATCH) (MDR); Final | June 9, 1999 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

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| Needlesticks—Medical Device Reporting Guidance | November 12, 2002 | Industry and user facilities | Do. |
| Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads) | June 9, 1993 | Industry and FDA reviewers | Do. |
| Guidance on Criteria and Approaches for Postmarket Surveillance | November 2, 1998 | Do. | Do. |
| Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies (FDAMA); Final | February 19, 1998 | FDA reviewers | Do. |
| Guidance on Procedures for Review of Postmarket Surveillance Submissions (FDAMA); Final | February 19, 1998 | Do. | Do. |
| Guidance for Industry and FDA Staff; SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance Protocols (FDAMA); Final | November 2, 1998 | Industry and FDA reviewers | Do. |
| Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads; Final | March 30, 1994 | Do. | Do. |
| Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket | February 2, 2000 | Do. | Do. |
| Office of Compliance | | | |
| Commercial Distribution/Exhibit Letter | March 11, 1992 | Do. | Do. |
| FDA Guide for Validation of Biological Indicator Incubation Time | January 1, 1986 | Do. | Do. |
| Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88–8264) | March 1, 1988 | Do. | Do. |
| General Principles of Software Validation; Draft Guidance | January 11, 2002 | Do. | Do. |
| Guidance on Medical Device Tracking (FDAMA); Guidance for Industry and FDA Staff | May 23, 2003 | Do. | Do. |
| Compliance Program Guidance Manual: Inspection of Medical Devices; Draft | February 7, 2001 | Do. | Do. |
| Procedures for Laboratory Compliance Testing of Television Revivers—Part of TV Packet | May 1, 1986 | Do. | Do. |
| Guidance on Quality System Regulation Information for Various Premarket Submissions; Draft | February 3, 2003 | Do. | Do. |
| Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves; Guidance for Industry | July 26, 2000 | Do. | Do. |
| Manufacturers/Assemblers of Diagnostic X-Ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g) | October 13, 1993 | Do. | Do. |
| Guidance for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components | January 1, 1982 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Exemption From Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers | September 16, 1981 | Do. | Do. |
| Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi) | May 17, 1993 | Do. | Do. |
| Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (FDA 89–8221) | March 1, 1989 | Do. | Do. |
| CPG 7133.19: Retention of Microwave Oven Test Record/Cover Letter: August 24, 1981; Retention of Records Required by 21 CFR 1002 | March 1, 1995 | Do. | Do. |
| A Guidance for the Submission of Abbreviated Radiation Safety Reports on Cephalometric X-Ray Devices: Defined as Dental Units With an Attachment for Mandible Work That Holds a Cassette and Beam Limiting Device | March 1, 1996 | Do. | Do. |
| A Guide for the Submission of an Abbreviated Radiation Safety Report on X-Ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use | March 1, 1996 | Do. | Do. |
| A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammography X-Ray Systems | March 1, 1996 | Do. | Do. |
| Compliance Program Guidance Manual; Field Compliance Testing of Diagnostic (Medical) X-Ray Equipment; Guidance for FDA Staff | March 15, 2000 | Do. | Do. |
| Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA | April 2, 2001 | Do. | Do. |
| Guide for Submission of Information on Accelerators Intended to Emit X-Radiation Required Pursuant to 21 CFR 1002.10 | April 1, 1971 | Do. | Do. |
| Abbreviated Report on Radiation Safety for Microwave Products (Other Than Microwave Ovens)—e.g., Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric Heaters, Security Systems | August 1, 1995 | Do. | Do. |
| Guide for Preparing Reports on Radiation Safety of Microwave Ovens | March 1, 1985 | Do. | Do. |
| Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) (FDA 88–8140) | September 1, 1995 | Do. | Do. |
| Guide for Filing Annual Reports for X-Ray Components and Systems | July 1, 1980 | Do. | Do. |
| Reporting and Compliance Guide for Television Products Including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Information, and Guidance | October 1, 1995 | Do. | Do. |
| Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (replaces FDA 82–8127) | September 1, 1995 | Do. | Do. |
| Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use | September 1, 1996 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Letter to Manufacturers and Importers of Microwave Ovens: Information Requirements for Cookbooks and User and Service Manuals | October 31, 1988 | Do. | Do. |
| Abbreviated Report on Radiation Safety of Nonmedical Ultrasonic Products | August 1, 1995 | Do. | Do. |
| Guide for Preparing Product Reports for Medical Ultrasound Products | September 1, 1996 | Do. | Do. |
| Letter to Manufacturers, Distributors, and Importers of Condom Products | February 23, 1994 | Do. | Do. |
| Letter to Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt) | February 13, 1989 | Do. | Do. |
| Letter to Condom Manufacturers and Distributors | April 5, 1994 | Do. | Do. |
| Letter to Manufacturers/Repackers Using Cotton | April 22, 1994 | Do. | Do. |
| Guide for Preparing Product Reports for Lasers and Products Containing Lasers | September 1, 1995 | Do. | Do. |
| Compliance Guide for Laser Products (FDA 86–8260) | September 1, 1985 | Do. | Do. |
| Condoms: Inspection and Sampling at Domestic Manufacturers and of All Repackers; Sampling From All Importers (Damaska memo to field on April 8, 1987) | April 8, 1987 | Do. | Do. |
| Dental Hand Piece Sterilization (dear doctor letter) | September 28, 1992 | Do. | Do. |
| Latex Labeling Letter (Johnson) | March 18, 1993 | Do. | Do. |
| Pesticide Regulation Notice 94–4: Interim Measures for the Registration of Antimicrobial Products/Liquid Chemical Germicides With Medical Device Use Claims Under the Memorandum of Understanding Between EPA and FDA | June 30, 1994 | Do. | Do. |
| Letter to Industry, Powered Wheelchair Manufacturers, from RM Johnson | May 10, 1993 | Do. | Do. |
| Hazards of Volume Ventilators and Heated Humidifiers | September 15, 1993 | Do. | Do. |
| Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals | February 3, 1994 | Do. | Do. |
| Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol: Proposed Maximum Residue Limits and Maximum Levels of Exposure | June 23, 1978 | Do. | Do. |
| Letter to Manufacturers and Users of Lasers for Refractive Surgery (excimer) | October 10, 1996 | Do. | Do. |
| Shielded Trocars and Needles Used for Abdominal Access During Laparoscopy | August 23, 1996 | Do. | Do. |
| Surveillance and Detention Without Physical Examination of Condoms; Draft Guidance for Industry | August 14, 2000 | Do. | Do. |
| All U.S. Condom Manufacturers, Importers, and Repackagers | April 7, 1987 | Do. | Do. |
| Manufacturers and Initial Distributors of Hemodialyzers | May 23, 1996 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Laser Light Show Safety—Who's Responsible? (FDA 86–8262) | May 1, 1986 | Do. | Do. |
| Suggested State Regulations for Control of Radiation; Volume II; Nonionizing Radiation—Lasers (FDA Pub. No. 83–8220) | January 1, 1982 | Do. | Do. |
| Letter to All Foreign Manufacturers and Importers of Electronic Products For Which Applicable FDA Performance Standards Exist | May 28, 1981 | Do. | Do. |
| Guide for Submission of Information on Industrial X-Ray Equipment Required Pursuant to 21 CFR 1002.10 | March 1, 1973 | Do. | Do. |
| Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1002.10 | April 30, 1974 | Do. | Do. |
| Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40 | February 1, 1975 | Do. | Do. |
| Guide for Preparing Annual Reports in Radiation Safety Testing of Electronic Products (General) | October 1, 1987 | Do. | Do. |
| Computerized Devices/Processes Guidance—Application of the Medical Device GMP to Computerized Devices and Manufacturing Processes | May 1, 1992 | Do. | Do. |
| Guide for Preparing Product Reports for Ultrasonic Therapy Products (Physical Therapy Only) | August 1, 1996 | Do. | Do. |
| Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 (FDA 81–8137) | November 1, 1980 | Do. | Do. |
| Guide for Preparing Annual Reports for Ultrasonic Therapy Products | September 1, 1996 | Do. | Do. |
| Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products (replaces FDA 82–8127) | September 1, 1995 | Do. | Do. |
| Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor (replaces FDA 82–8127) | September 1, 1995 | Do. | Do. |
| Quality Control Guide for Sunlamp Products (FDA 88–8234) | September 1, 1984 | Do. | Do. |
| Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems | December 1, 1985 | Do. | Do. |
| Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR 1002) | September 1, 1995 | Do. | Do. |
| Letter: Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products | June 25, 1985 | Do. | Do. |
| Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR 1002) | September 1, 1995 | Do. | Do. |
| Quality Control Practices for Compliance With the Federal Mercury Vapor Lamp Performance Standard | May 1, 1980 | Do. | Do. |
| Keeping Up With the Microwave Revolution (FDA Publication No. 91–4160) | March 1, 1990 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Quality Assurance Guidelines for Hemodialysis Devices | February 1, 1991 | Do. | Do. |
| Letter to Manufacturers and Importers of Microwave Ovens—Open Door Operation of Microwave Ovens as a Result of Oven Miswiring | March 28, 1980 | Do. | Do. |
| Reporting of New Model Numbers to Existing Model Families | June 14, 1983 | Do. | Do. |
| Import: Radiation-Producing Electronic Products (FDA 89–8008) | November 1, 1988 | Do. | Do. |
| Unsafe Patient Lead Wires and Cables | September 3, 1993 | Do. | Do. |
| Application of a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device (form FDA 3147) | July 1, 1998 | Do. | Do. |
| Letter to Trade Association: Reuse of Single-Use or Disposable Medical Devices | December 27, 1995 | Do. | Do. |
| Design Control Guidance for Medical Device Manufacturers | March 11, 1997 | Do. | Do. |
| Keeping Medical Devices Safe from Electromagnetic Interference | July 1, 1995 | Do. | Do. |
| Safety of Electrically Powered Products: Letter to Medical Devices and Electronic Products Manufacturers from Lilliam Gill and BHB Correction Memo | September 18, 1996 | Do. | Do. |
| Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Guidance for Industry and for FDA Staff | August 14, 2000 | Do. | Do. |
| Labeling for Electronic Anti-theft Systems; Final Guidance for Industry | August 15, 2000 | Do. | Do. |
| Wireless Medical Telemetry Risks and Recommendations; Final Guidance for Industry | September 27, 2000 | Do. | Do. |
| Policy on Warning Label Required on Sunlamp Products | June 25, 1985 | Do. | Do. |
| Policy on Lamp Compatibility (Sunlamps) | September 2, 1986 | Do. | Do. |
| Office of Science and Technology | | | |
| Guidance on Frequently Asked Questions on Recognition of Consensus Standards (FDAMA) | December 21, 1998 | Do. | Do. |
| Guidance on the Recognition and Use of Consensus Standards; appendix A (FDAMA) | February 19, 1998 | Do. | Do. |
| CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standard for Recognition | August 6, 1999 | Do. | Do. |
| Guidance for Industry and FDA Reviewers: Guidance on Immunotoxicity Testing | May 6, 1999 | Do. | Do. |
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| Medical Devices Made With Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEHP); Draft Guidance for Industry and FDA | September 6, 2002 | N/A | N/A |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
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| Modifications to Devices Subject to Premarket Approval—The PMA Supplement Decision Making Process; Draft | August 6, 1998 | Do. | Do. |
| Guidance for Industry; Contents of a Product Development Protocol; Draft | July 27, 1998 | Do. | Do. |
| New Model Medical Device Development Process; Final | July 21, 1998 | Do. | Do. |
| Document Review by the Office of the Chief Counsel (blue book memo G96–1) | June 6, 1999 | Do. | Do. |
| Letter: Vascular Graft Industry (Philip Phillips) | November 22, 1995 | Do. | Do. |
| Color Additives for Medical Devices (Snesko) | November 15, 1995 | Do. | Do. |
| PMA/510(k) Triage Review Procedures (blue book memo #G94–1) | May 20, 1994 | Do. | Do. |
| Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources | June 30, 1993 | Do. | Do. |
| 4-of-a-Kind PMAs | October 1, 1999 | Do. | Do. |
| Review of 510(k)s for Computer Controlled Medical Devices (blue book memo #K91–1) | August 29, 1991 | Do. | Do. |
| Review of Final Draft Medical Device Labeling (blue book memo #P91–4) | August 29, 1991 | Do. | Do. |
| Clinical Utility and Premarket Approval (blue book memo #P91–1) | May 3, 1991 | Do. | Do. |
| Review and Approval of PMAs of Licensees (blue book memo #P86–4) | October 22, 1990 | Do. | Do. |
| PMA Supplements: ODEs Letter to Manufacturers; Identifies Situation Which May Require the Submission of a PMA Supplement (blue book memo #P90–1) | April 24, 1990 | Do. | Do. |
| FDA Policy for the Regulation of Computer Products; Draft | November 13, 1989 | Do. | Do. |
| PMA Review Schedules (P87–1) (replaced by P94–2) | March 31, 1988 | Do. | Do. |
| Necessary Information for Diagnostic Ultrasound 510(k); Draft | November 24, 1987 | Do. | Do. |
| Guideline on Sterile Drug Products Produced by Aseptic Processing | June 1, 1987 | Do. | Do. |
| ODE Regulatory Information for the Office of Compliance; Information Sharing Procedures (blue book memo #G87–2) | May 15, 1987 | Do. | Do. |
| Panel Review of ''Me-Too'' Devices (blue book memo #P86–6) | July 1, 1986 | Do. | Do. |
| Criteria for Panel Review of PMA Supplements (blue book memo #P86–3) | January 30, 1986 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| PMAs-Early Review and Preparation of Summaries of Safety and Effectiveness (blue book memo #P86–1) | January 27, 1986 | Do. | Do. |
| Draft Guidance for the Preparation of Premarket Notification 510(k)s for Dental Alloys | March 3, 1997 | Do. | Do. |
| Premarket Guidance; Reprocessing and Reuse of Single-Use Devices; Draft | June 1, 2001 | Do. | Do. |
| Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Draft | November 16, 1999 | Do. | Do. |
| Draft Version Cardiac Ablation Preliminary Guidance (Data To Be Submitted to the FDA in Support Investigation Device Exemption Application) | March 1, 1995 | Do. | Do. |
| Draft Version Electrode Recording Catheter Preliminary Guidance (Data To Be Submitted to the FDA in Support of Premarket Notifications) | March 1, 1995 | Do. | Do. |
| Draft Replacement Heart Valve Guidance | October 14, 1994 | Do. | Do. |
| Draft Guidance on Human Heart Valve Allografts | June 21, 1991 | Do. | Do. |
| Draft Intravascular Brachytherapy—Guidance for Data To Be Submitted to FDA in Support of Investigational Device Exemption (IDE) Applications | May 24, 1996 | Do. | Do. |
| Draft Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents | May 1, 1995 | Do. | Do. |
| Draft Percutaneous Transluminal Coronary Angioplasty Package Insert Template | February 7, 1995 | Do. | Do. |
| Draft Guidance for Implantable Cardioverter-Defibrillators | June 19, 1996 | Do. | Do. |
| Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses | August 1, 1993 | Do. | Do. |
| Electroencephalograph Devices Draft Guidance for 510(k) Content | November 3, 1997 | Do. | Do. |
| Draft 510(k) Guideline for General Surgical Electrosurgical Devices | May 10, 1995 | Do. | Do. |
| Galvanic Skin Response Measurement Devices; Draft Guidance for 510(k) Content | August 23, 1994 | Do. | Do. |
| Draft Version 1; Biofeedback Devices; Draft Guidance for 510(k) Content | August 1, 1994 | Do. | Do. |
| Draft Version Cranial Perforator Guidance | July 13, 1994 | Do. | Do. |
| Draft Version Neuro Endoscope Guidance | July 7, 1994 | Do. | Do. |
| Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators | June 1, 1994 | Do. | Do. |
| Draft Guidance for Arthroscope and Accessory 510(k)s | May 1, 1994 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices; Draft | March 18, 1998 | Do. | Do. |
| Draft Guidance for Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices: The Basic Elements | July 16, 1997 | Do. | Do. |
| Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submission for Orthopedic and Dental Endosseous Implants | February 21, 1997 | Do. | Do. |
| Draft Guidance Document for Femoral Stem Prostheses | August 1, 1995 | Do. | Do. |
| Draft Guidance Document for Testing Acetabular Cup Prostheses | May 1, 1995 | Do. | Do. |
| Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices | March 23, 1995 | Do. | Do. |
| Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semiconstrained Total Knee Prostheses | April 1, 1993 | Do. | Do. |
| Draft Guidance for the Preparation of IDE Submission for Interactive Wound and Burn Dressing | April 4, 1995 | Do. | Do. |
| Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing | March 31, 1995 | Do. | Do. |
| Draft Version; Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model | September 12, 1994 | Do. | Do. |
| Protocol for Dermal Toxicity Testing for Devices in Contact with Skin; Draft | January 1, 1985 | Do. | Do. |
| Guide for TENS 510(k) Content; Draft | August 1, 1994 | Do. | Do. |
| Draft Version Guidance for Clinical Data To Be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators | August 20, 1992 | Do. | Do. |
| Draft Guidance for Cortical Electrode 510(k) Content | August 10, 1999 | Do. | Do. |
| Accountability Analysis for Clinical Studies for Ophthalmic Devices; Draft | August 4, 1999 | Do. | Do. |
| Refractive Implants: Guidance for Investigational Device Exemptions (IDE) and Premarket Approval (PMA) Applications; Draft | August 1, 2000 | Do. | Do. |
| Intraocular Lens Guidance Document; Draft | October 14, 1999 | Do. | Do. |
| Draft Guidance for Hemodialyzer Reuse Labeling | October 6, 1995 | Do. | Do. |
| Draft Guidance for Industry: Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors; Submission Guidance for an IDE/PMA | August 25, 1999 | Do. | Do. |
| Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures; Draft | September 10, 1988 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft Document | June 14, 1997 | Do. | Do. |
| Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons | May 25, 1995 | Do. | Do. |
| Information for a Latex Condom 510(k) Submission for Obstetrics-Gynecology Devices Branch; Draft | April 13, 1994 | Do. | Do. |
| Premarket Testing Guidelines for Falloscopes | November 20, 1992 | Do. | Do. |
| Draft Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions | July 29, 1991 | Do. | Do. |
| Draft Guidance for Review of Bone Densitometer 510(k) Submissions | November 9, 1992 | Do. | Do. |
| Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence | November 29, 1995 | Do. | Do. |
| Draft Guidance for Clinical Investigation of Urethral Stents | November 2, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology | August 16, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Urological Irrigation System and Tubing Set | August 1, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology | June 22, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence | June 6, 1995 | Do. | Do. |
| Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter) | May 1, 1995 | Do. | Do. |
| Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology | March 17, 1995 | Do. | Do. |
| Draft 510(k) Checklist for Condom Catheters | February 23, 1995 | Do. | Do. |
| Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) | November 11, 1994 | Do. | Do. |
| Draft Guidance Outline; PTC for Clinical Studies for Vasovasostomy Devices | November 30, 1993 | Do. | Do. |
| Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants | March 16, 1993 | Do. | Do. |
| Draft Guidance for Preparation of PMA Applications for Testicular Prostheses | March 16, 1993 | Do. | Do. |
| Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Catheters | January 24, 1992 | Do. | Do. |
| Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements | January 18, 1991 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CDRH—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Draft Guidance to Firms on Biliary Lithotripsy Studies | August 2, 1990 | Do. | Do. |
| Statistical Aspects of Submissions to FDA: A Medical Device Perspective (also includes as appendix the article "Observed Uses and Abuses of Statistical Procedures in Medical Device Submissions") | June 1, 1984 | Do. | Do. |
| Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads) | June 9, 1993 | Do. | Do. |
| Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads; Final | March 30, 1994 | Do. | Do. |
| Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors In Vitro Diagnostic Devices Using Steroid Hormone Binding (SBA) With Dextran-Coated Charcoal (DCC) Separation, Histochemical Receptor Bind; Draft | September 10, 1992 | Do. | Do. |
| Premarket Approval Applications for In Vitro diagnostic Devices Pertaining to Hepatitis C Viruses (HCV): Assays Intended for Diagnosis, Prognosis, or Monitoring of HCV Infection, Hepatitis C, Other HCV-Associated Disease; Draft Guidance for Industry and FDA | April 27, 2001 | Do. | Do. |
| Premarket Approval (PMA) Manual | January 1998 | Do. | Do. |
| SMDA Changes—PMA Manual Insert | April 17, 1992 | Do. | Do. |
| Investigational Device Exemptions (IDE) Manual (FDA 96–4159) | June 1, 1996 | Do. | Do. |
| 510(k) Manual—Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices | August 1, 1995 | Do. | Do. |
| Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Beds | July 26, 1995 | Do. | Do. |

[1]See Internet address for Facts-on-Demand number.

GUIDANCE DOCUMENTS ISSUED BY CFSAN

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Compliance Policy Guides Manual | August 2000; updated in April 2001 | General publications | *http://www.cfsan.fda.gov/guidance.html* |
| Compliance Programs Guidance Manual | March 1995 | Do. | Do. |
| FDA Recall Policy | 2002 | Do. | Do. |
| Guidance for FDA Staff; The Leveraging Handbook; An Agency Resource for Effective Collaborations | 2003 | Do. | Do. |
| Guidance for Small Businesses; Submission of Comments for CFSAN Rulemaking | 2002 | Do. | Do. |
| Investigations Operations Manual | May 1996 | Do. | Do. |
| Regulatory Procedures Manual | August 1997 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Draft Guidance: 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 | July 2003 | Chemical and pesticide contaminants publications | Do. |
| Channels of Trade Policy for Commodities With Vinclozolin Residues | June 2002 | Do. | Do. |
| FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments for Cry9C Protein Residues | January 2001 | Do. | Do. |
| Channels of Trade Policy for Commodities With Methyl Parathion Residues | December 2000 | Do. | Do. |
| Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed | 2000 | Do. | Do. |
| Pesticides Analytical Manual | 1999 | Do. | Do. |
| FDA Advisory for Deoxynivanol (DON) in Finished Wheat Products Intended for Human Consumption and in Grain and Grain By-Products for Animal Feed | September 1993 | Do. | Do. |
| FDA's Cosmetic Labeling Manual | October 1991 | Cosmetic publications | Do. |
| Draft Guidance: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients | December 2, 2002 | Do. | Do. |
| Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements | July 10, 2003 | Dietary supplements publications | Do. |
| Interim Evidence-Based Ranking System for Scientific Data | July 10, 2003 | Do. | Do. |
| Structure/Function Claims: Small Entity Compliance Guide | January 9, 2002 | Do. | Do. |
| Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide | January 1999 | Do. | Do. |
| Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements | December 1999 | Do. | Do. |
| Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body | July 1998 | Do. | Do. |
| Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide | October 17, 2003 | Do. | Do. |
| Providing Regulatory Submissions in Electronic Format; General Considerations | July 2001 | Food and color additives publications | Do. |
| Providing Food and Color Additive Petitions in Electronic Format | July 2001 | Do. | Do. |
| Electronic Submission Forms | July 2001 | Do. | Do. |
| FDA's Policy for Foods Developed by Biotechnology | 1995 | Do. | Do. |
| Partial List of Enzyme Preparations That Are Used in Foods | 2001 | Do. | Do. |
| Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food | 2001 | Do. | Do. |
| Use of Antibiotic Resistance Marker Genes in Transgenic Plants | September 1998 | Do. | Do. |
| Enzyme Preparations: Chemistry Recommendations for Food Additive and GRAS Affirmation Petitions | January 1993 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance for Submitting Requests Under 21 CFR 170.39; Threshold of Regulation for Substances Used in Food Contact Articles | 1996 | Do. | Do. |
| PTC for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations | December 1992 | Do. | Do. |
| How to Submit a GRAS Notice | April 17, 1997 | Do. | Do. |
| Recommendations for Submission of Chemical and Technological Data for Direct Food Additive and GRAS Food Ingredient Petitions | May 1993 | Do. | Do. |
| Statement of Policy; Foods Derived from New Plant Varieties; Notice | May 1992 | Do. | Do. |
| Guidelines for the Preparation of Petition Submissions | 1996 | Do. | Do. |
| Guidelines for Approval of Color Additives in Contact Lenses Intended as Colors | 1996 | Do. | Do. |
| FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drug, or Cosmetic Use | January 1997 | Do. | Do. |
| Estimating Exposure to Direct Food Additive and Chemical Contaminants in the Diet | September 1995 | Do. | Do. |
| Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as redbook I) | 1982 | Do. | Do. |
| Toxicological Principles for the Safety of Food Ingredients (redbook 2000) | April 2004 | Do. | Do. |
| Draft Guidance; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to CFSAN | September 17, 2003 | Do. | Do. |
| Environmental Assessment Technical Handbook | March 1987 | Do. | Do. |
| Toxicological Testing of Food Additives | 1983 | Do. | Do. |
| Guidance on Consultation Procedures Foods Derived From New Plant Varieties | October 1997 | Do. | Do. |
| Bovine Spongiform Encephalopathy (BSE) in Products for Human Use | 1997 | Do. | Do. |
| Food Additive Petition Expedited Review; Guidance for Industry and CFSAN | January 1999 | Do. | Do. |
| Antimicrobial Food Additives Guidance | July 1999 | Do. | Do. |
| Preparation of Premarket Notifications for Food Contact Substances (Food Contact Notifications (FCN)): Administrative Recommendations | May 2002 | Do. | Do. |
| Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations | April 2002 | Do. | Do. |
| Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations | April 2002 | Do. | Do. |
| A Food Labeling Guide | May 1997 | Food labeling publications | Do. |
| Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Small Entity Compliance Guide | August 20, 2003 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements | December 18, 2002 | Do. | Do. |
| Draft Guidance; Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering | January 2001 | Do. | Do. |
| Small Business Food Labeling Exemption | June 1996 | Do. | Do. |
| Food Labeling: Questions and Answers (volume I) | August 1994 | Do. | Do. |
| Food Labeling: Questions and Answers (volume II) | February 1996 | Do. | Do. |
| Fair Packaging and Labeling Act Manual | June 1978 | Do. | Do. |
| Implementation of Section 10809 of the Farm Security and Investment Act of 2002, Public Law No. 107–171, § 10809 (2002), Regarding the Petition Process to Request Approval of Labeling for Foods That Have Been Treated by Irradiation | 2002 | Do. | Do. |
| FDA Nutrition Labeling Manual—A Guide for Developing and Using Databases | March 1998 | Do. | Do. |
| Guidelines for Determining Metric Equivalents of Household Measures | October 1, 1993 | Do. | Do. |
| Food Labeling—Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution; Small Entity Compliance Guide | July 2001 | Do. | Do. |
| Exemptions From the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction | October 7, 2002 | Do. | Do. |
| Food Labeling—Serving Sizes Reference Amount for Baking Powder, Baking Soda, Pectin; Small Entity Compliance Guide | July 2001 | Do. | Do. |
| Bacteriological Analytical Manual (7th ed.) | 1992 | Food processing publicatons | Do. |
| Bacteriological Analytical Manual Online | 2001 | Do. | Do. |
| Questions and Answers Regarding Registration of Food Facilities (4th ed.) | August 6, 2004 | Food and cosmetic security publications | Do. |
| Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance | December 17, 2003 | Do. | Do. |
| Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance | December 17, 2003 | Do. | Do. |
| What You Need to Know About Registration of Food Facilities | November 25, 2003 | Do. | Do. |
| What You Need to Know About Prior Notice of Imported Food Shipments | November 25, 2003 | Do. | Do. |
| Necessity of the Use of Food Product Categories in Registration of Food Facilities | July 17, 2003 | Do. | Do. |
| Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations, and Fluid Milk Processors: Food Security Preventive Measures Guidance | July 11, 2003 | Do. | Do. |
| Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance | March 21, 2003 | Do. | Do. |
| Importers and Filers: Food Security Preventive Measures Guidance | March 21, 2003 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Compliance Policy Guide; Guidance for FDA Staff on Registration of Food Facilities | 2003 | Do. | Do. |
| Compliance Policy Guide; Guidance for FDA Staff on Prior Notice of Imported Foods | 2003 | Do. | Do. |
| Prior Notice of Imported Food Questions and Answers (2nd ed.) | May 2004 | Imports and exports publications | Do. |
| Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged With Prior Notice Indicators | August 2004 | Do. | Do. |
| Guidance for Industry and FDA; Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile | May 23, 2003 | Do. | Do. |
| FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods | 1985 | Do. | Do. |
| Guidance for Industry; FDA Export Certificates | 2002 | Do. | Do. |
| 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 | Do. | Do. |
| Guidelines Concerning Notification and Testing of Infant Formula | 1985 | Infant formula publications | Do. |
| Guidelines for Evaluation of the Safety and Suitability of New Infant Formulas for Feeding Preterm Infants | 1988 | Do. | Do. |
| Clinical Testing of Infant Formulas With Respect to Nutritional Suitability for Term Infants | 1988 | Do. | Do. |
| Guidelines for Evaluation of the Safety and Suitability of Infant Formulas for Feeding Infants With Allergic Diseases | 1990 | Do. | Do. |
| Guidelines for the Clinical Evaluation of New Products Used in the Dietary Management of Infants, Children, and Pregnant Women With Metabolic Disorders | 1987 | Do. | Do. |
| The Juice HACCP Regulation: Questions and Answers | September 4, 2003 | Juice publications | Do. |
| Standardized Training Curriculum for Application of HACCP Principles to Juice Processing | June 2003 | Do. | Do. |
| Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices | April 24, 2002 | Do. | Do. |
| Juice HACCP Small Entity Compliance Guide | April 4, 2003 | Do. | Do. |
| Draft Guidance; Juice HACCP Hazards and Control Guidance (1st ed.) | March 3, 2004 | Do. | Do. |
| Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration With Patulin | October 2001 | Do. | Do. |
| The Juice HACCP Regulation: Questions and Answers | August 31, 2001 | Do. | Do. |
| FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods | 1985 | Low-acid and acidified foods publications | Do. |
| Grade ''A'' Pasteurized Milk Ordinance (2001 revision) | May 15, 2002 | Milk sanitation publications | Do. |
| Importation of PMO Defined Dairy Products (M–I–00–4) | April 11, 2000 | Do. | Do. |
| Evaluation of Milk Laboratories | 1995 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Methods of Making Sanitation Ratings of Milk Supplies | 1999 | Do. | Do. |
| Procedures Governing the Cooperative State-Public Health Service/FDA Program for Certification of Interstate Milk Shippers | 1999 | Do. | Do. |
| Frozen Dessert Processing Guidelines | 1989 | Do. | Do. |
| Dry Milk Ordinance | 1995 | Do. | Do. |
| Pasteurized Milk Ordinance | 1999 | Do. | Do. |
| Fumonisin Levels in Human Foods and Animal Feeds | November 9, 2001 | Natural toxins publications | Do. |
| List of Products for Each Product Category | October 8, 1992 | Nutrition and food science publications | Do. |
| Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers | June 10, 1996 | Do. | Do. |
| Guidance on Labeling of Foods That Need Refrigeration by Consumers | February 24, 1997 | Do. | Do. |
| Interim Guidance on the Voluntary Labeling of Milk and Milk Products That Have Not Been Treated With Recombinant Bovine Somatropin | February 10, 1994 | Do. | Do. |
| Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables | October 26, 1998 | Produce publications | Do. |
| Reducing Microbial Food Safety Hazards for Sprouted Seeds | October 1999 | Do. | Do. |
| Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production | October 1999 | Do. | Do. |
| Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance | December 17, 2003 | Retail food protection publications | Do. |
| Foods—Adulteration Involving Hard or Sharp Foreign Objects | February 1999 | Sanitation publications | Do. |
| Defect Action Levels (DALs) | May 1998 | Do. | Do. |
| Action Levels for Poisonous or Deleterious Substances in Human Food and Feed | 2000 | Do. | Do. |
| Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products | July 2001 | Seafood publications | Do. |
| Seafood HACCP Transition Policy | December 1999 | Do. | Do. |
| Seafood List | 1993 | Do. | Do. |
| Fish and Fisheries Products Hazards and Control Guide (3rd ed.) | 2001 | Do. | Do. |
| HACCP Regulation for Fish and Fishery Products: Questions and Answers | 1998 | Do. | Do. |
| 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 | Do. | Do. |
| Letter to Various Seafood Trade Associations Regarding the Labeling of Catfish | February 28, 2003 | Do. | Do. |
| WITHDRAWN GUIDANCES | | | |

GUIDANCE DOCUMENTS ISSUED BY CFSAN—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds, Draft (replaced by Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds; Final (November 2001) | June 2000 | N/A | N/A |
| Guidance for Industry Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements (replaced by Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements and Interim Evidence-Based Ranking System for Scientific Data (July 2003)) | December 2002 | Do. | Do. |
| Guidance for Industry Preparation of Premarket Notifications for Food Contact Substances: Administrative; Draft (replaced by Guidance for Industry Preparation of Premarket Notifications for Food Contact Substances: Administrative; Final (May 2002)) | June 2000 | Do. | Do. |
| Guidance for Industry Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations, Draft (replaced by Guidance for Industry Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations; Final (April 2002)) | May 2000 | Do. | Do. |
| Recommendations for Chemistry Data for Indirect Food Additive Petitions (replaced by Guidance for Industry Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations; Final (April 2002)) | June 1995 | Do. | Do. |
| Guidance for Industry Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations (replaced by Guidance for Industry Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations; Final (April 2002)) | September 1999 | Do. | Do. |
| Iron-Containing Supplements and Drugs: Label Warning and Unit Dose Packaging Small Entity Compliance Guide (replaced by Guidance for Industry; Iron-Containing Supplements and Drugs: Label Warning Statements; Small Entity Compliance Guide (October 2003)) | November 1997 | Do. | Do. |
| Guidance for Industry Channels of Trade Policy for Commodities With Vinclozolin Residues; Draft (replaced by Guidance for Industry Channels of Trade Policy for Commodities With Vinclozolin Residues; Final (June 2002)) | July 2001 | Do. | Do. |
| Guidance for Industry Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products; Draft (replaced by Guidance for Industry Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products; Final (July 2001)) | November 2000 | Do. | Do. |
| Guidance Document for Arsenic | 1993 | Do. | Do. |
| Guidance Document for Cadmium | 1993 | Do. | Do. |
| Guidance Document for Chromium | 1993 | Do. | Do. |
| Guidance Document for Lead | 1993 | Do. | Do. |
| Guidance Document for Nickel | 1993 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CVM

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| #159 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI (VICH GL36) | November 12, 2003 | FDA personnel and regulated industry | Internet via *http://www.fda.gov/cvm/guidance/published.htm*, or Communications Staff (HFV–12), FDA/CVM, 7519 Standish Pl., Rockville, MD, 301–827–3800, FAX: 301–827–4065 |
| #158 Use of Material From Deer and Elk in Animal Feed; Final | September 15, 2003 | Regulated industry | Do. |
| #156 Comparability Protocols; Chemistry, Manufacturing, and Controls Information; Draft | February 2003 | Do. | Do. |
| #153 Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals; Draft | September 2002 | Do. | Do. |
| #152 Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern | October 23, 2003 | Do. | Do. |
| #151 FDA Export Certificates | July 2004 | Do. | Do. |
| #150 Status of Clove Oil and Eugenol for Anesthesia of Fish | June 11, 2002 | Do. | Do. |
| #149 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing (VICH GL33) | May 18, 2004 | Do. | Do. |
| #148 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing (VICH GL32); Final Guidance | March 19, 2004 | Do. | Do. |
| #147 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food; Repeat Dose (90-day) Toxicity Testing (VICH GL31) | November 12, 2003 | Do. | Do. |
| #145 Bioanalytical Method Validation | May 2001 | Do. | Do. |
| #144 Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-producing Animals with Respect to Antimicrobial Resistance (VICH GL27); Final Guidance | April 27, 2004 | Do. | Do. |
| #143 Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms (VICH GL30); Draft Guidance | February 1, 2002 | Do. | Do. |
| #142 Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs) (VICH GL29); Draft Guidance | December 12, 2001 | Do. | Do. |
| #141 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing (VICH GL28); Final Guidance | May 24, 2004 | Do. | Do. |
| #132 The Administrative New Animal Drug Application Process; Draft | November 6, 2002 | Do. | Do. |
| #126 BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation | February 2001 | Do. | Do. |
| #124 Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft | January 2001 | Do. | Do. |
| #122 Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores | November 9, 2004 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| #121 Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims | March 6, 2001 | Do. | Do. |
| # 120 Veterinary Feed Directive Regulation | March 1, 2001 | Do. | Do. |
| # 119 How CVM Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug; Final Guidance | August 29, 2002 | Do. | Do. |
| #118 Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues; Final Guidance | May 1, 2003 | Do. | Do. |
| #117 Pharmacovigilance of Veterinary Medical Products: Management of Adverse Event Reports (AERs) (VICH GL24); Draft Guidance | December 12, 2000 | Do. | Do. |
| #116 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing (VICH GL23); Final Guidance | January 3, 2002 | Do. | Do. |
| #115 Safety Studies for Veterinary Drug Residues in Human Food; Reproduction Toxicity Testing (VICH GL22); Final Guidance | January 3, 2002 | Do. | Do. |
| #114 Effectiveness of Anthelmintics: Specific Recommendations for Poultry-*Gallus Gallus* (VICH GL21); Final Guidance | June 19, 2002 | Do. | Do. |
| #113 Effectiveness of Anthelmintics: Specific Recommendations for Feline (VICH GL20); Final Guidance | June 19, 2002 | Do. | Do. |
| #112 Fumonisin Levels in Human Foods and Animal Feeds; Final Guidance | November 9, 2001 | Do. | Do. |
| #111 Effectiveness of Anthelmintics: Specific Recommendations for Canine (VICH GL19); Final Guidance | June 27, 2002 | Do. | Do. |
| #110 Effectiveness of Anthelmintics: Specific Recommendations for Porcine (VICH GL16); Final Guidance | June 27, 2002 | Do. | Do. |
| #109 Effectiveness of Anthelmintics: Specific Recommendations for Equine (VICH GL15); Final Guidance | June 27, 2002 | Do. | Do. |
| #108 How to Submit Information in Electronic Format by E-mail | May 21, 2004 | Do. | Do. |
| #107 How to Submit a Protocol in Electronic Format by E-mail | May 21, 2004 | Do. | Do. |
| #106 The Use of Published Literature in Support of New Animal Drug Approval | August 31, 2000 | Do. | Do. |
| #105 Computerized Systems Used in Clinical Trials | September 2004 | Do. | Do. |
| #104 Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports for Submission to the Division of Therapeutic Drugs for Nonfood Animals | July 10, 2001 | Do. | Do. |
| #103 Possible Dioxin/PCB Contamination of Drug and Biological Products | August 1999 | Do. | Do. |
| #102 Manufacture and Distribution of Unapproved Piperazine Products; Revised | August 27, 1999 | Do. | Do. |
| #100 Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (VICH GL18); Final Guidance | May 15, 2001 | Do. | Do. |
| #99 Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products (VICH GL17); Final Guidance | March 26, 2001 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| #98 Dioxin in Anticaking Agents Used in Animal Feed and Feed Ingredients; Revised | April 14, 2000 | Do. | Do. |
| #97 Effectiveness of Anthelmintics: Specific Recommendations for Caprine (VICH GL14); Final Guidance | March 26, 2001 | Do. | Do. |
| #96 Effectiveness of Anthelmintics: Specific Recommendations for Ovine (VICH GL13); Final Guidance | March 26, 2001 | Do. | Do. |
| #95 Efficacy of Anthelmintics: Specific Recommendations for Bovines; (VICH GL12); Final Guidance | March 26, 2001 | Do. | Do. |
| #93 Impurities in New Veterinary Medical Products (VICH GL11) | May 1, 2000 | Do. | Do. |
| #92 Impurities in New Veterinary Drug Substances (VICH GL10) | May 1, 2000 | Do. | Do. |
| #91 Stability Testing for Medicated Premixes (VICH GL8); Final Guidance | March 2000 | Do. | Do. |
| #90 Effectiveness of Anthelmintics: General Recommendations (VICH GL7); Final Guidance (replaces March 26, 2001) | October 11, 2001 | Do. | Do. |
| #89 Environmental Impact Assessments (EIAs) for Veterinary Medicinal Products (VMPs)—Phase I (VICH GL6); Final Guidance | March 7, 2001 | Do. | Do. |
| #88 How to Submit a Request for a Meeting or Teleconference in Electronic Format by E-mail | May 21, 2004 | Do. | Do. |
| #87 How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format by E-mail | May 21, 2004 | Do. | Do. |
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| #85 Good Clinical Practice (VICH GL9); Final Guidance | May 9, 2001 | Do. | Do. |
| #84 Product Name Placement, Size and Prominence in Advertising and Promotional Labeling; Draft Guidance | January 1999 | Do. | Do. |
| #83 Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA; Draft Guidance | June 1999 | Do. | Do. |
| #82 Development of Supplemental Applications for Approved New Animal Drugs; Final Guidance | October 28, 2002 | Do. | Do. |
| #80 Studies to Evaluate the Utility of Anti-*Salmonella* Chemical Food Additives in Feeds | November 21, 2002 | Do. | Do. |
| #79 Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by CVM; Draft Guidance | May 16, 2003 | Do. | Do. |
| #78 Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals | December 13, 1999 | Do. | Do. |
| #76 Questions and Answers: BSE Feed Regulation | July 1998 | Do. | Do. |
| #75 Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products; Final Guidance | September 1999 | Do. | Do. |
| #74 Stability Testing of New Veterinary Dosage Forms (VICH GL4); Final Guidance | September 1999 | Do. | Do. |
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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
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| #72 GMPs for Medicated Feed Manufacturers Not Required to Register and Be Licensed With FDA | May 1998 | Do. | Do. |
| #70 Para Alimentadores de Animales Rumiantes Sin Operaciones de Mezclado de Alimentos en la Granja | February 1998 | Do. | Do. |
| #70 Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations | February 1998 | Do. | Do. |
| #69 Para Alimentadores de Animales Rumiantes Con Operaciones de Mezclado de Alimentos en la Granja | February 1998 | Do. | Do. |
| #69 Small Entities Compliance Guide for Feeders of Ruminant Animals With On-Farm Feed Mixing Operations | February 1998 | Do. | Do. |
| #68 Para Mezcladores de Proteínas, Fabricantes de Alimentos para Animales y Distribuidores | February 1999 | Do. | Do. |
| #68 Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors | February 1998 | Do. | Do. |
| #67 Para Extractores de Grasa por Fusion | February 1998 | Do. | Do. |
| #67 Small Entities Compliance Guide for Renderers | February 1998 | Do. | Do. |
| #65 Industry-Supported Scientific and Educational Activities | November 1997 | Do. | Do. |
| #64 Validation of Analytical Procedures: Methodology; Final Guidance | July 1999 | Do. | Do. |
| #63 Validation of Analytical Procedures: Definition and Terminology | July 1999 | Do. | Do. |
| #62 Consumer-Directed Broadcast Advertisements; Final Guidance | August 1999 | Do. | Do. |
| #61 FDA Approval of New Animal Drugs for Minor Uses and for Minor Species | April 1999 | Do. | Do. |
| #59 How to Submit a Notice of Claimed Investigational Exemption in Electronic Format by E-mail | May 21, 2004 | Do. | Do. |
| #57 Guidance for Industry for the Preparation and Submission of Veterinary Master Files | 1995 | Do. | Do. |
| #56 Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials | July 10, 2001 | Do. | Do. |
| #55 Supportive Data for Cat Food Labels Bearing ''Reduces Urinary pH'' Claims: Guideline in Protocol Development | June 1994 | Do. | Do. |
| #54 Draft Guideline for Utility Studies for Anti-*Salmonella* Chemical Food Additives in Animal Feeds (see final guidance #80) | June 22, 1994 | Do. | Do. |
| #53 Guideline for the Evaluation of the Utility of Food Additives in Diets Fed to Aquatic Animals | May 1994 | Do. | Do. |
| #52 Assessment of the Effects of Antimicrobial Drug Residues From Food of Animal Origin on the Human Intestinal Flora | February 18, 2004 | Do. | Do. |
| #50 Draft Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products | February 1, 1993 | Do. | Do. |
| #49 Guidance Document for Target Animal Safety and Drug Effectiveness Studies for Antimicrobial Bovine Mastitis Products (Lactating and Nonlactating Cow Products) | April 4, 1996 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
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| #48 Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products | November 1994 | Do. | Do. |
| #45 Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle | August 1993 | Do. | Do. |
| #43 Guidance on Generic Animal Drug Products Containing Fermentation-Derived Drug Substances | October 1995 | Do. | Do. |
| #42 Animal Drug Manufacturing Guidelines | 1994 | Do. | Do. |
| #41 Draft Guideline for Formatting, Assembling, and Submitting New Animal Drug Applications | June 1992 | Do. | Do. |
| #40 Draft Guideline for the Evaluation of the Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry | April 1992 | Do. | Do. |
| #38 Guideline for Effectiveness Evaluation of Topical/OTIC Animal Drugs | August 21, 1984 | Do. | Do. |
| #37 Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Poultry Feeds for Pigmentation | March 1984 | Do. | Do. |
| #36 Guideline for Efficacy Evaluation of Canine/Feline Anthelmintics | July 18, 1985 | Do. | Do. |
| #35 Bioequivalence Guideline | Revised October 9, 2002 | Do. | Do. |
| #33 Target Animal Safety Guidelines for New Animal Drugs | June 1989 | Do. | Do. |
| #31 Guidelines for the Evaluation of Bovine Anthelmintics | July 1981 | Do. | Do. |
| #29 Guidelines for the Effectiveness Evaluation of Swine Anthelmintics | September 30, 1980 | Do. | Do. |
| #28 Animal Drug Applications Expedited Review Guideline (see Policy and Procedures Guide 1240.3135) | December 3, 1997 | Do. | Do. |
| #27 New Animal Drug Determination (see Policy and Procedures Guide 1240.3500) | July 1989 | Do. | Do. |
| #24 Guideline for Drug Combinations for Use in Animals | October 1983 | Do. | Do. |
| #23 Medicated Free-Choice Feeds-Manufacturing Controls | July 1, 1985 | Do. | Do. |
| #22 Labeling of Arecoline Base Drugs Intended for Animal Use | | Do. | Do. |
| #21 Nutritional Ingredients in Animal Drugs and Feeds (see Policy and Procedures Guide 1240.3420) | March 1993 | Do. | Do. |
| #16 Freedom of Information Summary Guidelines | May 10, 1985 | Do. | Do. |
| #13 Guidelines for Evaluation and Effectiveness of New Animal Drugs for Use in Free-Choice Feeds (revision of The Cattle Medicated Block Guideline) | January 1985 | Do. | Do. |
| #10 Amendment of Section II(G)(1)(b)(4) of the Preclearance Guidelines | October 1975 | Do. | Do. |
| #9 Preclearance Guidelines for Production Drugs | Withdrawn pending revisions | Do. | Do. |
| #6 Guideline for Submitting NADAs for Generic Drugs Reviewed by NAS/NRC | October 20, 1971; revised March 19, 1976 | Do. | Do. |
| #5 Drug Stability Guidelines | December 1, 1990 | Do. | Do. |

GUIDANCE DOCUMENTS ISSUED BY CVM—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| #3 General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (revised) (see guidance #118 for update to Section V.B.1) | July 1994 | Do. | Do. |
| WITHDRAWN DOCUMENTS | | | |
| #58 Guidance for Industry; Good Target Animal Study Practices: Clinical Investigators and Monitors | May 1997 | N/A | N/A |
| #155 Guidance for Industry; 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records | March 1997/February 2003 | Do. | Do. |
| #154 Draft Guidance for Industry on Part 11; Electronic Records, Electronic Signatures—Scope and Application | March 1997/February 2003 | Do. | Do. |
| #77 Interpretation of On-Farm Feed Manufacturing and Mixing Operations | September 1998/June 2003 | Do. | Do. |
| #66 Professional Flexible Labeling of Antimicrobial Drugs | August 1998/January 2002 | Do. | Do. |
| #20 Antibacterial Drugs in Animal Feeds: Antibacterial Effectiveness Criteria | December 2004 | Do. | Do. |
| #19 Antibacterial Drugs in Animal Feeds: Animal Health Safety Criteria | December 2004 | Do. | Do. |
| #18 Antibacterial Drugs in Animal Feeds: Human Health Safety Criteria | December 2004 | Do. | Do. |
| #15 Guideline for Reporting the Details of Clinical Trials Using an Investigational New Animal Drug in Non-Food Producing Animals | February 1977/December 2004 | Do. | Do. |
| #14 Guideline for Reporting the Details of Clinical Trials Using an Investigational New Animal Drug in Food-Producing Animals | December 2004 | Do. | Do. |
| #4 Guideline for Efficacy Studies for Systemic Sustained Release Sulfonamide Boluses for Cattle | December 2004 | Do. | Do. |
| #2 Anthelmintics | December 2004 | Do. | Do. |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document |
|---|---|---|---|
| FDA Information Sheets for Institutional Review Boards and Clinical Investigators | September 1998 | Regulated industry | Internet via *http://www.fda.gov/oc/ohrt/irbs/default.htm* or Good Clinical Practice Programs (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C–24, Rockville, MD 20857, 301–827–3340, *http://www.fda.gov/oc/gcp/guidance.html* |
| Guidance for Industry; Computerized Systems Used in Clinical Trials | April 1999 | Do. | Internet via *http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.pdf* or Good Clinical Practice Programs (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C–24, Rockville, MD 20857, 301–827–3340, *http://www.fda.gov/oc/gcp/guidance.htm* |
| Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exceptions From Informed Consent Requirements for Emergency Research | March 30, 2000 | Do. | Internet via *http://www.fda.gov/ora/compliance_ref/bimo/err_guide.htm* or Good Clinical Practice Programs (HF–34), Food and Drug Administration, 5600 Fishers Lane, rm. 9C–24, Rockville, MD 20857, 301–827–3340 |

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| Draft Guidance for Industry on Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996 | February 1998 | Do. | Internet via *http://www.fda.gov/opacom/fedregister/frexport.html* |
| Guidance for FDA and Industry: Direct Final Rule Procedures | November 21, 1997 | FDA personnel | Internet via *http://www.fda.gov/opacom/morechoices/industry/guidance.htm*, or Office of Policy, 301–827–3360 |
| International Harmonization; Policy on Standards | October 11, 1995 | Regulated industry and FDA personnel | 60 FR 53078, October 11, 1995; or Office of International Programs, 301–827–4480 |

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| Compliance Policy Guides Manual (replaces Compliance Policy Guide—January 1996) | Updated December 12, 2003 | FDA staff | National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 | *http://www.fda.gov/ora/cpgm* |
| Compliance Policy Guide, Section 615.115: Extra-Label Use of Medicated Feeds for Minor Species | April 2001 | Do. | Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 | *http://www.fda.gov/ora/compliance_ref/revisions.htm* |
| Compliance Policy Guide, Section 608.400: Compounding of Drugs for Use in Animals | July 2003 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 555.600: Filth From Insects, Rodents, and Other Pests in Foods | November 14, 2002 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 460.200: Pharmacy Compounding | May 29, 2002 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 575.100: Pesticide Residues in Food and Feed—Enforcement Criteria (CPG 7141.01) (revised) | May 16, 2002 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 230.150: Blood Donor Classification Statement, Paid or Volunteer Donor | May 7, 2002 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 510.150: Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration With Patulin | October 2001 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 555.250: Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens | April 2001 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 220.100: Interstate Shipment of Biological Products for Use in Medical Emergencies | Reformatted March 2001 | Do. | Do. | *http://www.fda.gov/ora/compliance_ref/cpg/* |

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| Compliance Policy Guide, Section 270.100: Final Container Labels—Allergenic Extracts Containing Glycerin; Reporting Changes | Reformatted March 2001 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 230.150: Blood Donor Incentives; Draft | December 2000 | Do. | Do. | Do. |
| Compliance Policy Guide, Section 7150.09: Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities | July 1991 | FDA staff and regulated industry | Do. | *http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg120-100.html* |
| Glossary of Computerized System and Software Development Terminology | August 1995 | Do. | National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB96–127352) | *http://www.fda.gov/ora/inspect_ref/igs/gloss.html* |
| Guidelines for Entry Review of Radiation-Emitting Electronic Devices | March 12, 1999 | FDA staff | Division of Import Operations and Policy (HFC–170), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1218 | N/A |
| Laboratory Procedures Manual | June 1994 | Do. | Division of Field Science (HFC–141), Food and Drug Administration, 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857 | *http://www.fda.gov/ora/science_ref/* |
| Laboratory Procedures Manual; ch. 10: Method Validation Samples | May 1999 | Do. | Do. | Do. |
| Memorandum: ORA Investigational Strategy on Gamma-Butyrolactone (GBL) and Related Products | May 15, 2000 | Do. | Division of Field Investigations, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 | N/A |
| IOM: Investigations Operations Manual | March 2004 | Do. | National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB2001–913399) | *http://www.fda.gov/ora/inspect_ref/* |
| Regulatory Procedures Manual | March 2004 | Do. | Do (NTIS Order No. PB97–196182) | *http://www.fda.gov/ora/compliance_ref/rpm/default.htm* |
| Regulatory Procedures Manual; ch. 5–7–10: Civil Money Penalty Reduction Policy for Small Entities | March 2004 | Do. | Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 | Do. |
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| Regulatory Procedures Manual; ch. 9: Import Operations/Actions | September 2002 | Do. | Do. | Do. |
| Regulatory Procedures Manual; ch. 6–1: Seizure | March 2004 | Do. | Do. | Do. |
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| Regulatory Procedures Manual; ch. 4–1: Warning Letters | March 2004 | Do. | Do. | *http://www.fda.gov/ora/compliance_ref/rpm_new2/ch4.html* |
| Guide to Inspections of Bulk Pharmaceutical Chemicals | May 1994 | Do. | National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB96–127154) | *http://www.fda.gov/ora/inspect_ref/igs/iglist.html* |
| Guide to Inspections of Pharmaceutical Quality Control Laboratories | July 1993 | Do. | Do (NTIS Order No. PB96–127279) | Do. |
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| Guide to Inspections of Validation of Cleaning Processes | July 1993 | Do. | Do (NTIS Order No. PB96–127246) | Do. |
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| Guide to Inspections of Dosage Form Drug Manufacturers—CGMPs | October 1993 | Do. | Do (NTIS Order No. PB96–127212) | Do. |
| Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation | January 1994 | Do. | Do (NTIS Order No. PB96–127345) | Do. |
| Guide to Inspections of Topical Drug Products | July 1994 | Do. | Do (NTIS Order No. PB96–127394) | Do. |
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| Guide to Nutritional Labeling and Education Act (NLEA) Requirements | February 1995 | Do. | Do (NTIS Order No. PB96–127378) | Do. |
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| Guide to Inspections of Manufacturers of Miscellaneous Foods—vol. 1 | May 1995 | Do. | Do (NTIS Order No. PB97–127220) | Do. |
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| Guide to Inspections of Low Acid Canned Food Manufacturers, Part 1—Administrative Procedures/Scheduled Processes | November 1996 | Do. | Do (NTIS Order No. PB97–196141) | Do. |
| Guide to Inspections of Low Acid Canned Food Manufacturers, Part 2—Manufacturing Processes/Procedures | April 1997 | Do. | Do (NTIS Order No. PB97–196158) | Do. |
| Guide to Inspections of Low Acid Canned Food Manufacturers, Part 3—Container/Closures | November 1998 | FDA staff | Do (NTIS Order No. PB00–133795) | N/A |
| Guide to Inspections of Blood Banks | September 1994 | Do. | Do (NTIS Order No. PB96–127303) | *http://www.fda.gov/ora/inspect_ref/igs/iglist.html* |
| Guide to Inspections of Source Plasma Establishments | Revised April 2001 | Do. | N/A | Do. |
| Guide to Inspections of Infectious Disease Marker Testing Facilities | October 1996 | Do. | National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB96–199476) | Do. |
| Biotechnology Inspection Guide Reference Materials and Training Aids | November 1991 | Do. | Do (NTIS Order No. PB96–127402) | Do. |
| Guide to Inspection of Computerized Systems in Drug Processing | February 1983 | Do. | Do (NTIS Order No. PB96–127337) | Do. |
| Guide to Inspections of Foreign Medical Device Manufacturers | September 1995 | Do. | Do (NTIS Order No. PB96–127311) | Do. |
| Guide to Inspections of Foreign Pharmaceutical Manufacturers | May 1996 | Do. | Do (NTIS Order No. PB96–199468) | Do. |
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| Mammography Quality Standards Act (MQSA) Auditor's Guide | January 1998 | Do. | Do (NTIS Order No. PB98–127178) | Do. |
| Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems | December 1997 | Do. | Do (NTIS Order No. PB98–127152) | Do. |
| Guide to Inspections of Acidified Food Manufacturers | May 1998 | Do. | N/A | Do. |
| Guide to Inspection of Aseptic Processing and Packaging for the Food Industry | February 2001 | Do. | Division of Field Investigations, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 | N/A |
| Guide to Inspections of Grain Product Manufacturers | July 2003 | Do. | Do (NTIS Order No. PB98–137128) | Do. |
| Guide to Bioresearch Monitoring Inspections of In Vitro Diagnostic Devices | February 1998 | Do. | Do (NTIS Order No. PB98–137151) | Do. |
| Guide to Inspections of Viral Clearance Processes for Plasma Derivatives | March 1998 | Do. | Do (NTIS Order No. PB–98137144) | Do. |

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| Guide to Inspections of Computerized Systems in the Food Processing Industry | August 1998 | Do. | National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB98–137136) | Do. |
| Guide to International Inspections and Travel (revision) (formerly FDA/ORA International Inspection Manual and Travel Guide) | November 2002 | Do. | N/A | *http://www.fda.gov/ora/inspect_ref/giit/default.htm* |
| Guide to Inspections of Quality Systems | August 1999 | Do. | N/A | *http://www.fda.gov/ora/inspect_ref/igs/qsit/QSITGUIDE.PDF* |
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| Compliance Program 7348.001: Bioresearch Monitoring, Human Drugs, In Vivo Bioequivalence | October 1, 1999 | Do. | Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 | Do. |
| Guide for Detecting Fraud in Bioresearch Monitoring Inspections | April 2003 | Do. | Division of Freedom of Information (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 | N/A |
| Good Laboratory Practice Program 7348.808A (Nonclinical Laboratories); EPA Data Audit Inspections | October 1, 2000 | Do. | Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 | *http://www.fda.gov/ora/compliance_ref/bimo/* |
| Guideline for the Monitoring of Clinical Investigations | January 1988 | FDA regulated industry | Do. | Do. |
| Small Business Guide to FDA | Revised March 31, 2004 | Do. | Federal-State Relations (HFC–150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2905 | *http://www.fda.gov/ora/fed_state/small_business/sb_guide/default.htm* |
| Compliance Program 7348.808; Bioresearch Monitoring, Good Laboratory Practice (Nonclinical Laboratories) | Revised February 21, 2001 | FDA staff | Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 | *http://www.fda.gov/ora/compliance_ref/bimo/* |

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| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
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| Compliance Program 7348.811; Bioresearch Monitoring, Clinical Investigators | October 1, 1997 | Do. | Do. | Do. |
| Good Laboratory Practice Regulations; Management Briefings; Post Conference Report | August 1979 | Do. | Do. | Do. |
| Good Laboratory Practices; Questions and Answers | June 1981 | Do. | Do. | Do. |
| Guidance for FDA Staff on Sampling or Detention Without Physical Examination of Decorative Contact Lenses (Import Alert #86–10) | April 4, 2003 | FDA staff | N/A | *http://www.fda.gov/ohrms/dockets/98fr/03-8315.pdf* |
| Compliance Policy Guide; Section 345.100: Male Condom Defects (CPG 7124.21); Draft | March 29, 2002 | FDA staff and industry | Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 | *http://www.fda.gov/ora/compliance_ref/cpg/* |
| PTC for Internal Reviews and Corrective Action Operating Plans | June 1991 | Do. | N/A | *http://www.fda.gov/ora/compliance_ref/aip_points.html* |
| WITHDRAWALS | | | | |
| Compliance Policy Guide—Section 305.100: Acupuncture Devices and Accessories (CPG 7124.11) | June 15, 1976 | FDA staff and industry | N/A | |
| Compliance Policy Guide—Section 396.100: Applicability of the Sunlamp Performance Standard to UVA Tanning Products (CPG 7133.16) | October 1, 1980 | Do. | Do. | |
| Compliance Policy Guide—Section 391.100: Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps (CPG 7133.13) | October 1, 1980 | Do. | Do. | |
| Compliance Policy Guide—Section 315.200: Status of Dental Supplies Such As Denture Cleaners, Adhesives, Cushions, and Repair Materials as a Device or Cosmetic (CPG 7124.05) | April 26, 1976 | Do. | Do. | |
| Compliance Policy Guide—Section 398.475: Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems With Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17) | October 1, 1980 | Do. | Do. | |
| Medical Device Warning Letter Pilot Termination | March 8, 1999 | Do. | Do. | |
| Compliance Policy Guide—Section 160.850: Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17) | May 13, 1999 | Do. | Do. | |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records | August 2002 | Do. | Do. | |

GUIDANCE DOCUMENTS ISSUED BY ORA—Continued

| Name of Document | Date of Issuance | Intended User or Regulatory Activity | How to Obtain a Copy of the Document | |
|---|---|---|---|---|
| | | | Mailing Address | Internet Address |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures Validation | August 2001 | Do. | Do. | |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms | August 2001 | Do. | Do. | |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Time Stamps | February 2002 | Do. | Do. | |
| Draft Guidance—21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records | July 2002 | Do. | Do. | |
| Compliance Policy Guide—Section 300.700: Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30) | February 26, 1991 | Do. | Do. | |
| Compliance Policy Guide—Section 405.100: Prescriptions Prepared From Certified Antibiotics (CPG 7122.01) | October 1, 1980 | Do. | Do. | |
| Compliance Policy Guide—Section 405.200: Export of Uncertified Antibiotics (CPG 7122.02) | October 1, 1980 | Do. | Do. | |
| Compliance Policy Guide—Section 405.210: Returned Antibiotics Exported Under 801(d) of the Act (CPG 7122.03) | July 1, 1981 | Do. | Do. | |
| Draft Compliance Policy Guide—Distributor Medical Device Reporting | August 28, 1997 | Do. | Do. | |

Dated: December 22, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0479]**

### Draft Risk Assessment of Streptogramin Resistance in Enterococcus faecium Attributable to the Use of Streptogramins in Animals; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to February 23, 2005, the comment period for the notice that appeared in the **Federal Register** of November 24, 2004 (69 FR 68384). In the notice, FDA requested comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit written and electronic comments by February 23, 2005.

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

**FOR FURTHER INFORMATION CONTACT:** Barry Hooberman, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8557, e-mail: *bhooberm@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of November 24, 2004 (69 FR 68384), FDA published a notice with a 60-day comment period to request comments on a draft risk assessment of the potential impact that food-animal use of streptogramin antimicrobials has on the resistance to chemically similar streptogramins used to treat human enterococcal infections. The veterinary drug of interest in this risk assessment is the streptogramin, virginiamycin, a drug approved for use in chicken, turkey, swine, and cattle feed. FDA will consider information received during the comment period in its preparation of a final risk assessment.

The agency has received a request for a 60-day extension of the comment period for the notice. This request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice.