• ''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 Identify comments with the corresponding docket number of the draft guidance as follows: Docket No. 2004D–0377 ''E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs'' and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Persons with access to the Internet may obtain the draft guidance documents at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.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

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	
			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.

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
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	
			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.

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 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	
			Mailing Address	Internet Address
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.

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
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*

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: 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.	

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
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.	
Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records	July 2002	Do.	Do.	

GUIDANCE DOCUMENTS ISSUED BY CDER

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
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.

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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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.

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	
			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*

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	
			Mailing Address	Internet Address
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*

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	
			Mailing Address	Internet Address
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	
			Mailing Address	Internet Address
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.

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	
			Mailing Address	Internet Address
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.

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	
			Mailing Address	Internet Address
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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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
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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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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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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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
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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	
			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.

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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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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

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	
			Mailing Address	Internet Address
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.

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	
			Mailing Address	Internet Address
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.

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	
			Mailing Address	Internet Address
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.

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	
			Mailing Address	Internet Address
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.	

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	
			Mailing Address	Internet Address
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.	

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	
			Mailing Address	Internet Address
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.	

GUIDANCE DOCUMENTS ISSUED BY CDRH

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.

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
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.

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
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.

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 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.

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
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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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.

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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.

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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 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.

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
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.

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 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.

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 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.

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 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.

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 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.

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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.

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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.

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
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.

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
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.

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
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.

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
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.
WITHDRAWN GUIDANCES			
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

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 on Evidence Models for the Least Burdensome Means to Market	September 1, 1999	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.
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.

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
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.

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 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.

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
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.
#86 How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format by E-mail	May 21, 2004	Do.	Do.
#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.
#73 Stability Testing of New Veterinary Drug Substances and Medicinal Products (VICH GL3); Final Guidance	September 1999	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
#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
#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.

GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF THE COMMISSIONER AND THE OFFICE OF POLICY

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

GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF THE COMMISSIONER AND THE OFFICE OF POLICY—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document
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

GUIDANCE DOCUMENTS ISSUED BY ORA

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Copy of the Document	
			Mailing Address	Internet Address
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/*

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
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.
Regulatory Procedures Manual; ch. 10–9: Application Integrity Policy	March 2004	Do.	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	
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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.
Regulatory Procedures Manual; ch. 6–6: Civil Penalties—Electronic Product Radiation Control	March 2004	Do.	Do.	Do.
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.
Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories	July 1993	Do.	Do (NTIS Order No. PB96–127287)	Do.
Guide to Inspections of Validation of Cleaning Processes	July 1993	Do.	Do (NTIS Order No. PB96–127246)	Do.
Guide to Inspections of Lyophilization of Parenterals	July 1993	Do.	Do (NTIS Order No. PB96–127253)	Do.
Guide to Inspections of High Purity Water Systems	July 1993	Do.	Do (NTIS Order No. PB96–127261)	Do.
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.
Guide to Inspections of Sterile Drug Substance Manufacturers	July 1994	Do.	Do (NTIS Order No. PB96–127295)	Do.
Guide to Inspections of Oral Solutions and Suspensions	August 1994	Do.	Do (NTIS Order No. PB96–127147)	Do.
Guide to Nutritional Labeling and Education Act (NLEA) Requirements	February 1995	Do.	Do (NTIS Order No. PB96–127378)	Do.
Guide to Inspections of Interstate Carriers and Support Facilities	April 1995	Do.	Do (NTIS Order No. PB96–127386)	Do.
Guide to Inspections of Dairy Product Manufacturers	April 1995	Do.	Do (NTIS Order No. PB96–127329)	Do.
Guide to Inspections of Manufacturers of Miscellaneous Foods—vol. 1	May 1995	Do.	Do (NTIS Order No. PB97–127220)	Do.
Guide to Inspections of Manufacturers of Miscellaneous Food Products—vol. 2	September 1996	Do.	Do (NTIS Order No. PB97–196133)	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
Guide to Inspections of Cosmetic Product Manufacturers	February 1995	Do.	Do (NTIS Order No. PB96–127238)	Do.
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.
Guide to Inspections of Medical Device Manufacturers	December 1997	Do.	Do (NTIS Order No. PB 98–127145)	Do.
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.

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	
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Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations	April 2001	Do.	N/A	Do.
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*
Guide to Inspection of Firms Producing Food Products Susceptible to Contamination With Allergenic Ingredients	August 2001	Do.	N/A	*http://www.fda.gov/ora/inspect_ref/igs/iglist.html*
Computerized Systems Used in Clinical Trials	April 1999	Do.	N/A	*http://www.fda.gov/ora/compliance_ref/bimo/*
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/*

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	
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Compliance Program 7348.809; Bioresearch Monitoring; Institutional Review Board	October 1, 1994	Do.	Do.	Do.
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

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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.

[FR Doc. 05–155 Filed 1–4–05; 8:45 am]

BILLING CODE 4160–01–S

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.