DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–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 21 CFR 10.115(n)(2) of FDA's regulation on Good Guidance Practices (GGPs). This list 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 It also provides information on guidance documents that have been added or withdrawn in the past year.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 Dockets Management Branch (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 below on where to obtain a single copy of any of the guidance documents listed.

FOR FURTHER INFORMATION CONTACT: Carol A. Kimbrough, Office of Policy, Planning, and Legislation (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

We published our final rule on GGPs in the **Federal Register** of September 19, 2000 (65 FR 56468), and they 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. We committed in the GGPs to publishing annually a comprehensive list of guidance documents. This list updates a comprehensive list published July 21, 2000 (65 FR 45428).

The following comprehensive list identifies all final guidances that have been issued and are in use, and all draft guidances that have been distributed for comment and not for implementation. Any guidances that have been withdrawn this year are also listed. We have organized the documents by the issuing Center or Office within FDA, and we 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 on the tables below.

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

CBER: http://www.fda.gov/cber/guidelines.htm

CDER: http://www.fda.gov/cder/guidance/index.htm

CDRH: http://www.fda.gov/cdrh/guidance.html

CFSAN: http://www.cfsan.fda.gov/dms/guidance.html

CVM: http://www.fda.gov/cvm/guidance/published.htm#documents

ORA: http://www.fda.gov/ora/compliance—;ref

II. Guidance Documents Issued by the Center for Biologics Evaluation and Research (CBER)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Interpretative Guidelines of the Source Plasma (Human) Standards	October 2, 1973	FDA Regulated Industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, FAX Information System: 1–888–CBER–FAX (within U.S.) or 301–827–3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
Guidelines for Reviewing Amendments to Include Plasmapheresis of Hemophiliacs	July 20, 1976	Do	Do
Package Insert: Immune Serum Globulin (Human)	March 30, 1978	Do	Do
Guidelines for Interpretation of Potency Test Results for All Forms of Adsorbed Diphtheria and Tetanus Toxoids	April 12, 1979	Do	Do
Guidelines for Immunization of Source Plasma (Human) Donors With Blood Substances	June 1, 1980	Do	Do
Collection of Human Leukocytes for Further Manufacturing (Source Leukocytes)	January 28, 1981	Do	Do
Platelet Testing Guidelines—Approval of New Procedures and Equipment	July 1, 1981	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Revised Guideline for Adding Heparin to Empty Containers for Collection of Heparinized Source Plasma (Human)	August 1, 1981	Do	Do
Requirements for Infrequent Plasmapheresis Donors	August 27, 1982	Do	Do
Recommendations to Decrease the Risk of Transmitting AIDS From Plasma Donors	March 24, 1983	Do	Do
PTC in the Manufacture of In Vitro Monoclonal Antibody Products Subject to Licensure	June 20, 1983	Do	Do
Draft PTC in the Production and Testing of Interferon Intended for Investigational Use in Humans (Interferon Test Procedures)	July 28, 1983	Do	Do
Interstate Shipment of Interferon for Investigational Use in Laboratory Research Animals or Tests in Vitro	November 21, 1983	Do	Do
Deferral of Blood Donors Who Have Received the Drug Accutane (Isotretinoin/Roche); 13-cis-retinoic acid)	February 28, 1984	Do	Do
Equivalent Methods for Compatibility Testing	December 14, 1984	Do	Do
Plasma Derived From Therapeutic Plasma Exchange	December 14, 1984	Do	Do
Draft PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology	April 10, 1985	Do	Do
Guidelines for Meningococcal Polysaccharide Vaccines	July 17, 1985	Do	Do
Guideline for the Uniform Labeling of Blood and Blood Components	August 1, 1985	Do	Do
Recommended Methods for Short Ragweed Pollen Extracts	November 1, 1985	Do	Do
Reduction of the Maximum Platelet Storage Period to 5 Days in an Approved Container	June 2, 1986	Do	Do
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
Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics	February 1, 1987	Do	Do
Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics	February 1, 1987	Do	Do
Guideline on General Principles of Process Validation	May 1, 1987	Do	Do
Guideline on Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone	November 25, 1987	Do	Do
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 1, 1987	Do	Do
Recommendations for the Management of Donors and Units That Are Initially Reactive for Hepatitis B Surface Antigen (HBsAg)	December 2, 1987	Do	Do
Extension of Dating Period for Storage of Red Blood Cells, Frozen	December 4, 1987	Do	Do
To Licensed In Vitro Diagnostic Manufacturers: Handling of Human Blood Source Materials	December 23, 1987	Do	Do
Recommendations for Implementation of Computerization in Blood Establishments	April 6, 1988	Do	Do
Control of Unsuitable Blood and Blood Components	April 6, 1988	Do	Do
Discontinuance of Prelicensing Inspection for Immunization Using Licensed Tetanus Toxoid and Hepatitis B and Rabies Vaccines	July 7, 1988	Do	Do
Physician Substitutes	August 15, 1988	Do	Do
To Licensed Manufacturers of Blood Grouping Reagents: Criteria for Exemption of Lot Release	August 26, 1988	Do	Do
Revised Guideline for the Collection of Platelets, Pheresis	October 7, 1988	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
Draft Guideline for the Design of Clinical Trials for Evaluation of Safety and Efficacy of Allergenic Products for Therapeutic Uses	November 1, 1988	Do	Do
HTLV–I Antibody Testing	November 29, 1988	Do	Do
Use of Recombigen HIV–1 LA Test	February 1, 1989	Do	Do
Guidelines for Release of Pneumococcal Vaccine, Polyvalent	February 1, 1989	Do	Do
Guidance for Autologous Blood and Blood Components	March 15, 1989	Do	Do
HTLV–I Antibody Testing	July 6, 1989	Do	Do
Use of Recombigen HIV–1 Latex Agglutination (LA) Test	August 1, 1989	Do	Do
Draft PTC in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to Human Immunodeficiency Virus Type 1 (1989)	August 8, 1989	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
PTC in the Collection, Processing and Testing of Ex Vivo Activated Mononuclear Leukocytes for Administration to Humans	August 22, 1989	Do	Do
Information Relevant to the Manufacture of Acellular Pertussis Vaccine	August 23, 1989	Do	Do
FDA Regulated Industries for Drug Master Files	September 1, 1989	Do	Do
Requirements for Computerization of Blood Establishments	September 8, 1989	Do	Do
Abbott Laboratories' HIVAG–1 Test for HIV–1 Antigen(s) Not Recommended for Requirements for Computerization of Blood Establishments	October 4, 1989	Do	Do
Guideline for Collection of Blood or Blood Products From Donors With PositiveTests for Infectious Disease Markers (''High Risk'' Donors)	October 26, 1989	Do	Do
Guideline for Determination of Residual Moisture in Dried Biological Products	January 1, 1990	Do	Do
Autologous Blood Collection and Processing Procedures	February 12, 1990	Do	Do
Cytokine and Growth Factor Pre-Pivotal Trial Information Package	April 2, 1990	Do	Do
Use of Genetic Systems HIV–2 EIA	June 21, 1990	Do	Do
PTC in the Safety Evaluation of Hemoglobin-Based Oxygen Carriers	August 21, 1990	Do	Do
Guideline on the Preparation of Investigational New Drug Products (Human and Animal)	March 1, 1991	Do	Do
FDA Request for Information on Blood Storage Patterns and Red Cell Contamination by Yersinia Enterocolitica	March 15, 1991	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)	March 17, 1991	Do	Do
Deficiencies Relating to the Manufacture of Blood and Blood Components	March 20, 1991	Do	Do
Responsibilities of Blood Establishments Related to Errors and Accidents in the Manufacture of Blood and Blood Components	March 20, 1991	Do	Do
To Biologic Product Manufacturers—Controlling Materials of Bovine or Ovine Origin	May 3, 1991	Do	Do
FDA Recommendations Concerning Testing for Antibody to Hepatitis B Core Antigen (Anti-HBc)	September 10, 1991	Do	Do
Disposition of Blood Products Intended for Autologous Use That Test Repeatedly Reactive for Anti-HCV	September 11, 1991	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing	December 12, 1991	Do	Do
Recommended Methods for Blood Grouping Reagents Evaluation	March 1, 1992	Do	Do
Recommended Methods for Evaluating Potency, Specificity and Reactivity of Anti-Human Globulin	March 1, 1992	Do	Do
PTC in the Design and Implementation of Field Trials for Blood Grouping Reagents and Anti-Human Globulin	March 1, 1992	Do	Do
PTC in the Manufacture of In Vitro Monoclonal Antibody Products for Further Manufacturing into Blood Grouping Reagent and Anti-Human Globulin	March 1, 1992	Do	Do
Supplement to the PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability	April 6, 1992	Do	Do
Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products	April 23, 1992	Do	Do
Use of Fluorognost HIV–1 Immunofluorescent Assay (IFA)	April 23, 1992	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
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
Changes in Equipment for Processing Blood Donor Samples	July 21, 1992	Do	Do
Nomenclature for Monoclonal Blood Grouping Reagents	September 28, 1992	Do	Do
Volume Limits for Automated Collection of Source Plasma	November 4, 1992	Do	Do
FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics	November 25, 1992	Do	Do
Revision of October 7, 1988, Memo Concerning Red Blood Cell Immunization Programs	December 16, 1992	Do	Do
Draft PTC in the Characterization of Cell Lines Used to Produce Biologicals	July 12, 1993	Do	Do
CBER Refusal to File (RTF) Guidance for Product and Establishment License Applications	July 12, 1993	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance on Alternatives to Lot Release for Licensed Biological Products	July 20, 1993	Do	Do
Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products	July 22, 1993	Do	Do
Deferral of Blood and Plasma Donors Based on Medications	July 28, 1993	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 19, 1993	Do	Do
Changes in Administrative Procedures	September 9, 1993	Do	Do
To Sponsors of INDs Using Retroviral Vectors	September 20, 1993	Do	Do
Draft Guideline for the Validation of Blood Establishment Computer Systems	September 28, 1993	Do	Do
Methods of the Allergenic Products Testing Laboratory	October 1, 1993	Do	Do
Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products; Notice	October 14, 1993	Do	Do
Guideline for Adverse Experience Reporting for Licensed Biological Products	October 15, 1993	Do	Do
Guidance Regarding Post Donation Information Reports	December 10, 1993	Do	Do
To Manufacturers: Bovine Derived Materials (BSE)	December 17, 1993	Do	Do
Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a History of Viral Hepatitis	December 22, 1993	Do	Do
Compliance Program Guidance Manual (Drugs and Biologics)	1994	Do	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–605–6050 (NTIS Order No. 94–920699)
Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors	January 3, 1994	Do	Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, FAX Information System: 1–888–CBER–FAX (within U.S.) or 301–827–3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
To Sponsors of INDs for Human Immunoglobulin Products	May 23, 1994	Do	Do
To Manufacturers of Licensed Anti-HIV Test Kits	May 26, 1994	Do	Do
Recommendations for Deferral of Donors for Malaria Risk	July 26, 1994	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ICH Guideline for Industry: Studies in Support of Special Populations	August 1, 1994	Do	Do
OELPS, Advertising and Promotional Labeling Staff Procedural Guidance Document (Draft)	August 1, 1994	Do	Do
ICH Guideline for Industry: Stability Testing of New Drug Substances and Products	September 1, 1994	Do	Do
Guide to Inspections of Blood Banks, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs	September 1, 1994	FDA Personnel	Do
Letter to Manufacturers of Immune Globulin Intravenous (Human) (IGIV), Aseptic Meningitis Syndrome	October 3, 1994	FDA Regulated Industry	Do
Guidance on Alternatives to Lot Release for Licensed Biological Products	October 27, 1994	Do	Do
Guidance for Industry: For the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	November 1994	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
To Manufacturers of Immune Globulin Products: Testing for Hepatitis C Virus RNA Immunoglobulin	December 27, 1994	Do	Do
Timeframe for Licensing Irradiated Blood Products	February 3, 1995	Do	Do
Home Specimen Collection Kit Systems Intended for Human Immunodeficiency Virus (HIV–1 and/or HIV–2) Antibody Testing; Revisions to Previous Guidance	February 23, 1995	Do	Do
ICH Guideline for Industry: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	March 1, 1995	Do	Do
To Manufacturers of Intramuscular Immune Globulin Products: HCV RNA Testing by PCR	March 3, 1995	Do	Do
Revision of 8/27/82 FDA Memo: Requirements for Infrequent Plasmapheresis Donors	March 10, 1995	Do	Do
To Manufacturers of Intramuscular Immune Globulin Products: Additional Information Regarding HCV RNA Testing by PCR	March 13, 1995	Do	Do
To Health Professionals: Implementation of Testing for HCV RNA by PCR for Immune Globulin Products for Intramuscular Administration	March 14, 1995	Do	Do
To All Establishments Performing Red Blood Cell Immunizations: Revised Recommendations for Red Blood Cell Immunization Programs for Source Plasma	March 14, 1995	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
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
Guideline for Quality Assurance in Blood Establishments	July 11, 1995	Do	Do
FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products	July 11, 1995	Do	Do
Disposition of Products Derived From Donors Diagnosed With, or at Known High Risk for, Creutzfeldt-Jakob Disease	August 8, 1995	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
Precautionary Measures to Further Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease by Blood and Blood Products	August 8, 1995	Do	Do
Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen	August 8, 1995	Do	Do
PTC in the Manufacture and Testing of Therapeutic Products for Human Use Derived From Transgenic Animals	August 22, 1995	Do	Do
Informed Consent for Plasmapheresis/Immunization	October 1, 1995	FDA Personnel	Do
Draft Reviewers' Guide: Changes in Personnel	October 1, 1995	FDA Personnel	Do
Disease Associated Antibody Collection Program	October 1, 1995	FDA Personnel	Do
Guidance Concerning Conversion to FDA-Reviewed Software Products	November 13, 1995	FDA Regulated Industry	Do
Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis	December 4, 1995	Do	Do
Interim Definition and Elimination of Lot-by-Lot Release for Well-Characterized Therapeutic Recombinant DNA-Derived and Monoclonal Antibody Biotechnology Products	December 8, 1995	Do	Do
Dear Colleague: Regarding Reverse Transcriptase Activity in Viral Vaccines Produced in Chicken Cells	January 4, 1996	Do	Do
Requesting All Manufacturers Immediately to Revise Warning Section for Package Insert on Thrombin	January 4, 1996	Do	Do
ICH Final Guideline: Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Dervied Protein Products	February 23, 1996	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ICH Final Guideline on the Need for Long-Term Rodent Carcinogenicity Study of Pharmaceuticals	March 1, 1996	Do	Do
Additional Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen	March 14, 1996	Do	Do
FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products	March 26, 1996	Do	Do
ICH Guideline on the Detection of Toxicity to Reproduction for Medicinal Products; Addendum on Toxicity to Male Fertility	April 5, 1996	Do	Do
ICH Guidance on Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	April 24, 1996	Do	Do
To Manufacturers of FDA-Regulated Drug/Biological/Device Products, Bovine Spongiform Encephalopathy (BSE)	May 9, 1996	Do	Do
Additional Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leucocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)	May 16, 1996	Do	Do
Guidance for Industry—The Content and Format for Pediatric Use Supplements	May 23, 1996	Do	Do
Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated Ex Vivo and Intended for Structural Repair of Reconstruction	May 24, 1996	Do	Do
Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products	May 29, 1996	Do	Do
Guide to Inspections of Infectious Disease Marker Testing Facilities	June 1, 1996	FDA Personnel	Do
To Manufacturers: Implementation of Testing for Hepatitis C Virus RNA by Manufacturers: Implementation of Testing for Hepatitis C Virus RNA by Polymerase Chain Reaction (PCR) of Intramuscular Immune Globulin Preparations	June 13, 1996	FDA Regulated Industry	Do
ICH Final Guidelines on Stablity Testing of Biotechnological/Biological Products	July 10, 1996		
ICH Guideline on Structure and Content of Clinical Study Reports	July 17, 1996	Do	Do
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
To Manufacturers: HIV–1 Group O	July 31, 1996	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
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 15, 1996	Do	Do
ICH Revised Guidance: Single Dose Acute Toxicity Testing for Pharmaceuticals	August 26, 1996	Do	Do
ICH Draft Guideline on Data Elements for Transmission of Individual Case Reports	October 1, 1996	Do	Do
To All Plasma Derivative Manufacturers and to ABRA: Warning Statement for Plasma Derivative Product Labeling	October 7, 1996	Do	Do
Advertising and Promotion; Guidance; Notice	October 8, 1996	Do	Do
To Biologic Product Manufacturers: Revised Procedures for Internal Labeling Review Number Assignment	December 3, 1996	Do	Do
Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection	December 11, 1996	Do	Do
PTC on Plasmid DNA Vaccines for Preventive Infectious Disease Indications	December 22, 1996	Do	Do
Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products	January 1997	Do	Do
Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software	January 13, 1997	FDA Personnel	Do
PTC in the Manufacturing and Testing of Monoclonal Antibody Products for Human Use	February 28, 1997	Do	Do
Proposed Approach to Regulation of Cellular and Tissue-Based Products	February 27, 1997	Do	Do
Tables 1 and 2 From Proposed Approach to Regulation of Cellular and Tissue-Based Products	March 4, 1997	Do	Do
Preclearance of Promotional Labeling; Clarification	March 5, 1997	Do	Do
Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies	April 1997	Do	Do
ICH Draft Guideline on Dose Selection for Carcinogenicity Studies for Pharmaceuticals: Addendum on the Limit Dose	April 2, 1997	Do	Do
ICH Draft Guideline on the Timing of Nonclinical Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	May 2, 1997	Do	Do
ICH Draft Guideline on Impurities: Residual Solvents	May 2, 1997 (Correction May 19, 1997)	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ICH Guideline on Stability Testing for New Dosage Forms	May 9, 1997	Do	Do
ICH Draft Guideline on Statistical Principles for Clinical Trials, Part III	May 9, 1997	Do	Do
ICH Good Clinical Practice: Consolidated Guideline, Part II	May 9, 1997	Do	Do
ICH Guideline for the Photostability Testing of New Drug Substances and Products, Part II	May 16, 1997	Do	Do
ICH Guideline on Impurities in New Drug Products, Part IV	May 19, 1997	Do	Do
ICH Guideline on Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs, Part VI	May 19, 1997	Do	Do
ICH Guideline on the Validation of Analytical Procedures: Methodology, Part V	May 19, 1997	Do	Do
To Plasma Fractionators—CBER's View on Product Recalls Conducted by the Plasma Fractionation Industry	May 29, 1997	Do	Do
ICH Draft Guideline on General Considerations for Clinical Trials	May 30, 1997	Do	Do
Guide to Inspections of Source Plasma Establishments (Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs)	June 1, 1997	FDA Personnel	Do
Draft Guidance for Industry: Computerized Systems Used in Clinical Trials; Availability	June 18, 1997	FDA Regulated Industry	Do
Guidance for Industry—Changes to an Approved Application: Biological Products	July 1997	Do	Do
Guidance for Industry—Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 1997	Do	Do
Guidance for Industry—Screening and Testing of Donors of Human Tissue Intended for Transplantation	July 1997	Do	Do
Guidance for Industry—Donor Screening for Antibodies to HTLV–II	August 1997	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
Draft Guidance for Industry Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers	September 1997	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

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Notification Process for Transfusion Related Fatalities and Donation Related Deaths (revised telephone number)	October 7, 1997	Do	Do
Submission Requirements for Requesting Certificates for Exporting Products to Foreign Countries	October 15, 1997	Do	Do
ICH Guidance on Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	November 18, 1997	Do	Do
ICH Guidance on Genotoxicity: A Standard Battery for Genotoxicity Testing for Pharmaceuticals	November 21, 1997	Do	Do
ICH Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	November 25, 1997	Do	Do
Guidance for FDA and Industry: Direct Final Rule Procedures	November 21, 1997	FDA Personnel and Regulated Industry	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
Guidance for Industry: Industry-Supported Scientific and Educational Activities	December 3, 1997	Do	Do
ICH Guidance on Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do	Do
To Biologic Product Manufacturers—Withdrawal of Human Blood-Derived Materials Because Donors Diagnosed With, or at Increased Risk for, CJD	December 11, 1997	Do	Do
To Allergenic Extract Manufacturers—Standardized Grass Pollen Extracts	December 23, 1997	Do	Do
ICH Guidance on Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998		
Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products	January 1998	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 1998	Do	Do
ICH Guidance on Testing for Carcinogenicity of Pharmaceuticals	February 28, 1998		
Draft Guidance for Industry: Manufacturing, Processing or Holding Active Pharmaceutical Ingredients	March 1998	Do	Do
Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy	March 1998	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research	May 1998	Do	Do
Draft Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products	May 1998	Do	Do
Guidance for Industry: Classifying Resubmissions in Response to Action Letters	May 1998	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
Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements	May 1998	Do	Do
Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products	May 1998	Do	Do
Draft Guidance for Industry: Stability Testing of Drug Substances and Drug Products	June 1998	Do	Do
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act	June 1998	Do	Do
Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing	June 1998	Do	Do
ICH Draft Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	June 9, 1998	Do	Do
ICH Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	Do	Do
Draft Guidance for Industry: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996	June 12, 1998	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
Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications	July 1998	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV	September 1998	Do	Do
Draft Guidance for Industry: Submitting Debarment Certification Statements	September 1998	Do	Do
Guidance for Industry: How to Complete the Vaccine Adverse Reporting System Form (VAERS–1)	September 1998	Do	Do
Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review	September 1998	Do	Do
ICH Guidance on Statistical Principles for Clinical Trials	September 16, 1998	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
ICH Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do	Do
Guidance for Industry: On Advisory Committees: Implementing Section 120 of the Food and Drug Administration Act of 1997	October 1998	Do	Do
Draft Guidance for Industry: General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products	November 1998	Do	Do
To Viral Vaccine IND Sponsors—Use of PCR-Based Reverse Transcriptase Assay	December 18, 1998	Do	Do
Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	December 1998	Do	Do
Draft Guidance for Industry: Content and Format of Geriatric Labeling	December 1998	Do	Do
Draft Guidance for Industry: Product Name Placement, Size and Prominence in Advertising and Promotional Labeling	January 1999	Do	Do
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
Guidance on Amended Procedures for Advisory Panel Meetings	January 1999	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations	January 1999	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
Guidance for Industry: Population Pharmacokinetics	February 1999	Do	Do
Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 1999	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
Draft Guidance for Industry: INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products, Chemistry, Manufacturing and Controls Content and Format	February 1999	Do	Do
Draft Guidance for Industry: Accelerated Approval Products—Submission of Promotional Materials	March 1999	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
Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans	April 1999	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
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
Guidance for Industry for Platelet Testing and Evaluation of Platelet Substitute Products	May 1999	Do	Do
Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use	May 1999	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation	May 1999	Do	Do
Draft Guidance for Industry: Establishing Pregnancy Registries	June 1999	Do	Do
Draft Reviewer Guidance: Evaluation of Human Pregnancy Outcome Data	June 1999	FDA Personnel	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
ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	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
Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	July 1999	Do	Do
Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics	August 1999	Do	Do
Guidance for Industry: Consumer-Directed Broadcast Advertisements	August 1999	Do	Do
Draft Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 1999	Do	Do
Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products	August 1999	Do	Do
Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	August 1999	Do	Do
ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do	Do
Draft Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors	September 1999	Do	Do
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act	September 1999	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
International Conference on Harmonisation Draft Guidance; Choice of Control Group in Clinical Trials	September 24, 1999	Do	Do
Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (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
Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products	November 1999	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
Draft Guidance for Industry: Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma	November 1999	Do	Do
Draft Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis and Impact on Dosing and Labeling	November 1999	Do	Do
International Conference on Harmonsation of Technical Requirements for Registration of Pharmaceuticals for Human Use M4: Common Technical Document	November 8, 1999	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
Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products From Xenotransplantation Product Recipients and Their Contacts	December 1999	Do	Do
Draft Guidance for Industry: Special Protocol Assessment	December 1999	Do	Do
Draft Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture	January 2000	Do	Do
Draft Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol	February 2000	FDA Personnel	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information	February 2000	FDA Regulated Industry	Do
Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products	February 2000	Do	Do
Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level	February 2000	Do	Do
Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing	February 2000	Do	Do
Draft Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank	March 2000	Do	Do
International Conference on Harmonisation; Draft Revised Guidance on Q1A(R) Stability Testing of New Drug Substances and Products	April 21, 2000	Do	Do
Draft Guidance for Industry: Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics	May 2000	Do	Do
Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components	June 2000	Do	Do
Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria	June 2000	Do	Do
Draft Guidance for Industry: Pediatric Oncology Studies in Response to a Written Request	June 2000	Do	Do
Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use With Cadaveric Blood Specimens (Level 2)	June 2000	Do	Do
Draft Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment	June 2000	Do	Do
Draft Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained From an Outside Supplier	June 2000	Do	Do
Draft Guidance for Industry: Developing Medical Imaging Drugs and Biological Products	June 2000	Do	Do
International Conference on Harmonisation (ICH) Draft Guidance; Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (March 17, 2000)	June 2000	Do	Do
International Conference on Harmonisation (ICH) Draft Revised Guidance on Impurities in New Drug Products	July 19, 2000	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
International Conference on Harmonisation (ICH) Draft Revised Guidance on Impurities in New Drug Substances	July 20, 2000	Do	Do
International Conference on Harmonisation (ICH) Draft Guideline: Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use	July 20, 2000	Do	Do
International Conference on Harmonisation (ICH) Draft Guideline on Safety Pharmacology Studies for Human Pharmaceuticals	August 2000	Do	Do
Draft Guidance for Industry: Analytical Procedures and Methods Validation—Chemistry, Manufacturing, and Controls Documentation	August 2000	Do	Do
Draft Guidance for Industry: Considerations for Reproductive Toxicity Studies for Preventive Vaccines for Infectious Disease Indications	August 2000	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
Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors	October 2000	Do	Do
Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds	October 2000	Do	Do
Draft Guidance for Industry: Cancer Drug and Biological Products—Clinical Data in Marketing Applications	November 2000	Do	Do
Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts	November 2000	Do	Do
Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices (Level 2)	November 2000	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
International Conference on Harmonisation (ICH) Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population	December 2000	Do	Do
Draft Guidance for Industry: Variances for Blood Collection From Individuals With Hereditary Hemochromatosis	December 2000	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees	December 2000	Do	Do
International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	December 29, 2000	Do	Do
PHS Guideline on Infectious Disease Issues in Xenotransplantation	January 19, 2001	Do	Do
Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion	January 2001	Do	Do
Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods	January 2001	Do	Do
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling	January 2001	Do	Do
Draft Guidance for Industry: Source Animal, Product, Preclinical and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans	February 2001	Do	Do
Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods—Technical Correction February 2001	February 2001	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
Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines	March 2001	Do	Do
Guidance for Industry: Acceptance of Foreign Clinical Studies	March 2001	Do	Do
Guidance for Industry: Financial Disclosure by Clinical Investigators	March 2001	Do	Do
Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing	March 2001	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
Draft Guidance for Industry: Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements	April 2001	Do	Do

II. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry: Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	April 2001	Do	Do
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports	May 2001	Do	Do
Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials	May 2001	Do	Do
Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing and Controls Information	May 2001	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Accelerated Approval Products—Submission of Promotional Materials—Draft	March 26, 1999	Advertising Draft	http://www.fda.gov/cder/guidance/index.htm 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
Product Name, Placement, Size, and Prominence in Advertising and Promotional Labeling—Draft	March 12, 1999	Do	Do
Promoting Medical Products in a Changing Healthcare Environment; Medical Product Promotion by Healthcare Organizations or Pharmacy Management Companies—Draft	January 5, 1998	Do	Do
Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements—Draft	April 23, 2001	Do	Do
Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling	January 12, 1998	Advertising	Do
Consumer-Directed Broadcast Advertisements	August 9, 1999	Do	Do
Industry-Supported Scientific and Educational Activities	December 3, 1997	Do	Do
Antifungal (Topical)—Draft	February 24, 1990	Biopharmaceutic Draft	Do
Antifungal (Vaginal)—Draft	February 24, 1990	Do	Do
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action—Draft	June 2, 1999	Do	Do
Conjugated Estrogens, USP: LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence—Draft	March 9, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Food-Effect Bioavailability and Bioequivalence Studies—Draft	December 30, 1997	Do	Do
In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Studies—Draft	December 10, 1997	Do	Do
Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies—Draft	June 18, 1998	Do	Do
Bioanalytical Method Validation	May 23, 2001	Biopharmaceutic	Do
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations	October 27, 2000	Do	Do
Cholestyramine Powder In Vitro Bioequivalence	July 15, 1993	Do	Do
Clozapine (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 15, 1996	Do	Do
Corticosteroids, Detmatologic (Topical) In Vivo	June 2, 1995	Do	Do
Dissolution Testing of Immediate Release Solid Oral Dosage Forms	August 25, 1997	Do	Do
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations	September 26, 1997	Do	Do
Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing	March 8, 2001	Do	Do
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	June 27, 1989	Do	Do
Phenytoin/Phenytion Sodium (Capsules, Tablets, Suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 4, 1994	Do	Do
Potassium Chloride (Slow-Release Tablets and Capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 6, 1994	Do	Do
Statistical Approaches to Establishing Bioequivalence	February 2, 2001	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
Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation—Draft	August 30, 2000	Chemistry Draft	Do
Botanical Drug Products—Draft	August 11, 2000	Do	Do
INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products, Chemistry, Manufacturing, and Controls Content and Format—Draft	April 20, 1999	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation—Draft	November 19, 1998	Do	Do
Monoclonal Antibodies Used as Reagents in Drug Manufacturing—Draft	June 24, 1999	Do	Do
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products—Draft	June 2, 1999	Do	Do
Stability Testing of Drug Substances and Drug Products—Draft	June 8, 1998	Do	Do
Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications—Draft	November 1, 1991	Do	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
SUPAC–SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum—Draft	January 5, 1999	Do	http://www.fda.gov/cder/guidance/index.htm 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
Tracking of NDA and NDA Reformulations for Solid, Oral, Immediate Release Drug Products—Draft	April 12, 1989	Do	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
BACPAC1: Intermediates in Drug Substance Synthesis: Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation	February 16, 2001	Chemistry	Do
Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 24, 1997	Do	Do
Changes to an Approved NDA or ANDA	November 23, 1999	Do	Do
Changes to an Approved NDA or ANDA: Questions and Answers	January 22, 2001	Do	Do
Container Closure Systems for Packaging Human Drugs and Biologics	July 7, 1999	Do	Do
Development of New Stereoisomeric Drugs	May 1, 1992	Do	Do
Drug Master Files	September 1, 1989	Do	Do
Drug Master Files for Bulk Antibiotic Drug Substances	November 29, 1999	Do	Do
Environmental Assessment of Human Drugs and Biologics Applications	July 27, 1998	Do	Do
Format and Content for the CMC Section of an Annual Report	September 1, 1994	Do	Do
Format and Content of the Chemistry, Manufacturing and Controls Section of an Application	February 1, 1987	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Format and Content of the Microbiology Section of an Application	February 1, 1987	Do	Do
IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information	May 25, 2001	Do	Do
Monoclonal Antibodies Used as Reagents in Drug Manufacturing	March 29, 2001	Do	Do
NDAs: Impurities in Drug Substances	February 25, 2000	Do	Do
PAC–ALTS: Postapproval Changes—Analytical Testing Laboratory Sites	April 28, 1998	Do	Do
Reviewer Guidance: Validation of Chromatographic Methods	November 1, 1994	Do	Do
Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances	November 1, 1994	Do	Do
Submission of Documentation for Sterilization Process Validation Applications for Human and Veterinary Drug Products	November 1, 1994	Do	Do
Submitting Documentation for the Manufacturing of and Controls for Drug Products	February 1, 1987	Do	Do
Submitting Documentation for the Stability of Human Drugs and Biologics	February 1, 1987	Do	Do
Submitting Samples and Analytical Data for Methods Validation	February 1, 1987	Do	Do
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Products	February 1, 1987	Do	Do
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances	February 1, 1987	Do	Do
SUPAC IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation	November 30, 1995	Do	Do
SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum	February 26, 1999	Do	Do
SUPAC–IR: Questions and Answers	February 18, 1997	Do	Do
SUPAC–MR: Modified Release Solid Oral Dosage Forms: Scale-Up and Post-approval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation	October 6, 1997	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	June 13, 1997	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy	December 20, 2000	Do	Do
Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Clinical Antimicrobial Draft	Do
Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Acute or Chronic Bacterial Prostatitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Acute Otitis Media; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment—Draft	October 18, 1999	Do	Do
Clinical Considerations for Accelerated and Traditional Approval of Antiretroviral Drugs Using Plasma HIV RNA Measurements—Draft	September 1, 1999	Do	Do
Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Complicated Urinary Tract Infections and Pylonephritis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Developing Antimicrobial Drugs—General Considerations for Clinical Trials—Draft	July 22, 1998	Do	Do
Empiric Therapy of Febrile Neutropenia; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products—Draft	February 17, 1997	Do	Do
Lyme Disease; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Nosocomial Pneumonia; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Secondary Bacterial Infections of Acute Bronchitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Streptococcal Pharyngitis and Tonsillitis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Uncomplicated and Complicated Skin and Skin Structure Infections; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Uncomplicated Gonorrhea—Cervical, Urethral, Rectal, and/or Pharyngeal; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Uncomplicated Urinary Tract Infections; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Vulvovaginal Candidiasis; Developing Antimicrobial Drugs for Treatment—Draft	July 22, 1998	Do	Do
Clinical Development and Labeling of Anti-Infective Drug Products	October 26, 1992	Clinical Antimicrobial	Do
Clinical Evaluation of Anti-Infective Drugs (Systemic)	September 1, 1977	Do	Do
Preclinical Development of Antiviral Drugs	November 1, 1990	Do	Do
Abuse Liability Assessment—Draft	July 1, 1990	Clinical Medical Draft	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
Allergic Rhinitis: Clinical Development Programs for Drug Products—Draft	June 21, 2000	Do	http://www.fda.gov/cder/guidance/index.htm 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
Cancer Drug and Biological Products—Clinical Data in Marketing Applications—Draft	November 9, 2000	Do	Do
Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment—Draft	June 28, 2000	Do	Do
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)—Draft	July 15, 1999	Do	Do
Clinical Evaluation of Anti-Anginal Drugs—Draft	January 1, 1989	Do	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
Clinical Evaluation of Anti-Arrhythmic Drugs—Draft	July 1, 1985	Do	http://www.fda.gov/cder/guidance/index.htm 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
Clinical Evaluation of Antihypertensive Drugs—Draft	May 1, 1988	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure—Draft	December 1, 1987	Do	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
Clinical Evaluation of Drugs for Ulcerative Colitis (3rd draft)—Draft	January 7, 1991	Do	Do
Clinical Evaluation of Lipid-Altering Agents In Adults and Children—Draft	September 1, 1990	Do	http://www.fda.gov/cder/guidance/index.htm 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
Clinical Evaluation of Motility-Modifying Drugs—Draft	Date not available	Do	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
Clinical Evaluation of Weight-Control Drugs—Draft	September 24, 1996	Do	http://www.fda.gov/cder/guidance/index.htm 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
Developing Medical Imaging Drugs and Biologics—Revised—Draft	July 31, 2000	Do	Do
Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders—Draft	February 12, 1992	Do	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
Development of Parathyroid Hormones for the Prevention and Treatment of Osteoporosis—Draft	June 14, 2000	Do	http://www.fda.gov/cder/guidance/index.htm 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
Establishing Pregnancy Registries—Draft	June 4, 1999	Do	Do
Evaluation of Human Pregnancy Outcome Data—Draft	June 4, 1999	Do	Do
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment—Draft	May 19, 2000	Do	Do
Institutional Review Boards, Clinical Investigators, and Sponsors: Exception From Informed Consent Requirements for Emergency Research—Draft	March 30, 2000	Do	Do
OTC Treatment of Herpes Labialis With Antiviral Agents—Draft	March 8, 2000	Do	Do
Pediatric Oncology Studies in Response to a Written Request—Draft	June 21, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines—Draft	March 12, 2001	Do	Do
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis—Draft	April 1, 1994	Do	Do
Preparation of IND Applications for New Drugs Intended for the Treatment of HIV-Infected Individuals—Draft	September 1, 1991	Do	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
Recommendations for Complying With the Pediatric Rule—Draft	December 4, 2000	Do	http://www.fda.gov/cder/guidance/index.htm 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
System Inflammatory Response Syndrome (SIRS) (1st draft)—Draft	July 1993	Do	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
Acceptance of Foreign Clinical Studies	March 13, 2001	Clinical Medical	http://www.fda.gov/cder/guidance/index.htm 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
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 17, 1999	Do	Do
Clinical Development Programs for MDI and DPI Drug Products	September 19, 1994	Do	Do
Clinical Evaluation of Analgesic Drugs	December 1, 1992	Do	Do
Clinical Evaluation of Antacid Drugs	April 1, 1978	Do	Do
Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (Adults and Children)	April 1, 1988	Do	Do
Clinical Evaluation of Antianxiety Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antidepressant Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antidiarrheal Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Antiepileptic Drugs (Adults and Children)	January 1, 1981	Do	Do
Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women	March 20, 1995	Do	Do
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs	September 1, 1977	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Clinical Evaluation of General Anesthetics	May 1, 1982	Do	Do
Clinical Evaluation of Hypnotic Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Laxative Drugs	April 1, 1978	Do	Do
Clinical Evaluation of Local Anesthetics	May 1, 1982	Do	Do
Clinical Evaluation of Psychoactive Drugs in Infants and Children	July 1, 1979	Do	Do
Clinical Evaluation of Radiopharmaceutical Drugs	October 1, 1981	Do	Do
Content and Format for Pediatric Use Supplements	May 24, 1996	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 20, 1995	Do	Do
Development of Vaginal Contraceptive Drugs (NDA)	April 19, 1995	Do	Do
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	February 2, 1999	Do	Do
FDA Requirements for Approval of Drugs to Treat Non-Small Lung Cancer	January 29, 1991	Do	Do
FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer	June 20, 1989	Do	Do
Format and Content of the Clinical and Statistical Sections of an Application	July 1, 1988	Do	Do
Format and Content of the Summary for New Drug and Antibiotic Applications	February 1, 1987	Do	Do
Formatting, Assembling and Submitting New Drug and Antibiotic Applications	February 1, 1987	Do	Do
General Considerations for the Clinical Evaluation of Drugs	December 1, 1978	Do	Do
General Considerations for the Clinical Evaluation of Drugs in Infants and Children	September 1, 1977	Do	Do
Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing	March 8, 2001	Do	Do
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer	April 13, 1988	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
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products; Clarification of What to Report	August 27, 1997	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Postmarketing Reporting of Adverse Drug Experiences	March 1, 1992	Do	Do
Preclinical Development of Immunomodulatory Drugs for the Treatment of HIV Infection and Associated Disorders	September 4, 1992	Do	Do
Preparation of Investigational New Drug Products (Human and Animal)	November 1, 1992	Do	Do
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products	May 15, 1998	Do	Do
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs	July 22, 1993	Do	Do
Study of Drugs Likely To Be Used in the Elderly	November 1, 1989	Do	Do
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	September 13, 1999	Do	Do
General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products—Draft	November 30, 1998	Clinical Pharmacology Draft	Do
Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling—Draft	December 7, 1999	Do	Do
Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro	April 7, 1997	Clinical Pharmacology	Do
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application	February 1, 1987	Do	Do
In Vivo Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling	November 24, 1999	Do	Do
Pharmacokinetics and Pharmacodynamics in Patients With Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	May 15, 1998	Do	Do
Population Pharmacokinetics	February 10, 1999	Do	Do
Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (21 CFR 50.24)—Draft	March 30, 2000	Compliance Draft	Do
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production—Draft	September 30, 1998	Do	Do
Manufacture, Processing or Holding of Active Pharmaceutical Ingredients—Draft	April 17, 1998	Do	Do
Repacking of Solid Oral Dosage Form Drug Products—Draft	February 1, 1992	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
A Review of FDA's Implementation of the Drug Export Amendments of 1986		Compliance	Do
Compressed Medical Gases	December 1, 1989	Do	Do
Computerized Systems Used in Clinical Trials	May 10, 1999	Do	Do
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron	June 27, 1997	Do	Do
General Principles of Process Validation	May 1, 1987	Do	Do
Good Laboratory Practice Regulations Questions and Answers		Do	Do
Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities	April 6, 2001	Do	Do
Monitoring of Clinical Investigations	January 1, 1988	Do	Do
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment	May 1, 1984	Do	Do
Possible Dioxin/PCB Contamination of Drug and Biological Products	August 23, 1999	Do	Do
Sterile Drug Products Produced by Aseptic Processing	May 1, 1987	Do	Do
Street Drug Alternatives	April 3, 2000	Do	Do
Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices	December 1, 1987	Do	Do
Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports—Draft	May 4, 2001	Electronic Submission Draft	Do
Providing Regulatory Submissions in Electronic Format: Prescription Drug Advertising and Promotional Labeling—Draft	January 31, 2001	Do	Do
Preparing Data for Electronic Submissions in ANDAs	September 23, 1999	Electronic Submission	Do
Regulatory Submissions in Electronic Format; General Considerations	January 28, 1999	Do	Do
Regulatory Submissions in Electronic Format; New Drug Applications	January 28, 1999	Do	Do
ANDAs; Blend Uniformity Analysis—Draft	August 26, 1999	Generic Drug Draft	Do
ANDAs; Impurities in Drug Products—Draft	January 5, 1999	Do	Do
Content and Format of an Abbreviated New Drug Application (ANDA)—Positron Emission Tomography (PET) Drug Products—With Specific Information for ANDAs for Fludeoxyglucose F18 Injection—Draft	April 18, 1997	Do	Do
Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs—Draft	December 12, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
ANDAs: Impurities in Drug Substances	December 3, 1999	Generic Drugs	Do
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	March 30, 2000	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 18, 1995	Do	Do
Letter Describing Efforts by CDER and ORA to Clarify the Responsibilities of CDER Chemistry Review Scientists and ORA Field Investigators in the New and Abbreviated Drug Approval Process in Order to Reduce Duplication or Redundancy in the Process	October 14, 1994	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 8, 1994	Do	Do
Letter on the Provision of New Information Pertaining to New Bioequivalence Guidelines and Refuse-to-File Letters	July 1, 1992	Do	Do
Letter on the Provision of New Procedures and Policies Affecting the Generic Drug Review Process	March 15, 1989	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 8, 1991	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 26, 1985	Do	Do
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 15, 1993	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 4, 1993	Do	Do
Major, Minor, Facsimile, and Telephone Amendments to Original Abbreviated New Drug Applications (Revised)	May 1, 2000	Do	Do
Organization of an ANDA	March 2, 1999	Do	Do
Revising ANDA Labeling Following Revision of the RLD Labeling	April 25, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products	February 3, 2000	Do	Do
Variations in Drug Products That May Be Included ANDA	January 27, 1999	Do	Do
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review—Draft	November 22, 1996	Good Review Practices Draft	Do
Pharmacology/Toxicology Review Format	May 10, 2001	Good Review Practices	Do
Q1A(R)—Stability Testing of New Drug Substances and Products—Draft	April 21, 2000	ICH Draft—Quality	Do
Q3A(R)—Impurities in New Drug Substances—Draft	July 20, 2000	Do	Do
Q3B(R)—Impurities in New Drug Products—Draft	July 19, 2000	Do	Do
Q6A—Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances—Draft	November 25, 1997	Do	Do
Q7A—Good Manufacturing Practice for Active Pharmaceutical Ingredients—Draft	August 1, 2000	Do	Do
S7—Safety Pharmacology Studies for Human Pharmaceuticals—Draft	August 7, 2000	ICH Draft—Safety	Do
E12 A—Principles for Clinical Evaluation of New Antihypertensive Drugs—Draft	August 9, 2000	ICH Draft—Efficacy	Do
M4—Common Technical Document—Draft	August 24, 2000	ICH Draft—Joint Safety/Efficacy (Multidisciplinary)	Do
Q1A—Stability Testing of New Drug Substances and Products	September 22, 1994	ICH—Quality	Do
QIB—Photostability Testing of New Drug Substances and Products	May 16, 1997	Do	Do
QIC—Stability Testing for New Dosage Forms	May 9, 1997	Do	Do
Q2A—Text on Validation of Analytical Procedures	March 1, 1995	Do	Do
Q2B—Validation of Analytical Procedures: Methodology	May 19, 1997	Do	Do
Q3A—Impurities in New Drug Substances	January 4, 1996	Do	Do
Q3B(R)— Impurities in New Drug Products	July 19, 2000	Do	Do
Q3C—Impurities: Residual Solvents	December 24, 1997	Do	Do
Q5A—Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin	September 24, 1998	Do	Do
Q5B—Quality of Biotechnology Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products	February 23, 1996	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Q5C—Quality of Biotechnological Products: Stability Testing of Biotechnology/ Biological Products	July 10, 1996	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
Q6A—Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	December 29, 2000	Do	Do
Q6B—Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	August 18, 1999	Do	Do
S1A—The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals	March 1, 1996	ICH—Safety	Do
S1B—Testing for Carcinogenicity in Pharmaceuticals	February 23, 1998	Do	Do
S1C—Dose Selection for Carcinogenicity Studies of Pharmaceuticals	March 1, 1995	Do	Do
S1C(R)—Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do	Do
S2A—Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	April 24, 1996	Do	Do
S2B—Genotoxicity: Standard Battery Testing	November 21, 1997	Do	Do
S3A—Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	March 1, 1995	Do	Do
S3B—Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	March 1, 1995	Do	Do
S4A—Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	June 25, 1999	Do	Do
S5A—Detection of Toxicity to Reproduction for Medicinal Products	September 22, 1994	Do	Do
S5B—Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility	April 5, 1996	Do	Do
S6—Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	November 18, 1997	Do	Do
S7A—Safety Pharmacology Studies for Human Pharmaceuticals	July 13, 2001	Do	Do
EIA—The Extent of Population Exposure to Assess Clinical Safety: for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions	March 1, 1995	ICH—Efficacy	Do
E2A—Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	March 1, 1995	Do	Do

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
E2B—Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998	Do	Do
E2C—Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	May 19, 1997	Do	Do
E3—Structure and Content of Clinical Study Reports	July 17, 1996	Do	Do
E4—Dose-Response Information to Support Drug Registration	November 9, 1994	Do	Do
E5—Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	Do	Do
E6—Good Clinical Practice: Consolidated Guideline	May 9, 1997	Do	Do
E7—Studies in Support of Special Populations: Geriatrics	August 2, 1994	Do	Do
E8—General Considerations for Clinical Trials	December 24, 1997	Do	Do
E9—Statistical Principles for Clinical Trials	September 16, 1998	Do	Do
E10—International Conference on Harmonisation: Choice of Control Group and Related Issues in Clinical Trials	May 14, 2001	Do	Do
E11—Clinical Investigation of Medicinal Products in the Pediatric Population	December 15, 2000	Do	Do
M3—Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	November 25, 1997	ICH—Joint Safety/Efficacy (Multidisciplinary)	Do
A Revision in Sample Collection Under the Compliance Program Pertaining to Pre-Approval Inspections	July 15, 1996	Industry Letters	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
Certification Requirements for Debarred Individuals in Drug Applications	June 1, 1990	Do	Do
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	Http://www.fda.gov/cder/guidance/index.htm 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
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 10, 1987	Do	Do
Fourth of a Series of Letters Providing Informal Notice to Affected Parties About Policy Developments and Interpretations Regarding the Act. Three-Year Exclusivity Provisions of Title 1	October 31, 1986	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Implementation of the Drug Price Competition and Patent Term Restoration Act; Preliminary Guidance	October 11, 1984	Do	Do
Implementation Plan USP Injection Nomenclature	October 2, 1995	Do	Do
Instructions for Filing Supplements Under the Provisions of SUPAC–IR	April 11, 1996	Do	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
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 Act	July 29, 1988	Do	Http://www.fda.gov/cder/guidance/index.htm 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
Sixth of a Series of Informal Notice Letters About the Act Discussing 3- and 5-year Exclusivity Provisions of Section 505(c)(3)(D) and (j)(4)(D) of the Act	April 28, 1988	Do	Do
Streamlining Initiative	December 24, 1996	Do	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
Supplement to 10/11/84 Letter About Policies, Procedures and Implementation of the Act (Q & A Format)	November 16, 1984	Do	http://www.fda.gov/cder/guidance/index.htm 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
Third of a Series of Letters Regarding the Implementation of the Act	May 1, 1985	Do	Do
Y2K Letter From Dr. Janet Woodcock	October 19, 1998	Do	Do
Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients—Draft	July 10, 2000	Labeling Draft	Do
Content and Format for Geriatric Labeling—Draft	January 21, 1999	Do	Do
Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics—Draft	June 21, 2000	Do	Do
Non-Contraceptive Estrogen Drug Products—Physician and Patient Labeling—Draft	January 8, 1999	Do	Do
Noncontraceptive Estrogen Class Labeling—Draft	September 27, 1999	Do	Do
Labeling of OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)—Draft	July 16, 1998	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications—Draft	October 26, 2000	Do	Do
Therapeutic Equivalence Code Placement on Prescription Drug Labels and Labeling—Draft	January 28, 1999	Do	Do
Acetaminophen and Codeine Phosphate Tablets/Capsules	December 1, 1993	Labeling	Do
Acetaminophen and Codeine Phosphate Oral Solution/Suspension	December 1, 1993	Do	Do
Acetaminophen, Aspirin and Codeine Phosphate Tablets/Capsules	December 1, 1993	Do	Do
Alprazolam Tablets USP	August 1, 1996	Do	Do
Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP	September 1, 1997	Do	Do
Amlodipine Besylate Tablets	September 1, 1997	Do	Do
Astemizole Tablets	September 1, 1997	Do	Do
Atenolol Tablets USP	August 1, 1997	Do	Do
Barbiturate, Single Entity-Class Labeling	March 1, 1981	Do	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
Butalbital, Acetaminophen and Caffeine Capsules/Tablets USP	September 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm 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
Butalbital, Acetaminophen, Caffeine and Hydocodone Bitartrate Tablets	September 21, 1997	Do	Do
Butorphanol Tartrate Injection USP	October 1, 1992	Do	Do
Captopril and Hydrochlorothiazide Tablets USP	April 1, 1995	Do	Do
Captopril Tablets	February 1, 1995	Do	Do
Carbidopa and Levodopa Tablets USP	February 1, 1992	Do	Do
Chlordiazepoxide Hydrochloride Capsules	January 1, 1988	Do	Do
Cimetidine Hydrochloride Injection	September 1, 1995	Do	Do
Cimetidine Tablets	September 1, 1995	Do	Do
Cisapride Oral Suspension	September 1, 1997	Do	Do
Cisapride Tablets	September 1, 1997	Do	Do
Clindamycin Phosphate Injection USP	September 1, 1998	Do	Do

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Clorazepate Dipotassium Capsules/Tablets	March 1, 1993	Do	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
Combination Oral Contraceptives—Physician and Patient Labeling	January 1, 1994	Do	Do
Cyproheptadine Hydrochloride Tablets/Syrup	December 1, 1986	Do	Do
Diclofenac Sodium Delayed-Release Tablets	January 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm 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
Diltiazem Hydrochloride Extended-Release Capsules	September 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP	April 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets USP	April 1, 1995	Do	Do
Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%	November 2, 1998	Do	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
Ergoloid Mesylates Tablets	January 1, 1988	Do	Do
Fludeoxyglucose F18 Injection	January 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm 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
Flurbiprofen Tablets USP	January 1, 1994	Do	Do
Fluvoxamine Maleate Tablets	September 1, 1997	Do	Do
Gentamicin Sulfate Ophthalmic Ointment and Solution USP	April 1, 1992	Do	Do
Heparin Sodium Injection USP	March 1, 1991	Do	Do
Hydrocodone Bitartrate and Acetaminophen Tablets USP	April 1, 1994	Do	Do
Hydroxyzine Hydrochloride Injection	December 1, 1989	Do	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
Hypoglycemic Oral Agents Federal Register	April 1, 1984	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Indomethacin Capsules USP	September 1, 1995	Do	http://www.fda.gov/cder/guidance/index.htm 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
Informal Labeling Guidance Texts for Estrogen Drug Products Patient Labeling	August 1, 1992	Do	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
Informal Labeling Guidance Texts for Estrogen Drug Products: Professional Labeling	August 1, 1992	Do	Do
Isoetharine Inhalation Solution	March 1, 1989	Do	Do
Itraconazole Capsules, USP	September 1, 1998	Do	http://www.fda.gov/cder/guidance/index.htm 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
Leucovorin Calcium for Injection	July 1, 1996	Do	Do
Leucovorin Calcium Tablets, USP	July 1, 1996	Do	Do
Local Anesthetics Class Labeling	September 1, 1982	Do	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
Meclofenamate Sodium Capsules	July 1, 1992	Do	Do
Medroxyprogesterone Acetate Tablets, USP	September 1, 1998	Do	http://www.fda.gov/cder/guidance/index.htm 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
Metaproterenol Sulfate Inhalation Solution USP	May 1, 1992	Do	Do
Metaproterenol Sulfate Syrup USP	May 1, 1992	Do	Do
Metaproterenol Sulfate Tablets	May 1, 1992	Do	Do
Metoclopramide Tablets USP/Oral Solution	February 1, 1995	Do	Do
Naphazoline Hydrochloride Ophthalmic Solution	March 1, 1989	Do	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

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Naproxen Sodium Tablets, USP	September 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm 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
Naproxen Tablets, USP	September 1, 1997	Do	Do
Niacin Tablets	July 1, 1982	Do	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
Paclitaxel Injection	September 1, 1997	Do	http://www.fda.gov/cder/guidance/index.htm 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
Phendimetrazine Tartrate Capsules/T Nets, and Extended-Release Capsules	February 1, 1991	Do	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
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 Tablets/Capsules USP	October 1, 1995	Do	http://www.fda.gov/cder/guidance/index.htm 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
Ranitidine Tablets USP	November 1, 1993	Do	Do
Risperidone Oral Solution	September 1, 1997	Do	Do
Risperidone Tablets	September 1, 1997	Do	Do
Sulfacetainide Sodium and Prednisolone Acetate Ophthalmic Suspension and Ointment	January 1, 1995	Do	Do
Sulfacetamide Sodium Ophthalmic Solution/Ointment	August 1, 1992	Do	Do
Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets	February 1, 1992	Do	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

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Sulfamethoxazole and Trimethoprim Tablets and Oral Suspension	August 1, 1993	Do	http://www.fda.gov/cder/guidance/index.htm 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
Theophylline Immediate-Release Dosage Forms	February 1, 1995	Do	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
Theophylline Intravenous Dosage Forms	September 1, 1995	Do	http://www.fda.gov/cder/guidance/index.htm 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
Thiamine Hydrochloride Injection	February 1, 1988	Do	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
Tobramycin Sulfate Injection USP	May 1, 1993	Do	http://www.fda.gov/cder/guidance/index.htm 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
Venlafaxine Hydrochloride Tablets	October 1, 1997	Do	Do
Verapamil Hydrochloride Tablets	October 1, 1991	Do	Do
Vitamin A Capsules	February 1, 1992	Do	Do
Zolpidem Tartrate Tablets	September 1, 1997	Do	Do
Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products	April 1, 1996	Microbiology	Do
Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals—Draft	December 19, 2000	OTC Draft	Do
Labeling OTC Human Drug Products: Updating Labeling in ANDAs—Draft	February 22, 2001	Do	Do
OTC Actual Use Studies—Draft	July 22, 1994	Do	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
OTC Nicotine Substitutes—Draft	March 1, 1994	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16)		OTC	http://www.fda.gov/cder/guidance/index.htm 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
General Guidelines for OTC Combination Products		Do	Do
Labeling OCT Human Drug Products Using a Column Format	December 19, 2000	Do	Do
Upgrading Category III Antiperspirants to Category 1 (43 FR 46728–46731)		Do	Do
Carcinogenicity Study Protocol Submissions—Draft	November 7, 2000	Pharmacology/Toxicology Draft	Do
Immunotoxicology Evaluation of Investigational New Drugs—Draft	May 11, 2001	Do	Do
Photosafety Testing—Draft	January 10, 2000	Do	Do
Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals—Draft	May 8, 2001	Do	Do
Content and Format of INDs for Phase 1 Studies of Drugs Including Well-Characterized, Therapeutic, Biotechnology-Derived Products	October 4, 2000	Pharmacology/Toxicology	Do
Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application	February 1, 1987	Do	Do
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 16, 1996	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 1, 1989	Do	Do
Single Dose Acute Toxicity Testing Toxicity Testing for Pharmaceuticals	August 26, 1996	Do	Do
Applications Covered by Section 505(b)(2)—Draft	December 8, 1999	Procedural Draft	Do
Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products—Draft	March 10, 2000	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—Draft	December 22, 1999	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—Draft	May 15, 2001	Do	Do
Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank—Draft	March 29, 2000	Do	Do
Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Implementation Plan—Draft	July 9, 2001	Do	Do
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act—Draft	August 17, 1999	Do	Do
PET Drug Applications—Content and Format for NDAs and ANDAs—Draft	March 10, 2000	Do	Do
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines—Draft	March 12, 2001	Do	Do
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies—Draft	January 4, 2001	Do	Do
Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997—Draft	April 4, 2001	Do	Do
Special Protocol Assessment—Draft	February 9, 2000	Do	Do
Submitting Debarment Certification Statements—Draft	October 2, 1998	Do	Do
180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	July 14, 1998	Procedural	Do
Advisory Committees: Implementing Section 120 of the Food and Drug Modernization Act of 1997	November 2, 1998	Do	Do
Court Decisions, ANDA Approvals, and 130-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	March 30, 2000	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
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act	November 23, 1998	Do	Do
Fast Track Drug Development Programs: Designation, Development, and Application Review	November 18, 1998	Do	Do
Financial Disclosure by Clinical Investigators	March 20, 2001	Do	Do
Formal Dispute Resolution: Appeals Above the Division Level	March 7, 2000	Do	Do

III. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Formal Meetings With Sponsors and Applicants for PDUFA Products	March 7, 2000	Do	Do
Implementation of Section 120 of the FDA Modernization Act of 1997—Advisory Committees	November 20, 1998	Do	Do
Implementation of Section 126 of the FDA Modernization Act of 1997—Elimination of Certain Labeling Requirements	July 21, 1998	Do	Do
Levothyroxine Sodium Products—Enforcement of August 14, 2001, Compliance Date and Submission of New Applications	July 13, 2001	Do	Do
National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs	April 9, 1998	Do	Do
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act—Revised	October 1, 1999	Do	Do
Reduction of Civil Money Penalties for Small Business Entities	March 20, 2001	Do	Do
Refusal to File	July 12, 1993	Do	Do
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act	June 15, 1998	Do	Do
Standards for the Prompt Review of Efficacy Supplements Including Priority Efficacy Supplements	May 15, 1998	Do	Do
Women and Minorities Guidance Requirements	July 20, 1998	Do	Do
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act	August 17, 1999	User Fee Draft	Do
Submitting Separate Marketing Applications and Definitions of Clinical Data for Purposes of Assessing User Fees—Draft	February 22, 2001	Do	Do
Waivers of and Reductions in User Fees (Attachment G)—Draft	July 16, 1993	Do	Do
Applicability of User Fees to: (1) Applications Withdrawn Before Filing Decision, 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
Application, Product, and Establishment Fees: Common Issues and Their Resolution (Attachment D)	December 16, 1994	Do	Do
Classifying Resubmissions in Response to Action Letters	May 14, 1998	Do	Do
Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act	August 25, 1999	Do	Do
Formal Meetings With Sponsors and Applicants for PDUFA Products	March 7, 2000	Do	Do
Submitting and Reviewing Complete Responses to Clinical Holds (Revised)	October 26, 2000	Do	Do

WITHDRAWALS

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal
Dissemination and Reprints of Certain Published Original Data (No Replacement)	October 8, 1996	Advertising	February 16, 2000
Funded Dissemination of Reference Texts (No Replacement)	October 8, 1996	Advertising	February 16, 2000
Buspirone Hydrochloride Tablets In Vivo Bioequivalence (No Replacement)	May 14, 1998	Biopharmaceutics	November 30, 2000
Cimetidine Tablets In Vivo Bioequivalence and In Vitro Dissolution (No Replacement)	Unknown	Biopharmaceutics	November 30, 2000
Diclofenac Sodium (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing (No Replacement)	October 6, 1994	Biopharmaceutics	November 30, 2000
Glipizide In Vivo Bioequivalence and In Vivo Dissolution Testing (No Replacement)	Unknown	Biopharmaceutics	November 30, 2000
Glyburide In Vivo Bioequivalence and In Vivo Dissolution Testing (No Replacement)	Unknown	Biopharmaceutics	November 30, 2000
Oral Extended (Controlled) Release Dosage Forms In Vivo Bioequivalence and In Vitro Dissolution Testing (No Replacement)	Unknown	Biopharmaceutics	November 30, 2000
Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design (No Replacement)	July 1, 1992	Biopharmaceutics	November 30, 2000
Clinical Evaluation of Drugs to Prevent Dental Caries (No Replacement)	November 1, 1978	Clinical Medical	May 18, 2000
Clinical Evaluation of Drugs to Prevent, Control, and/or Treat Periodontal Disease (No Replacement)	November 1, 1978	Clinical Medical	May 18, 2000
OTC Treatment of Hypercholesterolemia (No Replacement)	October 27, 1997	OTC	August 3, 2000
Levothyroxine Sodium: Questions and Answers (Replaced by Levothyroxine Sodium Products Enforcement of August 14, 2001, Compliance Date and Submission of New Applications issued on July 13, 2001)	March 8, 2001	Procedural	July 13, 2001

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
The FDA Export Reform and Enhancement Act of 1996/ Export Certification Package Including ''Instructions for Requests for Certificate to Foreign Governments''	February 7, 2000	Office of Compliance (OC)	Division of Small Manufacturers Assistance; 1–800–638–2041 or 301–827–0111 or (FAX) Facts-on-Demand (FOD) at 1–800–899–0381 or Internet at http://www.fda.gov/ cdrh/ ggpmain.html	865
Commercial Distribution/Exhibit Letter	April 10, 1992	OC	Do	246
Color Additive Status List (Inspection Operations Manual)	February 1, 1989	OC	Do	268
FDA Guide for Validation of Biological Indicator Incubation Time	January 1, 1986	OC	Do	283

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88–8264)	March 1, 1988	OC	Do	286
Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers (FDA 90–4236)	September 1, 1989	OC	Do	295
Color Additive Petitions (p. 11–19 of PMA Manual)	June 1, 1987	OC	Do	296
Guidance for Preparation of PMA Manufacturing Information	August 1, 1992	OC	Do	448
Civil Money Penalty Policy; Guidance for FDA Staff	June 8, 1999	OC	Do	1124
General Principles of Software Validation; Draft Guidance	June 9, 1997	OC	Do	938
Classification Names for Medical Devices and In Vitro Diagnostic Products (FDA Pub. No. 95–4246)	March 1, 1995	OC	Do	10
Cover Letter/Guidance Document on the Performance Standard for Electrode Lead Wires and Patient Cable	March 9, 1998	OC	Do	1197
Guidance on Medical Device Tracking [FDAMA]; Guidance for Industry and FDA Staff	January 24, 2000	OC	Do	169
Compliance Program Guidance Manual: Inspection of Medical Devices; Draft	August 12, 1999	OC	Do	1702
Procedures for Laboratory Compliance Testing of Television Receivers—Part of TV Packet	May 1, 1986	OC	Do	945
Sec. 300.600 Commercial Distribution with Regard to Premarket Notification [510(k)] [CPG 7124.19]	September 24, 1987	OC	Do	181
Letter to Medical Device Manufacturer on Pentium Processors	February 14, 1995	OC	Do	456
Implementation of the Biomaterials Access Assurance Act of 1998	April 2, 2001	OC	Do	1324
Guideline for the Monitoring of Clinical Investigations	January 1, 1988	OC	Do	428
Regulating In Vitro Diagnostic Device (IVD) Studies; Guidance for FDA Staff	December 17, 1999	OC/Division of Bioresearch Monitoring (DBM)	Do	1132
Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects	March 19, 1999	OC/DBM	Do	2229
Guidance on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables	November 15, 1999	OC/Division of Enforcement (DOE) I	Do	1129
Guidance on Quality System Regulation Information for Various Premarket Submissions; Draft	August 3, 1999	OC/DOEII	Do	1140
Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves; Guidance for Industry—Draft	July 26, 2000	OC/DOEII	Do	1141
Manufacturers/Assemblers of Diagnostic X-Ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g)	October 13, 1993	OC/DOEI	Do	116
Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and their Major Components	January 1, 1982	OC/DOEI	Do	257

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Exemption From Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers	September 16, 1981	OC/DOEI	Do	343
Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi)	May 17, 1993	OC/DOEI	Do	545
Clarification of Radiation Control Regulations for Diagnostic X-Ray Equipment (FDA 89–8221)	March 1, 1989	OC/DOEI	Do	758
CPG 7133.19: Retention of Microwave Oven Test Record/Cover Letter: 08/24, 1981 Retention of Records Required by 21 CFR [Part] 1002	March 1, 1995	OC/DOEI	Do	880
Guideline for the Manufacture of In Vitro Diagnostic Products	January 10, 1994	OC/DOEI	Do	918
A Guide 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	OC/DOEI	Do	977
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	OC/DOEI	Do	978
A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammographic X-Ray Systems	March 1, 1996	OC/DOEI	Do	979
Compliance Program Guidance Manual; Field Compliance Testing of Diagnostic (Medical) X-Ray Equipment; Guidance for FDA Staff	March 15, 2000	OC/DOEI	Do	1133
Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA	April 2, 2001	OC/DOEI	Do	2619
Guide for Submission of Information on Accelerators Intended to Emit X-Radiation Required Pursuant to 21 CFR 1002.10	April 1, 1971	OC/DOEI&III	Do	235
Abbreviated Reports on Radiation Safety for Microwave Products (Other Than Microwave Ovens)—E.G. Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric Heaters, Security Systems	August 1, 1995	OC/DOEI&III	Do	236
Guide for Preparing Reports on Radiation Safety of Microwave Ovens	March 1, 1985	OC/DOEI&III	Do	239
Reporting Guide for Laser Light Shows and Displays (21 CFR [Part] 1002) (FDA 88–8140)	September 1, 1995	OC/DOEI&III	Do	251
Guide for Filing Annual Reports for X-Ray Components and Systems	July 1, 1980	OC/DOEI&III	Do	253
Reporting and Compliance Guide for Television Products Including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Information and Guidance	October 1, 1995	OC/DOEI&III	Do	260
Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (Replaces FDA 82–8127)	September 1, 1995	OC/DOEI&III	Do	264

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use	September 1, 1996	OC/DOEI&III	Do	399
Letter to Manufacturers and Importers of Microwave Ovens: Information Requirements for Cookbooks and User and Service Manuals	October 31, 1988	OC/DOEI&III	Do	697
Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products	August 1, 1995	OC/DOEI&III	Do	951
Guide for Preparing Product Reports for Medical Ultrasound Products	September 1, 1996	OC/DOEI&III	Do	960
Letter—Manufacturers, Distributors and Importers of Condom Products	February 23, 1994	OC/DOEII	Do	52
Letter—Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt)	February 13, 1989	OC/DOEII	Do	53
Letter—Condom Manufacturers and Distributors	April 5, 1994	OC/DOEII	Do	56
Letter to Manufacturers/Repackers Using Cotton	April 22, 1994	OC/DOEII	Do	101
Guide for Preparing Product Reports for Lasers and Products Containing Lasers	September 1, 1995	OC/DOEII	Do	277
Compliance Guide for Laser Products (FDA 86–8260)	September 1, 1985	OC/DOEII	Do	278
Condoms: Inspection and Sampling at Domestic Manufacturers and of All Repackers; Sampling From All Importers (Damaska Memo to Field on 4/8, 1987)	April 8, 1987	OC/DOEII	Do	293
Dental Handpiece Sterilization (Dear Doctor Letter)	September 28, 1992	OC/DOEII	Do	589
Latex Labeling Letter (Johnson)	March 18, 1993	OC/DOEII	Do	831
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	OC/DOEII	Do	851
Letter to Industry, Powered Wheelchair Manufacturers From RM Johnson	May 10, 1993	OC/DOEII	Do	869
Hazards of Volume Ventilators and Heated Humidifiers	September 15, 1993	OC/DOEII	Do	901
Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals	February 3, 1994	OC/DOEII	Do	933
Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Levels of Exposure	June 23, 1978	OC/DOEII	Do	1019
Letter to: Manufacturers and Users of Lasers for Refractive Surgery [Excimer]	October 10, 1996	OC/DOEII	Do	1093
Shielded Trocars and Needles Used for Abdominal Access During Laparoscopy	August 23, 1996	OC/DOEII	Do	1122
Surveillance and Detention Without Physical Examination of Condoms; Guidance for Industry; Draft	August 14, 2000	OC/DOEII	Do	1139
All U.S. Condom Manufacturers, Importers and Repackagers	April 7, 1987	OC/DOEII	Do	2510

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Manufacturers and Initial Distributors of Hemodialyzers	May 23, 1996	OC/DOEII	Do	2507
Laser Light Show Safety—Who's Responsible? (FDA 86–8262)	May 1, 1986	OC/DOEIII	Do	13
Suggested State Regulations for Control of Radiation—Volume II Nonionizing Radiation—Lasers (FDA Pub. No. 83–8220)	January 1, 1982	OC/DOEIII	Do	70
Letter to All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist	May 28, 1981	OC/DOEIII	Do	231
Guide for Submission of Information on Industrial X-Ray Equipment Required Pursuant to 21 CFR 1002.10	March 1, 1973	OC/DOEIII	Do	237
Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1002.10	April 30, 1974	OC/DOEIII	Do	240
Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40	February 1, 1975	OC/DOEIII	Do	241
Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)	October 1, 1987	OC/DOEIII	Do	243
Computerized Devices/Processes Guidance—Application of the Medical Device GMP to Computerized Devices and Manufacturing Processes	May 1, 1992	OC/DOEIII	Do	247
Guide for Preparing Product Reports for Ultrasonic Therapy Products (Physical Therapy Only)	August 1, 1996	OC/DOEIII	Do	249
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)	September 1, 1980	OC/DOEIII	Do	254
Guide for Preparing Annual Reports for Ultrasonic Therapy Products	September 1, 1996	OC/DOEIII	Do	261
Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products (Replaces FDA 82–8127)	September 1, 1995	OC/DOEIII	Do	262
Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps (Replaces FDA 82–8127)	September 1, 1995	OC/DOEIII	Do	263
Quality Control Guide for Sunlamp Products (FDA 88–8234)	March 1, 1988	OC/DOEIII	Do	270
Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems	September 1, 1984	OC/DOEIII	Do	271
Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR [Part] 1002)	September 1, 1995	OC/DOEIII	Do	279
Letter: Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products	August 21, 1986	OC/DOEIII	Do	342
Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR [Part] 1002)	September 1, 1995	OC/DOEIII	Do	348
Quality Control Practices for Compliance With the Federal Mercury Vapor Lamp Performance Standard	May 1, 1980	OC/DOEIII	Do	349

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Keeping Up With the Microwave Revolution (FDA Pub. No. 91–4160)	March 1, 1990	OC/DOEIII	Do	356
Quality Assurance Guidelines for Hemodialysis Devices	February 1, 1991	OC/DOEIII	Do	507
Letter to Manufacturers and Importers of Microwave Ovens—Open Door Operation of Microwave Ovens as a Result of Oven Miswiring	March 28, 1980	OC/DOEIII	Do	646
Reporting of New Model Numbers to Existing Model Families	June 14, 1983	OC/DOEIII	Do	675
Import: Radiation-Producing Electronic Products (FDA 89–8008)	November 1, 1988	OC/DOEIII	Do	756
Unsafe Patient Lead Wires and Cables	September 3, 1993	OC/DOEIII	Do	889
Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device [Form FDA 3147]	July 1, 1998	OC/DOEIII	Do	903
Letter to Trade Association: Reuse of Single-Use or Disposable Medical Devices	December 27, 1995	OC/DOEIII	Do	961
Design Control Guidance for Medical Device Manufacturers	March 11, 1997	OC/DOEIII	Do	994
Keeping Medical Devices Safe From Electromagnetic Interference	July 1, 1995	OC/DOEIII	Do	1081
Medical Devices and EMI: The FDA Perspective	January 1, 1995	OC/DOEIII	Do	1082
Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations		OC/DOEIII	Do	1086
Safety of Electrically Powered Products: Letter to Medical Device and Electronic Product Manufacturers From Lillian Gill and BHB Correction Memo	September 18, 1996	OC/DOEIII	Do	1087
Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Guidance for Industry and for FDA Staff	August 14, 2000	OC/DOEIII	Do	1168
Labeling for Electronic Anti-Theft Systems; Guidance for Industry; Final	August 15, 2000	OC/DOEIII	Do	1170
Wireless Medical Telemetry Risks and Recommendations, Guidance for Industry; Final	September 27, 2000	OC/DOEIII	Do	1173
Policy on Warning Label Required on Sunlamp Products	June 25, 1985	OC/DOEIII	Do	1343
Policy on Lamp Compatibility (Sunlamps)	September 2, 1986	OC/DOEIII	Do	2343
Guidance for Industry on the Likelihood of Facilities Inspections When Modifying Devices Subject to Premarket Approval	August 5, 1999	OC/Division of Program Operations (DPO)	Do	1269
Guidance on IDE Policies and Procedures [FDAMA]; Final	January 20, 1998	Office of Device Evaluation (ODE)	Do	882
Color Additives for Medical Devices	November 15, 1995	ODE	Do	575
Preamendment Class III Devices	March 11, 1992	ODE	Do	584
Viable Bacteriophage in CO2 Laser Plume: Aerodynamic Size Distribution	Date not available	ODE	Do	595
Guidance for Submitting Reclassification Petition	June 1, 1989	ODE	Do	609

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Electromagnetic Compatibility for Medical Devices: Issues and Solutions; Memorandum	June 13, 1995	ODE	Do	639
SMDA Changes—Premarket Notification; Regulatory Requirements for Medical Devices [510(k)] Manual Insert	April 17, 1992	ODE	Do	655
''Real-Time'' Review Program for Premarket Approval Application (PMA) Supplements	April 22, 1997	ODE	Do	673
Classified Convenience Kits	April 30, 1993	ODE	Do	789
30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH [FDAMA]; Final	February 19, 1998	ODE	Do	795
Suggested Content for Original IDE Application Cover Letter—Version 4	February 27, 1996	ODE	Do	797
Device Specific Guidance Documents (List)	May 11, 1993	ODE	Do	815
PMA Shell Development and Modular Review; Guidances for the Medical Device Industry; Final	November 6, 1998	ODE	Do	835
Determination of Intended Use for 510(k) Devices—Guidance for Industry and CDRH Staff [FDAMA]; Final	January 30, 1998	ODE	Do	857
Premarket Notification [510(k)] Status Request Form, Revised	March 14, 1997	ODE	Do	858
CDRH's 510(k)/IDE/PMA Refuse to Accept/Accept/File Policies	June 30, 1993	ODE	Do	859
Indications for Use Statement	February 6, 1996	ODE	Do	879
The New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final	March 20, 1998	ODE	Do	905
Preamendments Class III Strategy; SXAlpert	April 19, 1994	ODE	Do	611
Letter to Industry, Powered Wheelchair/Scooter or Accessory/Component Manufacturer From Susan Alpert, Ph.D., M.D.	May 26, 1994	ODE	Do	883
ODE Executive Secretary Guidance Manual	August 7, 1987	ODE	Do	1338
Modifications to Devices Subject to Premarket Approval—The PMA Supplement Decision Making Process; Guidance for Industry; Draft	August 6, 1998	ODE	Do	102
CDRH Submissions Coversheet [PMA/PDP/510k/IDE]	May 8, 1998	ODE	Do	147
Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff [FDAMA]; Final	February 19, 1998	ODE	Do	159
Limulus Amebocyte Lysate; Reduction of Samples for Testing	October 23, 1987	ODE	Do	178
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance	April 1, 1996	ODE	Do	198
New Section 513(f)(2)—Evaluation of Automatic Class III Designation; Guidance for Industry and CDRH Staff [FDAMA]; Final	February 19, 1998	ODE	Do	199

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Methods for Conducting Recall Effectiveness Checks	June 16, 1978	ODE	Do	225
Suggestions for Submitting a Premarket Approval (PMA) Application	April 1, 1993	ODE	Do	228
Guidance for Off-the-Shelf Software Use in Medical Devices; Final	September 9, 1999	ODE	Do	1252
Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices	December 1, 1983	ODE	Do	267
Points to Consider in the Characterization of Cell Lines Used to Produce Biological Products (From John C. Petricciani, M.D.)	June 1, 1984	ODE	Do	269
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff [FDAMA]	February 19, 1998	ODE	Do	310
Format for IDE Progress Reports	June 1, 1996	ODE	Do	311
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—For Use by CDRH and Industry [FDAMA]; Final	February 19, 1998	ODE	Do	322
Industry Representatives on Scientific Panels	March 27, 1987	ODE	Do	329
PMA Review Schedule [P87–1]	March 31, 1988	ODE	Do	333
Necessary Information for Diagnostic Ultrasound 510(k) (Draft)	November 24, 1987	ODE	Do	335
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for FDA and Reviewers and Industry; Final	May 29, 1998	ODE	Do	337
Master Files Part III; Guidance on Scientific and Technical Information	June 1, 1987	ODE	Do	338
510(k) Quality Review Program (Blue Book Memo) (I96–1)	March 29, 1996	ODE	Do	344
FDA Policy for the Regulation of Computer Products (Draft)	November 13, 1989	ODE	Do	351
Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical Devices Marketed Prior to May 28, 1976	January 1, 1990	ODE	Do	352
4-of-A-Kind PMAs	October 1, 1991	ODE	Do	371
Supplements to Approved Applications for Class III Medical Devices: Use Published Literature, Use of Previously Submitted Materials, and Priority Review [FDAMA]; Guidance for Industry; Final	May 20, 1998	ODE	Do	380
Substantial Equivalence (SE) Decision Making Documentation ATTACHED: ''SE'' Decision Making Process (Detailed), i.e., the Decision Making Tree	January 1, 1990	ODE	Do	390
Shelf Life of Medical Devices	March 1, 1991	ODE	Do	415
Guideline on General Principles of Process Validation	May 1, 1987	ODE	Do	425
Guideline on Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	ODE	Do	426

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Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test	December 1, 1987	ODE	Do	427
General/Specific Intended Use [FDAMA]; Draft Guidance for Industry	November 4, 1998	ODE	Do	499
Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages [Blue Book Memo #P98–1]; Final	October 10, 1997	ODE	Do	563
Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources and T93–28 dated 6/25, 1993, Device ''Fast Track'' Plan Announcement (Include with 926–930)	June 30, 1993	ODE	Do	931
New Model Medical Device Development Process; Guidance for Industry; Final	July 21, 1998	ODE	Do	1101
Guidance on the Use of Standards in Substantial Equivalence Determinations; Final	March 12, 2000	ODE	Do	1131
Guidance for Industry and for FDA Reviewers; Interpretive Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997	August 9, 2000	ODE	Do	1135
Evidence Models for the Least Burdensome Means to Market; Guidance for Industry and FDA Reviewers; Draft	September 1, 1999	ODE	Do	1154
Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	September 3, 1996	ODE	Do	1198
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	ODE	Do	1073
Guidance on Amended Procedures for Advisory Panel Meetings	July 22, 2000	ODE	Do	413
Medical Devices Containing Materials Derived From Animal Sources (Except for In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry; Final	November 16, 1998	ODE	Do	2206
Frequently Asked Questions on the New 510(k) Paradigm; Guidance for Industry; Final	October 22, 1998	ODE	Do	2230
The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Draft Guidance for FDA and Industry	May 3, 2001	ODE	Do	1332
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters	September 12, 1994	ODE Division of Reproductive, Abdominal, and Radiological Devices (DRARD)	Do	97
Checklist for Mechanical Lithotripters and Stone Dislodgers Used in Gastroenterology and Urology	November 1, 1994	ODE/DRARD	Do	98
Convenience Kits Interim Regulatory Guidance (Include 874)	May 20, 1997	ODE/510K	Do	562

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Announcement: Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Att. A Interagency Agreement, Att. B Criteria for Categorization of Investigational Devices #D95–2 (Blue Book Memo)	September 15, 1995	ODE/BlueBook	Do	106
Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices #G90–2 (Blue Book Memo)	October 19, 1990	ODE/BlueBook	Do	30
Consolidated Review of Submissions for Lasers and Accessories #G90–1 (Blue Book Memo)	October 19, 1990	ODE/BlueBook	Do	31
Review of Final Draft Medical Device Labeling #P91–4 (Blue Book Memo)	August 29, 1991	ODE/BlueBook	Do	34
Review of 510(k)s for Computer Controlled Medical Devices #K91–1 (Blue Book Memo)	August 29, 1991	ODE/BlueBook	Do	35
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	ODE/BlueBook	Do	164
ODE Regulatory Information for the Office of Compliance—Information Sharing Procedures #G87–2 (Blue Book Memo)	May 15, 1987	ODE/BlueBook	Do	276
Panel Review of ''Me-Too'' Devices #P86–6 (Blue Book Memo)	July 1, 1986	ODE/BlueBook	Do	280
Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program #K86–3 (Blue Book Memo)	June 30, 1986	ODE/BlueBook	Do	289
PMA Filing Decisions #P90–2 (Blue Book Memo)	May 18, 1990	ODE/BlueBook	Do	297
PMAs—Early Review and Preparation of Summaries of Safety and Effectiveness #P86–1 (Blue Book Memo)	January 27, 1986	ODE/BlueBook	Do	302
Criteria for Panel Review of PMA Supplements #P86–3 (Blue Book Memo)	January 30, 1986	ODE/BlueBook	Do	304
Review and Approval of PMAs of Licensees #P86–4 (Blue Book Memo)	October 22, 1990	ODE/BlueBook	Do	305
Panel Report and Recommendations on PMA Approvals #P86–5 (Blue Book Memo)	April 18, 1986	ODE/BlueBook	Do	306
510(k) Sign-Off Procedures #K94–2 (Blue Book Memo)	June 3, 1994	ODE/BlueBook	Do	308
Review of Laser Submissions #G88–1 (Blue Book Memo)	April 15, 1988	ODE/BlueBook	Do	330
Delegation of IDE Actions #D88–1 (Blue Book Memo)	April 26, 1988	ODE/BlueBook	Do	331
Premarket Notification—Consistency of Reviews #K89–1 (Blue Book Memo)	February 28, 1989	ODE/BlueBook	Do	339
Telephone Communications Between ODE Staff and Manufacturers #I93–1 (Blue Book Memo)	January 29, 1993	ODE/BlueBook	Do	360
510(k) Sterility Review Guidance—and Revision of 11/18/1994 #K90–1 (Blue Book Memo)	February 12, 1990	ODE/BlueBook	Do	361
Review of IDEs for Feasibility Studies #D89–1 (Blue Book Memo)	May 17, 1989	ODE/BlueBook	Do	362

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Toxicology Risk Assessment Committee #G89–1 (Blue Book Memo)	August 9, 1989	ODE/BlueBook	Do	363
Assignment of Review Documents #I90–2 (Blue Book Memo)	August 24, 1990	ODE/BlueBook	Do	366
Meetings With the Regulated Industry #I89–3 (Blue Book Memo)	November 20, 1989	ODE/BlueBook	Do	367
Policy Development and Review Procedures #I90–1 (Blue Book Memo)	February 15, 1990	ODE/BlueBook	Do	368
PMA Supplements: ODE Letter to Manufacturers; Identifies Situations Which May Require the Submission of a PMA Supplement (When PMA Supplements Are Required) #P90–1 (Blue Book Memo)	April 24, 1990	ODE/BlueBook	Do	387
510(k) Refuse to Accept Procedures #K94–1 (Blue Book Memo)	May 20, 1994	ODE/BlueBook	Do	401
PMA Refuse to File Procedures #P94–1 (Blue Book Memo)	May 20, 1994	ODE/BlueBook	Do	402
Premarket Approval Application (PMA) Closure #P94–2 (Blue Book Memo)	July 8, 1994	ODE/BlueBook	Do	403
PMA/510(k) Triage Review Procedures #G94–1 (Blue Book Memo)	May 20, 1994	ODE/BlueBook	Do	404
Goals and Initiatives for the IDE Program #D95–1 (Blue Book Memo)	July 12, 1995	ODE/BlueBook	Do	405
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	ODE/BlueBook	Do	406
IDE Refuse to Accept Procedures #D94–1 (Blue Book Memo)	May 20, 1994	ODE/BlueBook	Do	410
Device Labeling Guidance #G91–1 (Blue Book Memo)	March 8, 1991	ODE/BlueBook	Do	414
Clinical Utility and Premarket Approval #P91–1 (Blue Book Memo)	May 3, 1991	ODE/BlueBook	Do	443
Panel Review of Premarket Approval Applications #P91–2 (Blue Book Memo)	May 3, 1991	ODE/BlueBook	Do	444
PMA Compliance Program #P91–3 (Blue Book Memo)	May 3, 1991	ODE/BlueBook	Do	445
Document Review Processing #I91–1 (Blue Book Memo)	February 12, 1992	ODE/BlueBook	Do	446
Integrity of Data and Information Submitted to ODE #I91–2 (Blue Book Memo)	May 29, 1991	ODE/BlueBook	Do	447
Nondisclosure of Financially Sensitive Information #I92–1 (Blue Book Memo)	March 5, 1992	ODE/BlueBook	Do	587
Memorandum of Understanding Regarding Patient Labeling Review (Blue Book Memo #G96–3))	August 9, 1996	ODE/BlueBook	Do	806
Continued Access to Investigational Devices During PMA Preparation and Review (Blue Book Memo) (D96–1)	July 15, 1996	ODE/BlueBook	Do	872

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510(k) Additional Information Procedures #K93–1 (Blue Book Memo)	July 23, 1993	ODE/BlueBook	Do	886
Overdue IDE Annual Progress Report Procedures #D93–1 (Blue Book Memo)	July 23, 1993	ODE/BlueBook	Do	887
Documentation and Resolution of Differences of Opinion on Product Evaluations #G93–1 (Blue Book Memo)	December 23, 1993	ODE/BlueBook	Do	920
Deciding When to Submit a 510(k) for a Change to an Exisiting Device; (Blue Book Memo #K97–1)	January 10, 1997	ODE/BlueBook	Do	1935
Interagency Agreement Between FDA and HCFA; #D95–2, Attachment A	September 15, 1995	ODE/BlueBook	Do	2106
Executive Secretaries Guidance Manual #G87–3	August 7, 1987	ODE/BlueBook	Do	2326
Criteria for Categorization of Investigational Devices (HCFA); #D95–2, Attachment B	September 15, 1995	ODE/BlueBook	Do	3106
Center for Devices and Radiological Health's Premarket Notification [510(k)] Refuse to Accept Policy—(Updated Checklist March 14, 1995)	June 30, 1993	ODE/BlueBook	Do	3859
HCFA Reimbursement Categorization Determinations for FDA-Approved IDEs	October 31, 1995	ODE/BlueBook	Do	4106
Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy	June 30, 1993	ODE/BlueBook	Do	4859
Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications; Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance; Draft Guidance—Not for Implementation	November 14, 2000	ODE Division of Clinical Laboratory Devices (DCLD)	Do	152
Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies	August 31, 1995	ODE/DCLD	Do	1191
Guidance for Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing; Draft	December 21, 1999	ODE/DCLD	Do	1359
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	ODE/DCLD	Do	51
Review Criteria for Blood Culture Systems	August 12, 1991	ODE/DCLD	Do	82
Points to Consider for Collection of Data in Support of In Vitro Device Submissions for 510(k) Clearance	September 26, 1994	ODE/DCLD	Do	95
Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	February 20, 1996	ODE/DCLD	Do	122
Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies; Draft	August 31, 1995	ODE/DCLD	Do	1191
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	ODE/DCLD	Do	165

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Assessing the Safety/Effectiveness of Home-Use In Vitro Diagnostic Devices (IVDs): Points to Consider Regarding Labeling and Premarket Submissions; Draft	October 1, 1988	ODE/DCLD	Do	272
Guidance for Submission of Immunohistochemistry Applications to the FDA; Final	June 3, 1998	ODE/DCLD	Do	364
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers	July 15, 1991	ODE/DCLD	Do	417
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	ODE/DCLD	Do	459
Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs using Monoclonal Antibodies; Draft	September 26, 1991	ODE/	Do	475
Points to Consider for Hematology Quality Control Materials	September 30, 1997	ODE/DCLD	Do	512
Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents	August 1, 1992	ODE/DCLD	Do	527
Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices/Cover Letter Dated March 14, 1996	February 1, 1996	ODE/DCLD	Do	553
Review Criteria for Devices Intended for the Detection of Hepatitis B ''e'' Antigen and Antibody to HBe	December 30, 1991	ODE/DCLD	Do	554
Guidance Criteria for Cyclosporine PMAs	January 24, 1992	ODE/DCLD	Do	564
Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter Pylori	September 17, 1992	ODE/DCLD	Do	588
Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)	September 27, 1995	ODE/DCLD	Do	592
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 Bi; Draft	September 10, 1992	ODE/DCLD	Do	603
Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology	February 14, 1996	ODE/DCLD	Do	604
Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use	July 14, 1995	ODE/DCLD	Do	605
Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases	May 31, 1990	ODE/DCLD	Do	629
Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for IVDs; Draft	September 30, 1991	ODE/DCLD	Do	658
Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	May 15, 1992	ODE/DCLD	Do	770

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Guidance Document for 510(k) Submission of Fecal Occult Blood Tests; Draft	July 29, 1992	ODE/DCLD	Do	772
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens	January 1, 1992	ODE/DCLD	Do	778
Guidance Document for 510(k) Submission of Immunoglobulins A, G, M, D and E Immunoglobulin System In Vitro Devices; Draft	September 1, 1992	ODE/DCLD	Do	785
Review Criteria for the Assessment of Allergen-Specific Immunoglobulin E (IGE) In Vitro Diagnostic Devices Using Immunological Test Methodologies	March 2, 1993	ODE/DCLD	Do	800
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	ODE/DCLD	Do	848
Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms; Draft	June 14, 1993	ODE/DCLD	Do	861
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. [Tuberculosis (TB)]	July 6, 1993	ODE/DCLD	Do	862
Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers	June 10, 1996	ODE/DCLD	Do	950
Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification [510(k)] to FDA	September 19, 1996	ODE/DCLD	Do	957
Points to Consider for Cervical Cytology Devices	July 25, 1994	ODE/DCLD	Do	968
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	ODE/DCLD	Do	980
In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1102
In Vitro Diagnostic Chloride Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1103
In Vitro Diagnostic Creatinine Test System; Guidance for Industry; Final	July 2, 1998	ODE/DCLD	Do	1104
In Vitro Diagnostic Glucose Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1105
In Vitro Diagnostic Potassium Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1107
In Vitro Diagnostic Sodium Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1109
In Vitro Diagnostic Urea Nitrogen Test System; Guidance for Industry; Final	July 6, 1998	ODE/DCLD	Do	1110
Guidance for Administrative Procedures for CLIA Categorization; Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance; Draft	August 14, 2000	ODE/DCLD	Do	1143

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA Applications	March 1, 2001	ODE/DCLD	Do	1147
Guidance for Over-the-Counter (OTC) Ovulation Predictor 510(k)s	July 22, 2000	ODE/DCLD	Do	1171
Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s	July 22, 2000	ODE/DCLD	Do	1172
Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices; Draft	March 8, 2000	ODE/DCLD	Do	631
In Vitro Diagnostic C-Reactive Protein Immunological Test System; Guidance for Industry; Final	July 20, 1998	ODE/DCLD	Do	1246
Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Guidance for Industry: Final	February 22, 1999	ODE/DCLD	Do	1247
Guidance on Labeling for Laboratory Tests; Guidance for Industry; Draft	June 24, 1999	ODE/DCLD	Do	1352
Premarket Approval Applications for Assays Pertaining to Hepatitis C Viruses (HCV) That Are Indicated for Diagnosis or Monitoring of HCV Infection or Associated Disease; Draft	October 8, 1999	ODE/DCLD	Do	1353
Class II Special Control Guidance Document for Anti-Saccharomyces Cerevisiae (S. Cerevisiae) Antibody (ASCA) Premarket Notifications; Final	August 23, 2000	ODE/DCLD	Do	1183
Guidance for Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final; Guidance for Industry and FDA	November 1, 2000	ODE/DCLD	Do	1184
Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs	October 30, 1996	ODE/DCLD	Do	1631
Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications; Guidance for Industry; Draft	November 14, 2000	ODE/DCLD	Do	2209
Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Guidance for Industry	February 3, 1999	ODE/DCLD	Do	2231
Document for Special Controls for Erythropoietin Assay Premarket Notifications [510(k)s]; Guidance for Industry; Final	April 28, 1999	ODE/DCLD	Do	2241
In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Guidance for Industry and FDA Reviewers/Staff; Final	April 27, 1999	ODE/DCLD	Do	2242
Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers	November 30, 2000	ODE/DCLD	Do	1072
Guidance for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions	June 28, 2000	ODE Division of Cardiovascular and Respiratory Devices (DCRD)	Do	1161
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions; Final	November 1, 2000	ODE/DCRD	Do	372

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Investigational Device Exemption (IDE) Study Enrollment for Cardiac Ablation of Typical Atrial Flutter; Final Guidance for Industry and FDA Reviewers	November 8, 2000	ODE/DCRD	Do	1199
Guidance Document for Vascular Prostheses 510(k) Submissions; Guidance for Industry and FDA Staff; Final	November 1, 2000	ODE/DCRD	Do	1357
Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff	January 31, 2001	ODE/DCRD	Do	1358
1–Consolidated Annual Report for a Device Product Line (1–CARD); Pilot for Preparation of Annual Reports for Pacemaker Premarket Approval Applications	July 6, 2000	ODE/DCRD	Do	1167
Excerpts Related to EMI From November 1993 Anesthesiology and Respiratory Devices Branch (Including Electromagnetic Compatibility Standard for Medical Devices; 10/1/79)	November 1, 1993	ODE/DCRD	Do	638
Guidance for Infant/Child Apnea Monitor 510(k) Submissions	September 22, 2000	ODE/DCRD	Do	1178
Guidance for Industry and for FDA Reviewers: Recommended Clinical Study Design for Ventricular Tachycardia Ablation	May 7, 1999	ODE/DCRD	Do	2244
Guidance for Industry: Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA; Draft	August 25, 1999	ODE/DCRD	Do	266
Guidance for Cardiovascular Intravascular Filter 510(k) Submission; Final	November 26, 1999	ODE/DCRD	Do	24
Guidance for the Submission of 510(k) Premarket Notifications for Electrocardiograph (ECG) Electrode—Version 1.0	February 11, 1997	ODE/DCRD	Do	25
Guidance for the Submission of 510(k) Premarket Notifications for Electrocardiograph (ECG) Lead Switching Adapter—Version 1.0	February 11, 1997	ODE/DCRD	Do	26
Guidance Document Device: Electrocardiograph (ECG) Surface Electrode Tester—Version 1.0	February 11, 1997	ODE/DCRD	Do	27
Draft Guidance Outline—Points to Consider for Clinical Studies for Vasovasostomy Devices	November 30, 1993	ODE/DCRD	Do	100
Medical Device Labeling—Suggested Format and Content; Draft Document	April 25, 1997	ODE/DCRD	Do	119
Non-Invasive Blood Pressure (NIBP) Monitor Guidance	March 10, 1997	ODE/DCRD	Do	123
Policy for Expiration Dating (DCRD RB92–G)	October 30, 1992	ODE/DCRD	Do	137
Human Heart Valve Allografts; Draft	June 21, 1991	ODE/DCRD	Do	224
Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final	February 16, 2000	ODE/DCRD	Do	1632
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final	February 21, 2000	ODE/DCRD	Do	1622
Balloon Valvuloplasty Guidance for the Submission of an IDE Application and a PMA Application	January 1, 1989	ODE/DCRD	Do	370
Replacement Heart Valve Guidance; Draft	October 14, 1994	ODE/DCRD	Do	375

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Implantable Pacemaker Testing Guidance	January 12, 1990	ODE/DCRD	Do	383
Letter/Guidance: Vascular Graft Manufacturer, Developer, or Representative	May 11, 1990	ODE/DCRD	Do	391
Reviewer Guidance for Ventilators; Draft	July 1, 1995	ODE/DCRD	Do	500
Draft 510(k) Checklist for Urological Irrigation System and Tubing Set	August 1, 1995	ODE/DCRD	Do	515
Draft Guidance to Firms on Biliary Lithotripsy Studies	August 2, 1990	ODE/DCRD	Do	522
Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)	November 11, 1994	ODE/DCRD	Do	533
Letter: Notice to Manufacturers of Bone Mineral Densitometers	September 25, 1997	ODE/DCRD	Do	552
Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: Draft	September 30, 1997	ODE/DCRD	Do	560
Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Catheters	January 24, 1992	ODE/DCRD	Do	567
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	ODE/DCRD	Do	577
Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses	April 1, 1990	ODE/DCRD	Do	582
Draft Version: Electrode Recording Catheter Preliminary Guidance (Data to Be Sumitted to the FDA in Support of Premarket Notifications [510(k)s])	March 1, 1995	ODE/DCRD	Do	602
Cardiac Ablation Preliminary Guidance (Data to Be Submitted to the FDA in Support Investigation Device Exemption Application; Draft	March 1, 1995	ODE/DCRD	Do	619
Premarket Testing Guidelines for Falloposcopes	November 20, 1992	ODE/DCRD	Do	621
Guidelines for Evaluation of Non-Drug IUDs	September 28, 1976	ODE/DCRD	Do	641
Simplified 510(k) procedures for certain radiology devices: 12/21, 1993, letter from L Yin, ODE/ODE/DRARD, to NEMA	December 21, 1993	ODE/DCRD	Do	708
Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology	August 16, 1995	ODE/DCRD	Do	768
Heated Humidifier Review Guidance	August 30, 1991	ODE/DCRD	Do	780
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	October 1, 1993	ODE/DCRD	Do	784
Reviewer Guidance for Automatic X-Ray Film Processor 510(k)	February 1, 1990	ODE/DCRD	Do	788
Guidance for the Technical Content of a Premarket Approval (PMA) Application for an Endolymphatic Shunt Tube With Valve	April 1, 1990	ODE/DCRD	Do	791
Guidance for Magnetic Resonance Diagnostic Devices—Criteria for Significant Risk Investigations	September 29, 1997	ODE/DCRD	Do	793

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Draft Guidance for Preparation of PMA Applications for Testicular Prostheses	March 16, 1993	ODE/DCRD	Do	809
Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants	March 16, 1993	ODE/DCRD	Do	810
Draft Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis	May 30, 1997	ODE/DCRD	Do	842
Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents; Draft	May 1, 1995	ODE/DCRD	Do	846
Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence	November 29, 1995	ODE/DCRD	Do	850
Draft Guidance for Review of Bone Densitometer 510(k) Submissions	November 9, 1992	ODE/DCRD	Do	866
Battery Guidance	July 12, 1993	ODE/DCRD	Do	873
Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses; Draft	August 1, 1993	ODE/DCRD	Do	885
510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments	September 19, 1994	ODE/DCRD	Do	892
Draft Guidance for Hemodialyzer Reuse Labeling	October 6, 1995	ODE/DCRD	Do	899
Hysteroscopes and Gynecology Laparoscopes—Submission Guidance for a 510(k)—Includes 00192	March 27, 1996	ODE/DCRD	Do	907
Draft Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions	July 29, 1991	ODE/DCRD	Do	953
Intravascular Brachytherapy—Guidance for Data to be Submitted to the Food and Drug Administration in Support of Investigational Device Exemption (IDE) Applications; Draft	May 24, 1996	ODE/DCRD	Do	955
Percutaneous Transluminal Coronary Angioplasty Package Insert Template; Draft	February 7, 1995	ODE/DCRD	Do	959
Coronary and Cerebrovascular Guidewire Guidance	January 1, 1995	ODE/DCRD	Do	964
Guidance for Implantable Cardioverter-Defibrillators; Draft	June 24, 1996	ODE/DCRD	Do	965
Carotid Stent—Suggestions for Content of Submissions to the Food and Drug Administration in Support of Investigational Devices Exemption (IDE) Applications	October 26, 1996	ODE/DCRD	Do	974
Emergency Resuscitator Guidance; Draft	April 14, 1993	ODE/DCRD	Do	985
Review Guidelines for Oxygen Generators and Oxygen Equipment; Draft Document	April 14, 1993	ODE/DCRD	Do	986
Draft 510(k) Checklist for Condom Catheters	February 23, 1995	ODE/DCRD	Do	991
CDRH Interim Regulatory Policy for External Penile Rigidity Devices	September 10, 1997	ODE/DCRD	Do	992

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Reviewer Guidance on Face Masks and Shield for CPR; Draft	March 16, 1994	ODE/DCRD	Do	996
General Guidance Document: Non-Invasive Pulse Oximeter	September 7, 1992	ODE/DCRD	Do	997
Guidance for Peak Flow Meters for Over-the-Counter Sale	June 23, 1992	ODE/DCRD	Do	998
510(K) Submission Requirements for Peak Flow Meters; Draft	January 13, 1994	ODE/DCRD	Do	999
Guidance for Industry and FDA; Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions	February 21, 2000	ODE/DCRD	Do	1126
Guidance Document for Premarket Notification Submission for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer; Final	January 24, 2000	ODE/DCRD	Do	1157
Latex Condoms for Men—Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions	July 23, 1998	ODE/DCRD	Do	1250
Guidance for Industry—Uniform Contraceptive Labeling; Final	July 23, 1998	ODE/DCRD	Do	1251
Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final	January 17, 2000	ODE/DCRD	Do	1361
Guidance for the Content of Premarket Notifications for Penile Rigidity Implants; Final	January 16, 2000	ODE/DCRD	Do	177
Federal Register Notice; Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures: Submission Guidance for a 510(k); Draft; Availability	September 10, 1998	ODE/DCRD	Do	1620
Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)	August 1, 1995	ODE/DCRD	Do	1907
Guidance for Industry and CDRH Reviewers—Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems; Final	August 7, 1998	ODE/DCRD	Do	2202
Noise Claims in Hearing Aid Labeling; Final	October 21, 1998	ODE/DCRD	Do	2210
Guidance for Industry—Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement); Final	November 5, 1998	ODE/DCRD	Do	2232
Guidance for Industry—Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm); Final	November 5, 1998	ODE/DCRD	Do	2233
Guidance for Industry—Harmonic Imaging With/Without Contrast—Premarket Notification; Final	November 16, 1998	ODE/DCRD	Do	2234
Guidance for Industry—Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters; Final	November 30, 1998	ODE/DCRD	Do	2235
Guidance for Industry—Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators; Final	November 20, 1998	ODE/DCRD	Do	2238
Guidance for Industry—Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance; Version 1; Final	November 19, 1998	ODE/DCRD	Do	2239

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Guidance for Industry—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	ODE/DCRD	Do	2240
Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents; Final	February 5, 1998	ODE/DCRD	Do	2243
Guidance for the Submission of 510(k)'s for Solid State X-Ray Imaging Devices; Final	August 6, 1999	ODE/DCRD	Do	644
Class II Special Control Guidance Document for Acute Upper Airway Obstruction Devices	July 30, 2000	ODE/DCRD	Do	1138
Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Draft	November 16, 1999	ODE Division of Dental, Infection Control and General Hospital Devices (DDIGD)	Do	1355
Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; Draft	February 8, 2000	ODE/DDIGD	Do	1156
Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA	March 2, 2001	ODE/DDIGD	Do	891
Guidance on the Content and Format of Premarket Notification 510(k) Submissions of Washers and Washer-Disinfectors	June 2, 1998	ODE/DDIGD	Do	4
Overview of Information Necessary for Premarket Notification Submissions for Endosseous Implants; Final	April 21, 1999	ODE/DDIGD	Do	86
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for an Endosseous Implant for Prosthetic Attachment	May 16, 1989	ODE/DDIGD	Do	353
Guidance on 510(k) Submissions for Implanted Infusion Ports	October 1, 1990	ODE/DDIGD	Do	392
Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles	April 1, 1993	ODE/DDIGD	Do	450
Guidance Document on Dental Handpieces	July 1, 1995	ODE/DDIGD	Do	556
Guidance on the Content and Format of Premarket Notification 510(k) Submissions for Liquid Chemical Germicides	December 6, 1996	ODE/DDIGD	Do	576
Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes	April 1, 1993	ODE/DDIGD	Do	821
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers	March 1, 1993	ODE/DDIGD	Do	822
Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps	March 1, 1993	ODE/DDIGD	Do	823
Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters	March 16, 1995	ODE/DDIGD	Do	824
Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities	March 1, 1993	ODE/DDIGD	Do	833

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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	ODE/DDIGD	Do	881
Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes	August 1, 1993	ODE/DDIGD	Do	888
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers	October 1, 1993	ODE/DDIGD	Do	895
Draft Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices With Sharps Injury Prevention Features (Antistick)	March 1, 1995	ODE/DDIGD	Do	934
Guidance for Industry and FDA Reviewers/Staff—Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Latex Products [Draize Testing]	January 13, 1999	ODE/DDIGD	Do	944
Information Necessary for Premarket Notification Submissions for Screw-Type Endossesous Implants	December 9, 1996	ODE/DDIGD	Do	948
Draft Guidance Document for the Preparation of Premarket Notification [510(k)'s] for Dental Alloys	March 3, 1997	ODE/DDIGD	Do	984
Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints	December 1, 1995	ODE/DDIGD	Do	993
Guidance on Premarket Notifications for Intravascular Administration Sets; Guidance for Industry and FDA Review Staff; Final	October 12, 2000	ODE/DDIGD	Do	1189
Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities	September 19, 1995	ODE/DDIGD	Do	1833
Groups Capable of Testing for Latex Skin Sensitization (Addendum to #944)	July 28, 1997	ODE/DDIGD	Do	1944
Guidance for Industry and FDA Reviewers; Neonatal and Neonatal Transport Incubators—Premarket Notifications; Final	September 18, 1998	ODE/DDIGD	Do	2201
Dental Impression Materials—Premarket Notification; Final	August 17, 1998	ODE/DDIGD	Do	2203
Dental Cements Premarket Notification; Final	August 18, 1998	ODE/DDIGD	Do	2204
OTC Denture Cushions, Pads, Reliners, Repair Kits and Partially Fabricated Denture Kits; Final	August 18, 1998	ODE/DDIGD	Do	2205
Guidance for the Preparation of a Premarket Notification [510(k)] for Direct Filling Dental Composites	November 27, 1998	ODE/DDIGD	Do	642
Guidance and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants; Final	January 3, 2000	ODE/DDIGD	Do	397
Class II Special Control Guidance Document: Pharmacy Compounding Devices; Final Guidance for Industry and FDA	March 12, 2001	ODE/DDIGD	Do	1326
Guidance for Industry: Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses; Final	April 28, 1998	ODE Division of General, Restorative and Neurological Devices (DGRND)	Do	6

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants	February 21, 1997	ODE/DGRND	Do	33
510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants	February 20, 1997	ODE/DGRND	Do	47
Letter: Core Study for Silicone Breast Implants	January 11, 1996	ODE/DGRND	Do	107
Protocol for Dermal Toxicity Testing for Devices in Contact With Skin (Draft)	January 1, 1985	ODE/DGRND	Do	124
Draft Version 1—Biofeedback Devices—Draft Guidance for 510(k) Content	August 1, 1994	ODE/DGRND	Do	143
Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices	March 28, 1995	ODE/DGRND	Do	180
Draft Guidance Document for Femoral Stem Prostheses	August 1, 1995	ODE/DGRND	Do	187
Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	June 1, 1994	ODE/DGRND	Do	207
Draft Version Guide for Cortical Electrode 510(k) Content	August 10, 1992	ODE/DGRND	Do	208
Draft Version Guidance for Clinical Data to be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators	August 20, 1992	ODE/DGRND	Do	209
Draft Version Cranial Perforator Guidance	July 13, 1994	ODE/DGRND	Do	212
Draft Version Neuro Endoscope Guidance	July 7, 1994	ODE/DGRND	Do	214
Galvanic Skin Response Measurement Devices—Draft Guidance for 510(k) Content	August 1, 1994	ODE/DGRND	Do	215
Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament Devices	February 18, 1993	ODE/DGRND	Do	233
Guidance for Industry, FDA Reviewers/Staff and Compliance Guidance Document for Powered Muscle Stimulator 510(k)s; Final	June 9, 1999	ODE/DGRND	Do	2246
Guidance for Industry—Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater; Final	August 30, 1999	ODE/DGRND	Do	54
Guide for TENS 510(k) Content (Draft)	August 1, 1994	ODE/DGRND	Do	300
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Submerged (Underwater) Exercise Equipment	July 26, 1995	ODE/DGRND	Do	307
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Electromyograph Needle Electrodes	July 26, 1995	ODE/DGRND	Do	325
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Exercise Equipment	July 26, 1995	ODE/DGRND	Do	326
Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	July 26, 1995	ODE/DGRND	Do	346

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance Document for the Preparation of Premarket Notification for Ceramic Ball Hip Systems	January 10, 1995	ODE/DGRND	Do	355
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	June 1, 1995	ODE/DGRND	Do	386
Draft Guidance Document for Testing Acetabular Cup Prostheses	May 1, 1995	ODE/DGRND	Do	453
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	ODE/DGRND	Do	487
Copy of October 9, 1992, Letter and Original Suture Labeling Guidance (Reformatted 12/17/1997)	October 9, 1992	ODE/DGRND	Do	502
Alternate Suture Labeling Resulting From the January 11, 1993, Meeting With HIMA (Reformatted 12/17/1997)	January 11, 1993	ODE/DGRND	Do	503
Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators	February 1, 1997	ODE/DGRND	Do	593
Draft Version—Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model	September 12, 1994	ODE/DGRND	Do	627
Guidance for Studies for Pain Therapy Devices—General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices	May 12, 1988	ODE/DGRND	Do	640
ORDB 510(k) Sterility Review Guidance	July 3, 1997	ODE/DGRND	Do	659
Draft Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices (ELD)	August 30, 1994	ODE/DGRND	Do	667
Draft Outline for a Guidance Document for Testing Orthopedic Bone Cement, Request for Comments by December 10, 1993	November 1, 1993	ODE/DGRND	Do	668
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Beds	July 26, 1995	ODE/DGRND	Do	689
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Immersion Hydrobaths	July 26, 1995	ODE/DGRND	Do	729
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables	July 26, 1995	ODE/DGRND	Do	735
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems	July 26, 1995	ODE/DGRND	Do	762
Electroencephalograph Devices Guidance for 510(k) Content; Draft	November 3, 1997	ODE/DGRND	Do	767
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Therapeutic Massagers and Vibrators	July 26, 1995	ODE/DGRND	Do	818
Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement (Replaces 8623 and 8093)	April 28, 1994	ODE/DGRND	Do	827

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices	July 26, 1995	ODE/DGRND	Do	828
Reviewers Guidance Checklist for Orthopedic External Fixation Devices	February 21, 1997	ODE/DGRND	Do	829
Draft Guidance for the Preparation of Premarket Notifications [510(k)]s for Cemented, Semi-Constrained Total Knee Prostheses	April 1, 1993	ODE/DGRND	Do	830
Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices—The Basic Elements	July 16, 1997	ODE/DGRND	Do	832
Draft 510(k) Guideline for General Surgical Electrosurgical Devices	May 10, 1995	ODE/DGRND	Do	904
Draft Guidance for Arthroscopes and Accessory 510(k)s	May 1, 1994	ODE/DGRND	Do	909
Guidance Document for Testing Biodegradable Polymer Implant Devices; Draft	April 20, 1996	ODE/DGRND	Do	914
Guidance Document for Testing Bone Anchor Devices; Draft	April 20, 1996	ODE/DGRND	Do	915
Guidance Document for Testing Non-Articulating, ''Mechanically Locked'', Modular Implant Components; Draft	May 1, 1995	ODE/DGRND	Do	916
Reviewers Guidance Checklist for Intramedullary Rods	February 21, 1997	ODE/DGRND	Do	956
Draft Guidance for Testing MR Interaction With Aneurysm Clips	May 22, 1996	ODE/DGRND	Do	958
Guidance for Industry—Guidance Document for Dura Substitute Devices; Final	August 13, 1999	ODE/DGRND	Do	1152
Guidance Document for Surgical Lamp 510Ks; Final	July 13, 1998	ODE/DGRND	Do	1244
Guidance for Industry—Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses; Draft	October 5, 1999	ODE/DGRND	Do	1354
Guidance Document for the Preparation of IDEs for Spinal Systems; Final	January 13, 2000	ODE/DGRND	Do	2250
Draft Guidance for the Preparation of an IDE Submission for a Interactive Wound and Burn Dressing	April 4, 1995	ODE/DGRND	Do	1817
Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance—Guidance Document for Powered Suction Pump 510(k)s	October 30, 1998	ODE/DGRND	Do	2207
Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Final	March 2, 1999	ODE/DGRND	Do	2247
Class II Special Controls Guidance Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis; Final	October 31, 2000	ODE/DGRND	Do	1193
Guidance for Dermabrasion Devices; Final	March 2, 1999	ODE/DGRND	Do	2248
Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing [510(k)]	May 31, 1995	ODE/DGRND	Do	2817

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; Draft	December 16, 1999	ODE/DGRND	Do	1356
Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief; Guidance for Industry; Draft	September 6, 2000	ODE/DGRND	Do	1179
Guidance for Surgical Suture 510(k)s; Guidance for Industry; Final	August 10, 2000	ODE/DGRND	Do	1180
Guidance for Neurological Embolization Devices; Guidance for Industry; Final	November 1, 2000	ODE/DGRND	Do	1151
Guidance for Spinal System 510(k)s	September 27, 2000	ODE/DGRND	Do	636
FDA Guidelines for Multifocal Intraocular Lens IDE Studies and PMAs	May 29, 1997	ODE Division of Ophthalmic and Ear, Nose, and Throat Devices (DOED)	Do	55
Announcement: Information for Manufacturers and Users of Lasers for Refractive Surgery [Excimer]	September 22, 1997	ODE/DOED	Do	93
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Surgical Mask—Draft	January 16, 1998	ODE/DOED	Do	94
New FDA Recommendations and Results of Contact Lens Study (7-Day Letter)	May 30, 1989	ODE/DOED	Do	265
Draft Premarket Notification 510(k) Guidance for Contact Lens Care Products	May 1, 1997	ODE/DOED	Do	674
Important Information About Rophae Intraocular Lenses	August 20, 1992	ODE/DOED	Do	811
Draft Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses and 6/28, 1994, Corrections to Pages 18 and 20	May 12, 1994	ODE/DOED	Do	896
Retinoscope Guidance; Final	July 8, 1998	ODE/DOED	Do	1240
Guidance for Industry—Ophthalmoscope Guidance (Direct and Indirect)	July 8, 1998	ODE/DOED	Do	1241
Slit Lamp Guidance; Final	July 13, 1998	ODE/DOED	Do	1242
Guidance for Industry and FDA Staff—Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval (PMA) Applications for Class III Rigid Gas Permeable Contact Lenses for Extended Wear; Final	August 11, 1998	ODE/DOED	Do	1249
Accountability Analysis for Clinical Studies for Ophthalmic Devices; Draft	August 4, 1999	ODE/DOED	Do	1350
Guidance on 510(k) Submissions for Keratoprostheses; Final	March 3, 1999	ODE/DOED	Do	1351
Amendment 1: Draft Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses	June 28, 1994	ODE/DOED	Do	1896
Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers [Excimer]	October 10, 1996	ODE/DOED	Do	2093
Third Party Review Guidance for Vitreous Aspiration and Cutting Device Premarket Notification [510(k)]	January 31, 1997	ODE/DOED	Do	2196

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance Document for Nonprescription Sunglasses; Final	October 9, 1998	ODE/DOED	Do	2208
Aqueous Shunts—510(k) Submissions; Final	November 16, 1998	ODE/DOED	Do	2236
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	ODE/DOED	Do	7093
Intraocular Lens (IOL) Guidance Document; Draft	October 14, 1999	ODE/DOED	Do	834
Refractive Implants: Guidance for Investigational Device Exemptions (IDE) and Premarket Approval (PMA) Applications	August 1, 2000	ODE/DOED	Do	1145
Guidance on Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses; Final	April 10, 2000	ODE/DOED	Do	1134
Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers; Final	March 12, 2000	ODE/DOED	Do	954
Information for a Latex Condom 510(k) Submission for Obstetrics-Gynecology Devices Branch—Draft	April 13, 1994	ODE Division of Reproductive, Abdominal, and Radiological Devices (DRARD)	Do	398
Guidance for the Content of Premarket Notifications for Urine Drainage Bags	June 7, 1994	ODE/DRARD	Do	96
Draft—510(k) Checklist for Conditioned Response Enuresis Alarms	November 23, 1994	ODE/DRARD	Do	99
Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter)	May 1, 1995	ODE/DRARD	Do	161
Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology	March 17, 1995	ODE/DRARD	Do	162
Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons	May 25, 1995	ODE/DRARD	Do	166
Draft 510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence	June 6, 1995	ODE/DRARD	Do	189
Draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology	June 22, 1995	ODE/DRARD	Do	190
Guidance (''Guidelines'') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories)	May 1, 1978	ODE/DRARD	Do	232
Guidance (''Guidelines'') for Evaluation of Fetal Clip Electrode	March 8, 1977	ODE/DRARD	Do	244
Guidance (''Guidelines'') for Evaluation of Tubal Occlusion Devices	November 22, 1977	ODE/DRARD	Do	245
Guidance (''Guidelines'') for Evaluation of Hysteroscopic Sterilization Devices	May 10, 1978	ODE/DRARD	Do	248
Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft Document	June 14, 1997	ODE/DRARD	Do	298

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application For A Cochlear Implant in Children Ages 2 Through to 17 Years	May 1, 1990	ODE/DRARD	Do	327
Guidance for Industry—Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Final	November 14, 1998	ODE/DRARD	Do	340
Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases	April 4, 1990	ODE/DRARD	Do	384
Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements	January 18, 1991	ODE/DRARD	Do	418
Guidance for the Content of Premarket Notifications for Conventional and Permeability Hemodialyzers; Final	August 7, 1998	ODE/DRARD	Do	421
Guidance for the Content of Premarket Notifications for Urethral Stents	February 10, 1993	ODE/DRARD	Do	431
Testing Guidance for Male Condoms Made From New Material (Non-Latex)	June 29, 1995	ODE/DRARD	Do	455
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology	February 10, 1993	ODE/DRARD	Do	482
Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems	July 29, 1994	ODE/DRARD	Do	490
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	ODE/DRARD	Do	1164
Guidance for the Submission of Premarket Notifications for Medical Image Management Devices; Guidance for Industry; Final	July 27, 2000	ODE/DRARD	Do	416
Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; Final	August 9, 2000	ODE/DRARD	Do	1226
Guidance for the Submission of Premarket Notifications for Photon-Emitting Brachytherapy Sources; Guidance for Industry; Final	August 2, 2000	ODE/DRARD	Do	1177
Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA	February 16, 2001	ODE/DRARD	Do	983
Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers	March 9, 2001	ODE/DRARD	Do	820
Class II Special Controls Guidance Document for Clitoral Engorgement Devices; Guidance for Industry and FDA Reviewers	July 3, 2000	ODE/DRARD	Do	1144
Thermal Endometrial Ablation Devices (Submission Guidance for an IDE); Final	March 14, 1996	ODE/DRARD	Do	547
Draft Guidance for the Clinical Investigation of Urethral Stents	November 2, 1995	ODE/DRARD	Do	573

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Tympanostomy Tubes Submission Guidance for a 510(k) Premarket Notification; Final	January 14, 1998	ODE/DRARD	Do	930
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff	February 28, 2001	ODE Program Operations Staff (POS)	Do	310
PMA/510(k) Expedited Review #G98–4 (Blue Book Memo)	March 20, 1998	ODE/POS	Do	7
PMA/510(k) Expedited Review—Guidance for Industry and CDRH Staff [FDAMA]; Final	March 20, 1998	ODE/POS	Do	108
Deciding When to Submit a 510(k) for a Change to an Existing Device	January 10, 1997	ODE/POS	Do	935
A Suggested Approach to Resolving Least Burdensome Issues	September 11, 2000	ODE/POS	Do	1188
Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA; Final; Guidance for Industry and FDA Staff	November 2, 2000	ODE/POS	Do	1195
FDA Modernization Act of 1997 Guidance for the Device Industry on Implementation of Highest Priority Provisions [FDAMA]	February 6, 1998	Office of Health and Industry Programs (OHIP)	Do	434
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations to State and Local Agencies	August 13, 1998	OHIP	Do	1071
Compliance Guidance—The Mammography Quality Standards Act Final Regulations—Preparing for MQSA Inspections	May 5, 1999	OHIP Division of Mammography Quality and Radiation Programs (DMQRP)	Do	6400
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	March 26, 1998	OHIP/DMQRP	Do	69
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	March 26, 1998	OHIP/DMQRP	Do	83
Compliance Guidance; The Mammography Quality Standards Act Final Regulations Document #4; Draft	September 13, 2000	OHIP/DMQRP	Do	1159
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	OHIP/DMQRP	Do	1317
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3 (Incorporated into PGHS)	December 8, 1999	OHIP/DMQRP	Do	1496
Guidance: The Mammography Quality Standards Act Final Regulations Document #1 (Incorporated into PGHS)	March 4, 1999	OHIP/DMQRP	Do	1499
Policy and Standard Operating Procedures When Mammography Facilities in States That Have Accreditation Bodies Intend to Change Accreditation Bodies	April 15, 1998	OHIP/DMQRP	Do	1186

IV. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
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)	May 4, 1999	OHIP/DMQRP	Do	2217
Continuing Education Credit for Reading/Writing Articles/Papers and Presenting Courses/Lectures (Incorporated into PGHS)	March 17, 1998	OHIP/DMQRP	Do	66206
Guidance for Industry—Requalification for Interpreting Physician's Continuing Experience Requirement (Incorporated into PGHS)	May 28, 1998	OHIP/DMQRP	Do	66301
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly (Incorporated into PGHS)	March 23, 1999	OHIP/DMQRP	Do	2256
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Quality Assurance Documentation (Incorporated into PGHS)	December 7, 1999	OHIP/DMQRP	Do	1194
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2 (Incorporated into PGHS)	February 25, 2000	OHIP/DMQRP	Do	1498
Compliance Guidance—Mammography Facility Survey, Equipment Evaluation and Medical Physicist Qualification Requirements Under MQSA; Final	November 6, 2000	OHIP/DMQRP	Do	6409
Medical Glove Guidance Manual Draft FDA 99–4257	August 12, 1999	OHIP Division of Small Manufacturers Assistance (DSMA)	Do	852
Instructions for Completion of Medical Device Registration and Listing Forms FDA 2891, 2891a and 2892	July 1, 1997	OHIP/DSMA	Do	12
An Introduction to Medical Device Regulations (FDA 92–4222)	January 1, 1992	OHIP/DSMA	Do	18
Regulatory Requirements for Devices for the Handicapped (FDA 87–4221)	August 1, 1987	OHIP/DSMA	Do	22
Impact Resistant Lenses: Questions and Answers (FDA 87–4002)	September 1, 1987	OHIP/DSMA	Do	23
Comparison Chart: 1996 Quality System Reg vs. 1978 Good Manufacturing Practices Reg vs. ANSI/ISO/ASQC Q9001 and ISO/DI 13485:1996 (Include 126)	November 29, 1996	OHIP/DSMA	Do	133
Medical Device Appeals and Complaints: A Guidance on Dispute Resolution	February 19, 1998	OHIP/DSMA	Do	396
Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices (FDA 95–4158) [Available on Disk]	August 1, 1995	OHIP/DSMA	Do	469
Labeling—Regulatory Requirements for Medical Devices (FDA 89–4203)	September 1, 1989	OHIP/DSMA	Do	470
In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (FDA 97–4224) [Available on Disk]	January 1, 1997	OHIP/DSMA	Do	471
Investigational Device Exemptions [IDE] Manual (FDA 96–4159) DSMA [Available on Disk]	June 1, 1996	OHIP/DSMA	Do	472

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Regulation of Medical Devices; Background Information for International Officials (Entire Document Available on Disk)	April 14, 1999	OHIP/DSMA	Do	610
Medical Device Reporting for Manufacturers [Available on Disk]	March 1, 1997	OHIP/DSMA	Do	987
Premarket Approval (PMA) Manual	January 1, 1998	OHIP/DSMA	Do	1051
Overview of FDA Modernization Act of 1997 Medical Device Provisions [FDAMA]	February 19, 1998	OHIP/DSMA	Do	1174
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	OHIP/DSMA	Do	1175
Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties	February 2, 2001	OHIP/DSMA	Do	1160
CDRH Manual for the Good Guidance Practices (GGP) Regulations; Final Guidance for FDA Staff	February 9, 2001	OHIP Division of Device User Programs and Systems Analysis (DUPSA)	Do	1323
Human Factors Principles for Medical Device Labeling	September 1, 1993	OHIP/DUPSA	Do	227
Human Factors Points to Consider for IDE Devices	January 17, 1997	OHIP/DUPSA	Do	839
Write It Right	August 1, 1993	OHIP/DUPSA	Do	897
Medical Device Reporting for User Facilities	April 1, 1996	OHIP/DUPSA	Do	989
Do It By Design—An Introduction to Human Factors in Medical Devices	December 1, 1996	OHIP/DUPSA	Do	995
Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management; Guidance for Industry and FDA Premarket and Design Control Reviewers	July 18, 2000	OHIP/DUPSA	Do	1497
Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers	April 19, 2001	OHIP/DUPSA	Do	1128
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)		Office of Surveillance and Biometrics (OSB) Division of Biostatistics (DB)	Do	78
PMA Review Statistical Checklist	(no date available)	OSB/DB	Do	84
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	OSB/DB	Do	537
MDR Guidance Document: Remedial Action Exemption—E1996001; Final	July 30, 1996	OSB/DSS	Do	188
Guidance on Adverse Event Reporting for Hospitals That Reprocess Devices Intended by the Originial Equipment Manufacturer for Single Use	April 24, 2001	OSB/DSS	Do	1334
MDR Guidance Document No. 1–IOL–E1996004; Final	August 7, 1996	OSB/DSS	Do	216
MDR Guidance Document No. 3—Needlestick and Blood Exposure—E1996003; Final	August 9, 1996	OSB/DSS	Do	250

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Common Problems: Baseline Reports and Medwatch Form 3500A	January 1, 1997	OSB/DSS	Do	379
MDR Reporting Guidance for Breast Implants—E1996002; Final	August 7, 1996	OSB/DSS	Do	452
Medical Device Reporting: An Overview; Final	April 1, 1996	OSB/DSS	Do	509
Instructions for Completing FDA Form 3500A With Coding Manual for Form 3500A (MEDWATCH)(MDR); Final	December 15, 1995	OSB/DSS	Do	853
MEDWATCH FDA Form 3500A for Use by User Facilities, Distributors and Manufacturers for Mandatory Reporting (MDR); Final	June 1, 1993	OSB/DSS	Do	854
Variance From Manufacturer Report Number Format [MDR Letter]; Final	July 16, 1996	OSB/DSS	Do	1059
Instructions for Completing Form 3417: Medical Device Reporting Baseline Report [MDR]; Final	March 31, 1997	OSB/DSS	Do	1061
MDR Internet List Server (listserv) Instruction Sheet; Final	August 29, 1996	OSB/DSS	Do	1094
Medical Device Reporting-Alternative Summary Reporting (ASR) Program; Guidance for Industry	October 19, 2000	OSB/DSS	Do	315
Addendum to the Instructions for Completing FDA Form 3500A With Coding Manual (MEDWATCH) (MDR); Final	June 9, 1999	OSB/DSS	Do	1853
Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)	June 9, 1993	OSB Issues Management Staff (IMS)	Do	206
Guidance on Criteria and Approaches for Postmarket Surveillance	November 2, 1998	OSB/IMS	Do	9
Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies [FDAMA]; Final	February 19, 1998	OSB/IMS	Do	316
Guidance on Procedures for Review of Postmarket Surveillance Submissions [FDAMA]; Final	February 19, 1998	OSB/IMS	Do	317
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	OSB/IMS	Do	318
Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads; Final	March 30, 1994	OSB/IMS	Do	374
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket	February 2, 2000	OSB/IMS	Do	946
Guidance on Frequently Asked Questions on Recognition of Consensus Standards [FDAMA]	December 21, 1998	Office of Science and Technology (OST)	Do	109
Guidance on the Recognition and Use of Consensus Standards/Appendix A [FDAMA]	February 19, 1998	OST	Do	321
A Primer on Medical Device Interactions With Magnetic Resonance Imaging Systems; Draft	February 7, 1997	OST	Do	952
CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standard for Recognition	August 6, 1999	OST	Do	616

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Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)	FOD No.
Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problems	May 15, 1998	OST	Do	2000
Guidance for Industry and FDA Reviewers: Guidance on Immunotoxicity Testing	May 6, 1999	OST Division of Life Sciences (DLS)	Do	635

WITHDRAWALS

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal	FOD No.
Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, Draft Guidance—Not for Implementation (Replaced by Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Guidance for Industry and for FDA Staff 8/14/00)	February 8, 2000	OC	August 8, 2000	801029
Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Guidance for Industry (Replaced by Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems; Final Guidance for Industry and FDA 4/2/01)	October 18, 1999	OC/DOEI	March 30, 2001	802619
Final Design Control Report and Guidance (No Replacement)	June 1, 1998	OC/DOEIII	July 24, 2000	800949
Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule (No Replacement)	July 1, 1995	OC/OT	April 24, 2000	800303
Guidance on Amended Procedures for Advisory Panel Meetings [FDAMA]; Final (Replaced by Guidance on Amended Procedures for Advisory Panel Meetings, 7/22/00)	January 26, 1999	ODE	August 4, 2000	800413
Review Criteria for Assessment of Antimicrobial Susceptibility Devices (Replaced by Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices, 3/8/00)	May 31, 1991	ODE/DCLD	June 16, 2000	800631
Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used by the Consumer; Guidance for Industry; Draft (Replaced by Over-the-Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications; Guidance for Industry; Draft 11/14/00)	December 30, 1998	ODE/DCLD	October 30, 2000	802209
Guidance Document for Vascular Prostheses 510(k) Submission; Final (Replaced by Guidance Document for Vascular Prostheses 510(k) Submissions; Guidance for Industry and FDA Staff; Final 11/1/00)	November 1, 2000	ODE/DCRD	January 16, 2000	801357
Guidance to Manufacturers on the Development of Required Postapproval Epidemiological Study Protocols for Testicular Implants (No Replacement)	Date not available	ODE/DCRD	June 15, 2000	800202
510(k) Reviewer Guidelines—Tracheostomy Tubes 868.5800 (No Replacement)	Date not available	ODE/DCRD	June 15, 2000	800550

WITHDRAWALS—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal	FOD No.
Guidance for the Comment and Review of 510(k) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices (Replaced by Guidance for the Submission of Premarket Notifications for Medical Image Management Devices; Guidance for Industry; Final 7/27/00)	August 1, 1993	ODE/DCRD	August 8, 2000	800416
Guidance for Industry—Guidance for the Content of Premarket Notifications [510(k)s] for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi (Replaced by Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; Final 8/9/00)	February 8, 1999	ODE/DCRD	August 10, 2000	801226
Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II (No Replacement)	February 1, 1989	ODE/DCRD	August 30, 2000	800583
Reviewer's Guidance for Oxygen Concentrator (No Replacement)	August 30, 1991	ODE/DCRD	August 30, 2000	800781
Guidance Document for Vascular Prostheses 510(k) Submission; Final (Replaced by Guidance Document for Vascular Prostheses 510(k) Submissions; Guidance for Industry and FDA Staff; Final 11/1/00)	November 26, 1999	ODE/DCRD	November 16, 2000	801357
Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions; Final (Replaced by Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions; Final 11/1/00)	January 14, 2000	ODE/DCRD	January 21, 2000	800372
Draft Guidance for Information on Clinical Safety and Effectiveness Data for Extracorporeal Shock Wave Lithotripsy of Upper Urinary Tract (Renal Pelvis, Renal Calyx and Upper Ureteral) Calculi (Replaced by Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; Final 8/9/00)	February 5, 1992	ODE/DCRD	January 10, 2001	800864
Guidance for Annuloplasty Rings 510(k) Submissions; Final (Replaced by Guidance for Annuloplasty Rings 510(k) Submissions; Final Guidance for Industry and FDA Staff 1/31/01)	November 26, 1999	ODE/DCRD	February 12, 2001	801358
Home Uterine Activity Monitors: Guidance for the Submission of 510(k) Premarket Notifications (Replaced by Class II Special Controls Guidance for Home Uterine Activity Monitors; Final Guidance for Industry and FDA Reviewers, 3/9/01)	July 30, 1999	ODE/DCRD	March 2001	800820
Status Update—Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems (Replaced by Premarket Applications for Digital Mammography Systems; Final Guidance for Industry and FDA 2/16/01)	February 4, 1999	ODE/DCRD	February 27, 2001	800983
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants (includes Addendum of 3/9, 1994) (No Replacement)	October 1, 1993	ODE/DDIGD	August 10, 2000	800902
Guidance for the Preparation of Premarket Notification [510(k)] for Resorbable Periodontal Barriers (No Replacement)	April 1, 1991	ODE/DDIGD	September 1, 2000	800028

WITHDRAWALS—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal	FOD No.
Guidance for Spinal System 510(k); Final (Replaced by Guidance for Spinal System 510(k)s 9/27/00)	May 7, 1999	ODE/DGRND	October 2, 2000	800636
Guidance for Industry—Guidance Document for Neurological Embolization Devices; Final (Replaced by Guidance for Neurological Embolization Devices; Guidance for Industry; Final 11/1/00)	August 13, 1999	ODE/DGRND	November 7, 2000	801151
Ophthalmic Device Triage (No Replacement)	March 19, 1998	ODE/DOED	June 20, 2000	800160
Announcement by Dr Alpert at 7/26, 1996, Ophthalmic Panel Meeting Concerning Manufacturers and Users of Lasers for Refractive Surgery [Excimer] (No Replacement)	August 26, 1996	ODE/DOED	July 17, 2000	803093
Owners Certification of Lasers as PMA Approved Devices [Excimer] (No Replacement)	September 26, 1996	ODE/DOED	July 17, 2000	804093
Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA (Replaced by Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA; Final 11/6/00)	May 5, 1999	OHIP/DMORP	April 8, 2000	806409
A Pocket Guide to Device GMP Inspections—Inspections of Medical Device Manufacturers and GMP Regulation Requirements (No Replacement)	November 1, 1991	OHIP/DSMA	June 28, 2000	800508
Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997—June 2000; Draft (Replaced by Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties 2/2/01)	June 12, 2000	OHIP/DSMA	February 2, 2001	801160
Guidance for Industry—Device Use Safety: Incorporating Human Factors in Risk Management (No Replacement)	August 3, 1999	OHIP/DUPSA	July 20, 2000	801497
Guidance on Medical Device Patient Labeling; Final Guidance for Industry (Replaced by Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers 4/19/01)	March 3, 2000	OHIP/DUPSA	April 9, 2001	801128
MDR Documents Access Information for National Technical Information Service (NTIS) (No Replacement)	May 10, 1996	OSB	June 28, 2000	803799
Proposed Draft Guidance to Sponsors Regarding Required Postmarket Surveillance Studies of Plasma-Sprayed Porous-Coated Hip Prostheses (Archived by OSB—Replaced by Guidance Testing Metallic Plasma Sprayed Orthopedic Implants, 2/2/00)	October 7, 1994	OSB/DPS	June 16, 2000	800323
Letter to Manufacturers: Summary Reporting Approval for Adverse Events; Final (Replaced by Medical Device Reporting—Alternative Summary Reporting (ASR) Program; Guidance for Industry 10/19/00)	July 31, 1997	OSB/DSS	October 30, 2000	800315
Draft Thermal Endometrial Ablation Devices (Submission Guidance for an IDE) (Replaced by Thermal Endometrial Ablation Devices (Submission Guidance for an IDE); Final 3/14/96))	March 14, 1996	ODE/DCRD	March 1996	800547
Guidance for Review of Cases of Possible Suspension or Revocation of Mammography Facility Certificates Under the Mammography Quality Standards Act, 42 U.S.C. 263(b)/4/8, 1998 (No Replacement)	March 26, 1998	OHIP/DMORP	May 23, 2001	800080

WITHDRAWALS—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date of Withdrawal	FOD No.
Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA , Draft (replaced by Compliance Guidance—Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA; Final 11/6/00	May 5, 1999	OHIP/DMORP	November 8, 2000	806409

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Compliance Policy Guides Manual	1998	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, NTIS Order No. PB96–920500
Compliance Programs Guidance Manual	1995	FDA Regulated Industries	Do (NTIS Order No. PB95–915499
FDA Recall Policy	1995	FDA Regulated Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204
Investigators' Operations Manual	May 1996	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, (NTIS Order No. PB–95–913399)
Regulatory Procedures Manual	August 1995	FDA Regulated Industries	Do (NTIS Order No. PB95–265534)
Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration ''Blue Book''	1997	FDA Regulated Industries	Superintendent of Documents, Government Printing Office, Washington, DC 20402
Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed	1995	Food and Animal Feed Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, (NTIS Order No. PB96–920500)
Pesticides Analytical Manual	1996	Food Industry	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, (NTIS Order No. PB94–911899)
FDA Advisory for Deoxynivanol (DON) in Finished Wheat Products Intended for Human Consumption and in Grain and Grain By-Products for Animal Feed	September 16, 1993	Food and Animal Feed Industries	Office of Plant and Dairy Foods and Beverages, Food and Drug Administration (HFS–306), 200 C St. SW., Washington, DC 20204, 202–205–4681
FDA's Cosmetic Labeling Manual	October 1991	Cosmetic Industry	Food and Drug Administration, Office of Colors and Cosmetics (HFS–105), 200 C St. SW., Washington, DC 20204, 202–205–4493
Statement of Policy: Foods Derived From New Plant Varieties: Notice	May 29, 1992	Developers of New Plant Food Varieties	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
A Food Labeling Guide	May 1997	Food Industry	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Model Small Business Food Labeling Exemption Notice	1998	Food Industry	Do
Food Labeling: Questions and Answers	August 1994	Food Industry	Do

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Food Labeling: Questions and Answers: Volume II	February 1996	Food Industry	Superintendent of Documents, Government Printing Office, Washington, DC 20420, 202–512–1800
Fair Packaging and Labeling Act Manual	June 1978	Food Industry	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650, (NTIS Order No. PB–83–222117)
Bacteriological Analytical Manual 7th Edition	1992	FDA Regulated Industries	AOAC International, 481 N. Frederick Ave., suite 500, Gaithersburg, MD 20877–2417, 301–924–7077
FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods	1985	Food Industry	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Evaluation of Milk Laboratories	1995	States	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Methods of Making Sanitation Ratings of Milk Supplies	1999	States	Do
Dry Milk Ordinance	1995	States	Do
Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers	1999	Dairy Industry	Do
Frozen Dessert Processing Guidelines	1989	Dairy Industry	Office of Plant and Dairy Foods and Beverages (HFS–302), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Pasteurized Milk Ordinance	1999	States	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Guidelines for Determining Metric Equivalents of Household Measures	October 1, 1993	Food Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Food and Drug Administration (HFS–800), 200 C St. SW., Washington, DC 20204, 202–205–4561
List of Food Defect Action Levels (DALs)	1995	Food and Animal Feed Industries	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Action Levels for Poisonous or Deleterious Substances in Human Food and Feed (Also Found in CPGs)	1995	Food and Animal Feed Industries	Do
FDA Food Code	1999	States	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650
Seafood List	1993	Seafood Industry	Superintendent of Documents, Government Printing Office, Washington, DC 20402, 202–512–1800
Manual of Operations National Shellfish Sanitation	1992	States	Office of Seafood (HFS–407), Shellfish Sanitation Branch, 200 C St. SW., Washington, DC 20204, 202–418–3150

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Fish and Fisheries Product Hazards and Control Guide	1996	Seafood Industry	Do
Guidance for Submitting Requests Under 21 CFR 170.39, Threshold of Regulation for Substances Used in Food Articles	1996	Food Packaging Industry	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
Guidelines for the Preparation of Petition Submissions	1996	Food Ingredient or Packaging Industry	Do
Guideline for Approval of Color Additives in Contact Lenses Intended as Colors	1996	Color or Contact Lens Industry	Do
FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs or Cosmetics Use	February 1993	Color Additives Industry	Do
Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations	December 1992	Food Packaging Industry	Do
Recommendations for Submission of Chemical and Technological Data for Direct Food Additive and GRAS Food Ingredient Petitions	May 1993	Food Packaging Industry	Do
Recommendations for Chemistry Data for Indirect Food Additive Petitions	June 1995	Food Packaging Industry	Do
Enzyme Preparations: Chemistry Recommendations for Food Additive and GRAS Affirmation Petitions	January 1993	Food Enzyme Industry	Do
Estimating Exposure to Direct Food Additive and Chemical Contaminants in the Diet	September 1995	Food and Food Ingredient Industry	Do
Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as Redbook I)	1982	Petitioners for Food or Color Additives	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 2216, (NT IS Order No. PR–83–170696
Environmental Assessment Technical Handbook	March 1987	Petitioners for Food or Color Additives	Do (NTIS Order No. PB87175345–AS, A–01)
Color Additive Petitions Information and Guidance	1996	Petitioners for Color Additives	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
Toxological Testing of Food Additives	1983	Petitioners for Food or Color Additives	Do
List of Products for Each Product Category	October 8, 1992	Food Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561
Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers	June 10, 1996	Food Industry	Do
Guidance on Labeling of Foods That Need Refrigeration by Consumers	February 24, 1997	Food Industry	Do
Guidelines Concerning Notification and Testing of Infant Formula	1985	Infant Formula Manufacturers	Do

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Guidelines for the Evaluation of Safety and Suitability of New Infant Formulas for Feeding Preterm Infants	1988	Infant Formula Manufacturers	Do
Clinical Testing of Infant Formulas With Respect to Nutritional Suitability for Term Infants	1988	Infant Formula Manufacturers	Do
Guidelines for the Evaluation of the Safety and Suitability of Infant Formulas for Feeding Infants With Allergic Diseases	1990	Infant Formula Manufacturers	Do
Guidelines for the Clinical Evaluation of New Products Used in the Dietary Management of Infants, Children and Pregnant Women With Metabolic Disorders	1987	Infant Formula Manufacturers	Do
Guidance Document for Arsenic (Trace Elements in Seafood)	January 1993	States	Office of Seafood, Food and Drug Administration (HFS–400), 200 C St. SW., Washington, DC 20204, 202–418–3150, Internet: FDA Home Page Http://vm.cfsan.fda.gov/list.html
Guidance Document for Cadmium (Trace Elements in Seafood)	January 1993	States	Do
Guidance Document for Chromium (Trace Elements in Seafood)	January 1993	States	Do
Guidance Document for Lead (Trace Elements in Seafood)	August 1993	States	Do
Guidance Document for Nickel (Trace Elements in Seafood)	January 1993	States	Do
Guidance on Consultation Procedures for Foods Derived From New Plant Varieties	October 1997	Regulated Industry	Office of Premarket Approval (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100, Internet: FDA Home Page Http://vm.cfsan.fda.gov
FDA's Policy for Foods Developed by Biotechnology	1995	Food Industry	Do
Bovine Spongiform Encephalopathy (BSE) in Products for Human Use	1997	Food Industry	Office of Plant and Dairy Foods and Beverages (HFS–302), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175, Internet: FDA Home Page Http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm
Interim Guidance on the Voluntary Labeling of Milk and Milk Products That Have Not Been Treated With Recombinant Bovine Somatropin	February 1994	Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168
Shellfish Sanitation Model Ordinance	1995	States	Shellfish Program Implementation Branch, Division of Cooperative Programs, Office of Field Programs (HFS–628), 200 C St. SW., Washington, DC 20204, 202–205–8137
Guide to Minimize Microbial Hazards for Fresh Fruits and Vegetables (Available in English, Spanish, Portuguese, and French)	1998	Farmers and Food Packers	Food Safety Initiative (HFS–32), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, or jsaltsman@bangate.fda.gov

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Iron-Containing Supplements and Drugs: Label Warning and Unit Dose Packaging; Small Entity Compliance Guide	1997	Dietary Supplement Manufacturers: Small Entities	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–450), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
Partial List of Enzyme Preparations That Are Used in Foods	1998	FDA Regulated Industry	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food	1998	FDA Regulated Industry	Do
Fish and Fishery Products Hazards and Controls Guide, 2d Edition	January 1998	FDA Regulated Industry	Office of Seafood (HFS–400), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
HACCP Regulations for Fish and Fishery Products: Questions and Answers	1998	FDA Regulated Industry	Do
Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body	1998	FDA Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–150), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
FDA Nutrition Labeling Manual, A Guide for Developing and Using Data Bases	March 1998	FDA Regulated Industry	Do
HACCP Regulation for Fish and Fishery Products: Questions and Answers, Issue Three, Revised January 1999	January 1999	Seafood Processors	Office of Seafood (HFS–400), Center for Food Safety and Nutrition, 200 C St. SW., Washington, DC 20204, Ellen Nesheim, 202–418–3150
Foods—Adulteration Involving Hard or Sharp Foreign Objects (CPG)	February 1999	FDA Field Offices	Office of Plant and Dairy Foods and Beverages (HFS–300), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204
Food Additive Petition Expedited Review	January 1999	Guidance for Industry and Center for Food Safety and Applied Nutrition Staff	Robert L. Martin (HFS–215), OPA/CFSAN/FDA, 200 C St. SW., Washington, DC 20204, 202–418–3074, premarkt@cfsan.fda.gov or http://vm.cfsan.fda.gov/≤dms/opa-expe.html
Use of Antibiotic Resistance Marker Genes in Transgenic Plants	September 1998	Guidance for Industry	Nega Beru (HFS–206), OPA/CFSAN/FDA, 200 C St. SW., Washington, DC 20204, 202–418–3097, premarkt@cfsan.fda.gov or http://vm.cfsan.fda.gov//≤dms/opa-armg.html
Guidance: Channels of Trade Policy for Commodities With Methyl Parathion Residues	December 2000	Regulated Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition (HFS–300), FDA, 200 C St. SW., Washington, DC 20204, http://vm.cfsan.fda.gov/‘dms
Draft Guidance: Fumonisin Levels in Human Foods and Animal Feeds	June 2000	Regulated Industry	Do
Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide	January 1999	Small Business Entities	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–5251
Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (December 1999)	December 1999	Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4561

V. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
Antimicrobial Food Additives	July 1999	Regulated Industry	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–418–3100
Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations	November 1999	Regulated Industry	Do
Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations	November 1999	Regulated Industry	Do
Guidance for Small Businesses: Submission of Comments for CFSAN Rulemaking	October 1999	Small Business Entities	Division of Market Studies (HFS–726), Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, DC 20204, 202–401–4590
Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide	September 1998	Regulated Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4561
Reducing Microbial Food Safety Hazards for Sprouted Seeds	October 1999	Regulated Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4064
Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production	October 1999	Regulated Industry	Do
Seafood HACCP Transition Policy	December 1999	Regulated Industry	Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–3150
FDA Recommendations for Sampling and Testing Yellow Corn Shipments for Cry9C Protein Residues	January 19, 2001	Regulated Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4064
Draft Guidance: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering	January 2001	Regulated Industry	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–418–3100
Bacteriological Analytical Manual	2001	Regulated Industry	Do
Importation of PMO Defined Dairy Products	April 11, 2000	Dairy Industry	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Draft Guidance: Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin	June 2000	Juice Industry	Office of Plant and Dairy Foods and Beverages, Center for Food Safety and Applied Nutrition, FDA, 200 C St. SW., Washington, DC 20204, 202–205–4064
Draft Guidance for Industry on Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products	November 2000	Seafood Industry	Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–3150

WITHDRAWALS

Name of Document	Date of Issuance/ Date Withdrawn	Intended User or Regulatory Activity	How to Obtain A Hard Copy of the Document (Name and Address, Phone, Fax, E–Mail or Internet)
FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases (Replaced by 1998 update with the same title.)	1993/June 2001	Food Industry	Office of Nutritional Products, Labeling, and Dietary Supplements, Food and Drug Administration (HFS–800), 200 C St. SW., Washington, DC 20204, 202–205–4561
Fabrication of Single Service Containers and Closures for Milk and Milk Products (Incorporated into Pasteurized Milk Ordinance as an appendix.)	1995/June 2001	States	Milk Safety Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–9175

VI. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR VETERINARY MEDICINE (CVM)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Equine (VICH GL15)—Draft	September 2000	Animal Drug Industry	Internet via: http://www.fda.gov/cvm Communications Staff (HFV–12), FDA/CVM, 7500 Standish Pl., Rockville, MD 20855, 301–827–4582, FAX 301–594–1831
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Porcine (VICH GL16)—Draft	September 2000	Do	Do
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Canine (VICH GL19)—Draft	September 2000	Do	Do
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Feline (VICH GL20)—Draft	December 2000	Do	Do
Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Poultry (VICH GL21)—Draft	December 2000	Do	Do
Guidance for Industry: Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies (VICH GL22)—Draft	December 2000	Do	Do
Guidance for Industry: Safety Studies for Veterinary Drug Residues in Human Food: Genotoxicity Studies (VICH GL23)—Draft	December 2000	Do	Do
Guidance for Industry: Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AERs)(VICH GL24)—Draft	December 2000	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: General Recommendations (VICH GL7)—Final	March 2000	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Bovines (VICH GL12)—Final	March 2000	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Ovines (VICH GL13)—Final	March 2000	Do	Do
Guidance for Industry: Efficacy of Anthelmintics: Specific Recommendations for Caprines (VICH GL14)—Final	March 2000	Do	Do

VI. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR VETERINARY MEDICINE (CVM)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry: Environmental Impact Assessments (EIAs) for Veterinary Medicinal Products (VMPs)—Phase I (VICH GL6)—Final	March 2000	Do	Do
Guidance for Industry: Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products (VICH GL17)—Final	March 2000	Do	Do
Guidance for Industry: Good Clinical Practices (VICH GL9)—Final	May 2000	Do	Do
Guidance for Industry: Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (VICH GL18)—Final	May 2000	Do	Do
Guidance for Industry: How to Use E-Mail to Submit a Notice of Final Disposition of Animals Not Intended for Immediate Slaughter (NFDAs)	February 2000	Do	Do
Guidance for Industry: How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes	February 2000	Do	Do
Guidance for Industry: How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation	February 2000	Do	Do
How to Use E-Mail to Submit Information to the Center for Veterinary Medicine—Final	February 2000	Do	Do
Dioxin in Anti-Caking Agents Used in Animal Feed and Feed Ingredients	Revised April 2000	Do	Do
Guidance for Industry: Fumonisin Levels in Human Foods and Animal Feeds—Draft	June 2000	Do	Do
The Use of Published Literature in Support of New Animal Drug Approval	November 2000	Do	Do
Guidance for Industry: Bioequivalence Guidance	Revised October 2000	Do	Do
Guidance for Industry #124: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering—Draft	January 2001	Do	Do
Guidance for Industry #126: BACPAC I: Intermediates in Drug Substance Synthesis Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation, February 2001	February 2001	Do	Do
Guidance for Industry #120: Veterinary Feed Directive Regulation	March 2001	Do	Do
Guidance for Industry #121: Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims	March 2001	Do	Do

VI. GUIDANCE DOCUMENTS ISSUED BY THE CENTER FOR VETERINARY MEDICINE (CVM)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guidance for Industry and Reviewers: How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug—Draft	March 2001	Do	Do

VII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF POLICY (OP)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Draft Guidance for Industry; Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996	June 12, 1998	Regulated Industry	Internet via www.fda.gov/opacom/fedregister/frexport.html or 63 FR 32219, June 12, 1998, or Office of Policy, 301–827–3360
Direct Final Rule Guidance	November 21, 1997	FDA Personnel	Internet via www.fda.gov/opacom/morechoices/industry/guidance.htm or 62 FR 62467, November 21, 1997, or Office of Policy, 301–827–3480
International Harmonization; Policy on Standards	October 1995	FDA Personnel and Regulated Industry	60 FR 53078, October 11, 1995, or Office of Policy, 301–827–3360

WITHDRAWALS

Name of Document	Date of Issuance	Intended User or Regulatory Activity	Date Withdrawn
FDA's Development, Issuance and Use of Guidance Documents	February 27, 1997	FDA Personnel and Regulated Industry	September 19, 2000
Small Entities Compliance Guide On: Regulations To Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents (21 CFR Part 897)	February 1997	Regulated Industry	March 31, 2000
Children and Tobacco—Frequently Asked Questions About the New Regulations (Draft)	July 1997	Regulated Industry	March 31, 2000
Children and Tobacco—A Retailers Guide to the New Federal Regulations	October 1997	Regulated Industry	March 31, 2000
Children and Tobacco—A Guide to the New Federal Regulations	October 1997	Regulated Industry	March 31, 2000

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Compliance Policy Guide Manual—Compliance Policy Guidance for FDA Staff (Replaces Compliance Policy Guide—January 1996)	August 2000	FDA Staff	National Technical Information Service (NTIS) 5285 Port Royal Rd., Springfield, VA 22161 or Internet at: www.fda.gov/ora/cpgm/default.html
Compliance Policy Guide, New Sec. 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 or via Internet at: www.fda.gov/ora/compliance—;ref/rpm/rpmtc.html

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Compliance Policy Guide, New Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens	April 2001	Do	Do
Compliance Policy Guide, Reformat Sec. 220.100 Interstate Shipment of Biological Products for Use in Medical Emergencies	March 2001	Do	Do
Compliance Policy Guide, Reformat Sec. 270.100 Final Container Labels—Allergenic Extracts Containing Glycerin; Reporting Changes	March 2001	Do	Do
Compliance Policy Guide, Draft Sec. 230.150, Blood Donor Incentives	December 2000	Do	Do
Compliance Policy Guide, Draft Distributor Medical Reporting	August 28, 1997	FDA Staff Personnel and Regulated Industry	Do Internet at: www.fda.gov/ora/compliance—;ref/cpg—;mdr3.txt
Compliance Policy Guide Sec. 7150.09 Fraud, Statements of Material Facts, Bribery, and Illegal Gratuities	July 1991	FDA Staff and Regulated Industry	Do Internet at: www.fda.gov/ora/compliance—;ref/aip—;page.html
Medical Device Warning Letter Pilot	March 8, 1999	FDA Staff and Regulated Industry	Do Internet at: www.fda.gov/ohrms/Dockets/98fr/030899e.pdf
Glossary of Computerized System and Software Development Terminology	August 1995	Do	National Technical Information Service (NTIS) 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB96–127352) or via Internet: www.fda.gov/ora/inspect—;ref/igs/iglist.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
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, or Internet at: www.fda.gov/ora/science—;ref/lpm/lpmtc.html
Laboratory Procedures Manual Chapter X, New: Method Validation Samples	May 1999	Do	Do
Memorandum: ORA Investigational Strategy on Gamma-Butyrolactone (GBL) and Related Products	May 15, 2000	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Not Available on the Internet
Investigations Operations Manual	January 2001	Do	National Technical Information Service (NTIS) 5285 Port Royal Rd., Springfield, VA 22161 (NTIS Order No. PB2001–913399 and Internet at www.fda.gov/ora/inspect—;ref/iom/default.htm)
Medical Devices: Draft Guidance entitled ''Guidance for FDA Staff on Civil Money Penalty Policy''	Released for Comment June 8, 1999	FDA Staff	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420, or Internet at: http://www.fda.gov/ohrms/dockets/98fr/060899e.pdf

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Regulatory Procedures Manual Update/ New Subchapter 5 Civil Money Penalty Reduction Policy for Small Entities	April 19, 2001	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm/rpmtc.html
Regulatory Procedures Manual New RPM Subchapter: Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food	January 2001	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm/rpmtc.html
Regulatory Procedures Manual: Update, New Subchapter Application Integrity Policy	March 1998	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 or via Internet at: www.fda.gov/ora/compliance—;ref/rpm/rpmtc.html
Regulatory Procedures Manual: Update/ Revision Subchapter/Priority Enforcement Strategy for Problem Importers	April 1998	Do	Do
Regulatory Procedures Manual: Update/ Revision Subchapter/Import Procedures	April 1998	Do	Do
Regulatory Procedures Manual: Update/ Revision Subchapter/Notice of Sampling	April 1998	FDA Staff	Do
Regulatory Procedures Manual: Update New Subchapter/Granting and Denying Transportation and Exportation (T&E) Entries	May 1998	Do	Do
Regulatory Procedures Manual: Update/ Revision Subchapter/Seizure	June 1998	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm—;new2/ch6.html
Regulatory Procedures Manual: Update/ Revision Subchapter/Supervisory Charges	June 1998	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/new2/ch9chgs.html
Regulatory Procedures Manual: New Subchapter: Civil Penalties—Electronic Product Radiation Control	July 1998	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/ch6civpen.html
Regulatory Procedures Manual: Update/ Revision, Chapter 4, Subchapter/ Warning Letters	March 21, 2000	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm—;new2/ch4.html
Regulatory Procedures Manual New Chapter 9, Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs in Cases Involving Imported Food	January 2001	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm—;new2/ch9civmonpen.html
Regulatory Procedures Manual New Chapter 9, Secured Storage	January 2001	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/rpm—;new2/ch9securedstorage.html
Guide to Inspections of Bulk Pharmaceutical Chemicals	May 1994	Do	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, (NTIS Order No. PB96–127154) or via Internet at: 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) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories	July 1993	Do	Do (NTIS Order No. PB96–127287) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Validation of Cleaning Processes	July 1993	Do	Do (NTIS Order No. PB96–127246) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Lyophilization of Parenterals	July 1993	Do	Do (NTIS Order No. PB96–127253) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of High Purity Water Systems	July 1993	Do	Do (NTIS Order No. PB96–127261) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Dosage Form Drug Manufacturers—CGMPs	October 1993	Do	Do (NTIS Order No. PB96–127212) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Vaccination	January 1994	Do	Do (NTIS Order No. PB96–127345) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Topical Drug Products	July 1994	Do	Do (NTIS Order No. PB96–127394) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Sterile Drug Substance Manufacturers	July 1994	Do	Do (NTIS Order No. PB96–127295) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Oral Solutions and Suspensions	August 1994	Do	Do (NTIS Order No. PB96–127147) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Nutritional Labeling and Education Act (NLEA) Requirements	February 1995	Do	Do (NTIS Order No. PB96–127378) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Interstate Carriers and Support Facilities	April 1995	Do	Do (NTIS Order No. PB96–127386) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Dairy Product Manufacturers	April 1995	Do	Do (NTIS Order No. PB96–127329) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Miscellaneous Foods Vol. 1	May 1995	Do	Do (NTIS Order No. PB97–127220) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Miscellaneous Foods Vol. 11	September 1996	Do	Do (NTIS Order No. PB97–196133) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 1—Administrative Procedures/Scheduled Processes	November 1996	Do	Do (NTIS Order No. PB97–196141) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Cosmetic Product Manufacturers	February 1995	Do	Do (NTIS Order No. PB96–127238) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 2—Processes/ Procedures	April 1997	Do	Do (NTIS Order No. PB97–196158) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 3—Container Closurers	July 2001	FDA Staff	Do (NTIS Order No. PB00–133795)
Guide to Inspections of Blood Banks	September 1994	Do	Do (NTIS Order No. PB96–127303) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Source Plasma Establishments	December 1994	Do	Do (NTIS Order No. PB96–127360) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Infectious Disease Marker Testing Facilities	June 1996	Do	Do (NTIS Order No. PB96–199476) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Biotechnology Inspections Guide	November 1991	Do	Do (NTIS Order No. PB96–127402) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Computerized Systems in Drug Processing	February 1983	Do	Do (NTIS Order No. PB96–127337) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Foreign Medical Device Manufacturers	September 1995	Do	Do (NTIS Order No. PB96–127311) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Foreign Pharmaceutical Manufacturers	May 1996	Do	Do (NTIS Order No. PB96–199468) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Mammography Quality Standards Act (MQSA) Auditors Guide	January 1998	Do	Do (NTIS Order No. PB98–127178) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems	December 1997	Do	Do (NTIS Order No. PB98–127152) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Acidified Food Manufacturers	May 1998	Do	http://www.fda.gov/ora/inspect—;ref/igs/acidfgde.htm
Guide to Inspection of Aseptic Processing and Packaging for the Food Industry	February 2001	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1240
Guide to Inspections of Grain Product Manufacturers	March 1998	Do	(NTIS Order No. PB–98–137128) or via Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Bioresearch Monitoring Inspections of In Vitro Devices	February 1998	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Viral Clearance Processes for Plasma Derivatives	March 1998	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Trace Back of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations	April 2001	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igs/iglist.html
Guide to Inspections of Computerized Systems in the Food Processing Industry	August 1998	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igf/foodcomp.html
Guide to International Inspections and Travel, Revision (Formerly, FDA/ORA International Inspection Manual and Travel Guide)	July 1999	Do	Do Revision not available on Internet

VIII. GUIDANCE DOCUMENTS ISSUED BY THE OFFICE OF REGULATORY AFFAIRS (ORA)—Continued

Name of Document	Date of Issuance	Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document
Guide to Inspections of Quality Systems	August 1999	Do	Do Internet at: www.fda.gov/ora/inspect—;ref/igs/qsit/QSITGUIDE.PDF
Guide to Inspection of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients	April 2001	Do	Do Internet at: http://www.fda.gov/ora/inspect—;ref/igs/iglist.html
Computerized Systems Used in Clinical Trials	April 1999	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/bimo/ffinalact.html
Compliance Program 7348.001: Bioresearch Monitoring, Human Drugs, In Vivo Bioequivalence	October 1, 1999	D0	Do Internet at: www.fda.gov/ora/compliance—;ref/Bimo/7348—;001/default.html
Good Laboratory Practice Program (Nonclinical Laboratories) 7348.808A; EPA Data Audit Inspections	October 1, 1991	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420
Guideline for the Monitoring of Clinical Investigators	January 1988	FDA Regulated Industry	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420
Small Business Guide to FDA (FDA 96–1092)	January 1, 1996	Do	Federal-State Relations (HFC–150), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2905 Internet at: www.fda.gov/ora/indust—;assit/default.htm
Compliance Program 7348.808 Bioresearch Monitoring: Good Laboratory Practices (Nonclinical)	Revised August 17, 1998	FDA Staff	Do Internet at: www.fda.gov/ora/compliance—;ref/bimo/default.html
Compliance Program 7348.809 Bioresearch Monitoring: Institutional Review Board	August 18, 1994	Do	Do
Compliance Program 7348.810: Sponsors, Contract Research Organizations and Monitors	Revised October 30, 1998	Do	Do
Good Laboratory Practice Regulations Management Briefings	August 1979	Do	Do Internet at: www.fda.gov/ora/compliance—;ref/bimo/default.html
Draft: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research	March 31, 2000	FDA Regulated Industry	Do

Dated: October 9, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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