Application No.	Drug	Applicant
ANDA 85–805	Aeroseb-HC (hydrocortisone 0.5%) Topical Aerosol Spray	Allergan Herbert.
ANDA 86–164	Nitrol Ointment (Nitroglycerin Ointment, 2%)	Savage Laboratories.
ANDA 86–604	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 5 mg	Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022–4731.
ANDA 87–171	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 2.5 mg	Do.
ANDA 87–286	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 1 mg	Do.
ANDA 87–322	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 1.5 mg	Do.
ANDA 87–323	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 2 mg	Do.
ANDA 87–615	Sustachron (Nitroglycerin Extended-release) Buccal Tablets, 3 mg	Do.
ANDA 87–782	Nitrol Ointment (Nitroglycerin Ointment, 2% unit-dose)	Savage Laboratories.
ANDA 87–998	Spironolactone Tablets USP, 25 mg	Purepac Pharmaceutical Co.
ANDA 88–421	Amitriptyline Hydro-chloride Tablets USP, 10 mg	Copley Pharmaceutical Inc.
ANDA 88–422	Amitriptyline Hydro-chloride Tablets USP, 25 mg	Do.
ANDA 88–423	Amitriptyline Hydro-chloride Tablets USP, 50 mg	Do.
ANDA 88–424	Amitriptyline Hydro-chloride Tablets USP, 75 mg	Do.
ANDA 88–425	Amitriptyline Hydro-chloride Tablets USP, 100 mg	Do.
ANDA 88–426	Amitriptyline Hydro-chloride Tablets USP, 150 mg	Do.
ANDA 89–817	DEY-LUTE (Isoetharine Inhalation Solution USP) Sulfite-Free, 0.08%	Dey, L.P., 2751 Napa Valley Corporate Dr., Napa, CA 94558.
ANDA 89–818	DEY-LUTE (Isoetharine Inhalation Solution USP) Sulfite-Free, 0.1%	Do.
ANDA 89–819	DEY-LUTE (Isoetharine Inhalation Solution USP) Sulfite-Free, 0.17%	Do.
ANDA 89–820	DEY-LUTE (Isoetharine Inhalation Solution USP) Sulfite-Free, 0.25%	Do.
ANDA 89–932	Theophylline Extended-Release Capsules, 300 mg	F.H. Faulding & Co., Ltd., U.S. Agent: Faulding Inc., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 89–976	Theophylline Extended-Release Capsules, 100 mg	Do.
ANDA 89–977	Theophylline Extended-Release Capsules, 200 mg	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective July 12, 1999.

Dated: May 24, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–14656 Filed 6–9–99; 8:45 am]

BILLING CODE 4160–01–F

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 an annual comprehensive list of all guidance documents currently in use at the agency. FDA committed to publishing this list in its February 1997 ''Good Guidance Practices'' (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to inform the public of the existence and availability of all current guidance documents.

DATES: General comments on this list and on agency guidance documents are welcome 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. Information on where to obtain a single copy of listed guidance documents is provided for each agency Center individually in the specific Center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: Lisa M. Helmanis, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publish an annual comprehensive list of guidance documents and quarterly updates that list all guidance documents that were issued and withdrawn during that quarter, including ''Level 2'' guidance documents.

On June 1, 1998, the President instructed all Federal agencies to ensure the use of ''plain language'' in all new documents. As part of this initiative,

FDA uses the principles of ''plain language'' set forth by the President when writing its guidance documents. The agency seeks public comment on the clarity of its guidances.

The following comprehensive list of guidance documents represents all guidances currently in effect. This comprehensive list is maintained on the FDA World Wide Web home page. This list will be updated and published annually in the **Federal Register**. The guidance documents on this comprehensive list are organized by the issuing Center or Office within FDA, and are further grouped by the intended users or regulatory activities to which they pertain. Dates provided in the following list refer to the date of issuance or, where applicable, the date of last revision of the document. Document numbers are provided where available.

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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Requirements for Infrequent Plasmapheresis Donors	August 27, 1982	FDA regulated industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), 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: http://www.fda.gov/cber
Recommendations to Decrease the Risk of Transmitting AIDS from Plasma Donors	March 24, 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
Reduction of the Maximum Platelet Storage Period to 5 Days in an Approved Container	June 2, 1986	Do	Do
Deferral of Donors Who Have Received Human Pituitary-Derived Growth Hormone	November 25, 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
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
HTLV–1 Antibody Testing	November 29, 1988	Do	Do
Use of Recombigen HIV–1 LA Test	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
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
Autologous Blood Collection and Processing Procedures	February 12, 1990	Do	Do
Use of Genetic Systems HIV–2 EIA	June 21, 1990	Do	Do
Deficiencies Relating to the Manufacture of Blood and Blood Components	March 20, 1991	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood and Blood Components	March 20, 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)	April 17, 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
Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing	December 12, 1991	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	August 19, 1993	Do	Do
Volume Limits for Automated Collection of Source Plasma	November 4, 1992	Do	Do
Revision of October 7, 1988 Memo Concerning Red Blood Cell Immunization Programs	December 16, 1992	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
Guidance Regarding Post Donation Information Reports	December 10, 1993	Do	Do
Donor Suitability Related to Laboratory Testing for Viral Hepatitis and a History of Viral Hepatitis	December 22, 1993	Do	Do
Recommendations for the Invalidation of Test Results When Using Licensed Viral Marker Assays to Screen Donors	January 3, 1994	Do	Do
Recommendations for Deferral of Donors for Malaria Risk	July 26, 1994	Do	Do
Use of and FDA Cleared or Approved Sterile Docking Device (STCD) in Blood Bank Practices (transmittal memo 8/12/94) (corrects 7/29/94 Memo)	August 5, 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
Timeframe for Licensing Irradiated Blood Products	February 3, 1995	Do	Do
Revision of 8/27/82 FDA Memo: Requirements for Infrequent Plasmapheresis Donors	March 10, 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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
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
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
Guidance Concerning Conversion to FDA-Reviewed Software Products	November 13, 1995	Do	Do
Donor Deferral Due to Red Blood Cell Loss During Collection of Source Plasma by Automated Plasmapheresis	December 4, 1995	Do	Do
Additional Recommendations for Donor Screening With a Licensed Test for HIV–1 Antigen	March 14, 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
Recommendations and Licensure Requirements for Leukocyte-Reduced Blood Products	May 29, 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
Interim Recommendations for Deferral of Donors at Increased Risk for HIV–1 Group O Infection	December 11, 1996	Do	Do
Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products	December 11, 1996	Do	Do
Interstate Shipment of Interferon for Investigational Use in Laboratory Research Animals or Tests in Vitro	November 21, 1983	Do	Do
Alternatives to Lot Release	July 20, 1993	Do	Do
Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products; Notice	October 14, 1993	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
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
Draft Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation; Notice	September 23, 1996	Do	Do
The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents	February 27, 1997	Do	Do
Preclearance of Promotional Labeling; Clarification	March 5, 1997	Do	Do
Draft Guidance for Industry: Computerized Systems Used in Clinical Trials; Availability	June 18, 1997	Do	Do
Recommended Methods for Short Ragweed Pollen Extracts	November 1, 1985	Do	Do
Information Relevant to the Manufacture of Acellular Pertussis Vaccine	August 23, 1989	Do	Do
Recommended Methods for Blood Grouping Reagents Evaluation	March 1, 1992	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Recommended Methods for Evaluating Potency, Specificity and Reactivity of Anti-Human Globulin	March 1, 1992	Do	Do
Methods of the Allergenic Products Testing Laboratory	October 1, 1993	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
Guide to Inspections of Infectious Disease Marker Testing Facilities	June 1, 1996	Do	Do
Guide to Inspections of Source Plasma Establishments (Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs)	June 1, 1997	Do	Do
Notification Process for Transfusion Related Fatalities and Donation Related Deaths (revised telephone number)	October 7, 1997	FDA regulated industry	Do
Submission Requirements for Requesting Certificates for Exporting Products to Foreign Countries	October 15, 1997	Do	Do
CBER Refusal to File (RTF) Guidance for Product and Establishment License Applications	July 12, 1993	Do	Do
OELPS, Advertising and Promotional Labeling Staff Procedural Guidance Document (Draft)	August 1, 1994	Do	Do
Guidance on Alternatives to Lot Release for Licensed Biological Products	October 27, 1994	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 1, 1995	Do	Do
Computer Assisted Product License Application (CAPLA) Guidance Manual	March 1, 1996	Do	Do
FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products	April 26, 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
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
Draft Guidance for Industry: Manufacture, Processing or Holding of Active Pharmaceutical Ingredients	September 20, 1996	Do	Do
Draft Guidance for Industry; Submitting Application Archival Copies in Electronic Format	November 4, 1996	Do	Do
Draft Guidance for Industry; Electronic Submission of Case Report Forms and Case Report Tabulations	November 4, 1996	Do	Do
Guidance for the Submission of Chemistry, Manufacturing, and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products	January 10, 1997	Do	Do
Proposed Approach to Regulation of Cellular and Tissue-Based Products	February 28, 1997	Do	Do
Tables 1 and 2 from Proposed Approach to Regulation of Cellular and Tissue-Based Products	March 4, 1997	Do	Do
Guidance for Industry—Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products	March 13, 1997	Do	Do
Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies	April 10, 1997	Do	Do
Guidance for Industry—Changes to an Approved Application: Biological Products	July 24, 1997	Do	Do
Guidance for Industry—Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products	July 24, 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for Industry—Screening and Testing of Donors of Human Tissue Intended for Transplantation	July 29, 1997	Do	Do
Guidance for Industry—Donor Screening for Antibodies to HTLV–II	August 15, 1997	Do	Do
Draft Guidance for Industry on Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts	August 25, 1997	Do	Do
Guidance for Industry—Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report	August 27, 1997	Do	Do
Draft Guidance for Industry Efficacy Evaluation of Hemoglobin-and Perfluorocarbon-Based Oxygen Carriers	September 1, 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	October 7, 1997	Do	Do
FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics	November 25, 1992	Do	Do
FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacture of Biological Products; Availability	July 11, 1995	Do	Do
Advertising and Promotion; Guidance; Notice	October 8, 1996	Do	Do
Interpretative Guidelines of the Source Plasma (Human) Standards	October 2, 1973	Do	Do
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
Revised Guideline for Adding Heparin to Empty Containers for Collection of Heparinized Source Plasma (Human)	August 1, 1981	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
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
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
Revised Guideline for the Collection of Platelets, Pheresis	October 7, 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
Guidelines for Release of Pneumococcal Vaccine, Polyvalent	February 1, 1989	Do	Do
FDA Regulated Industries for Drug Master Files	September 1, 1989	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
FDA Regulated Industries for Collection of Blood or Blood Products from Donors With Positive Tests 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
Guideline on the Preparation of Investigational New Drug Products (Human & Animal)	March 1, 1991	Do	Do
Draft Guideline for the Validation of Blood Establishment Computer Systems	September 28, 1993	Do	Do
Guideline for Adverse Experience Reporting for Licensed Biological Products	October 15, 1993	Do	Do
Guideline for Quality Assurance in Blood Establishments	July 11, 1995	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
To Biologic Product Manufacturers—Controlling Materials of Bovine or Ovine Origin	May 3, 1991	Do	Do
To Sponsors of INDs Using Retroviral Vectors	September 20, 1993	Do	Do
To Manufacturers: Bovine Derived Materials (BSE)	December 17, 1993	Do	Do
To Blood Establishment Computer Software Manufacturers	March 31, 1994	Do	Do
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
Letter to Manufacturers of Immune Globulin Intravenous (Human) (IGIV), Aseptic Meningitis Syndrome	October 3, 1994	Do	Do
To Manufacturers of Immune Globulin Products: Testing for Hepatitis C Virus RNA Immunoglobulin	December 27, 1994	Do	Do
To Blood Establishment Computer Software Manufacturers	February 10, 1995	Do	Do
To Manufacturers of Intramuscular Immune Globulin Products: HCV RNA Testing by PCR	March 3, 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
Dear Colleague: Regarding Reverse Transcriptase Activity in Viral Vaccines Produced in Chicken Cells	January 4, 1996	Do	Do
To Manufacturers of FDA-Regulated Drug/Biological/Device Products, Bovine Spongiform Encephalopathy (BSE)	May 9, 1996	Do	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	Do	Do
To Manufacturers: HIV–1 Group O	July 31, 1996	Do	Do
To All Plasma Derivative Manufacturers and to ABRA: Warning Statement for Plasma Derivative Product Labeling	October 7, 1996	Do	Do
To Biologic Product Manufacturers: Revised Procedures for Internal Labeling Review Number Assignment	December 3, 1996	Do	Do
To Plasma Fractionators—CBER's View on Product Recalls Conducted by the Plasma Fractionation Industry	May 29, 1997	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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft PTC in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology	April 10, 1985	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
PTC in the Collection, Processing and Testing of Ex Vivo Activated Mononuclear Leukocytes for Administration to Humans	August 22, 1989	Do	Do
Cytokine and Growth Factor Pre-Pivotal Trial Information Package	April 2, 1990	Do	Do
PTC in the Safety Evaluation of Hemoglobin-Based Oxygen Carriers	August 21, 1990	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
Draft PTC in the Characterization of Cell Lines Used to Produce Biologicals	July 12, 1993	Do	Do
PTC in the Manufacture and Testing of Therapeutic Products for Human Use Derived from Transgenic Animals	August 22, 1995	Do	Do
PTC on Plasmid DNA Vaccines for Preventive Infectious Disease Indications	December 22, 1996	Do	Do
PTC in the Manufacture and Testing of Monoclonal Antibody Products for Human Use	February 28, 1997	Do	Do
Reviewer Guidance, Computer Software	April 26, 1995	FDA Personnel	Do
Informed Consent for Plasmapheresis/Immunization	October 1, 1995	Do	Do
Draft Reviewers' Guide: Changes in Personnel	October 1, 1995	Do	Do
Disease Associated Antibody Collection Program	October 1, 1995	Do	Do
Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software	January 13, 1997	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 (Publication No. 94–920699)
Guidance for Industry: Industry-Supported Scientific and Educational Activities	November 1997	FDA regulated industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), 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: http://www.fda.gov/cber
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
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	Do	Do
Dear Doctor Letter—Difficulty in Obtaining Immune Globulin Intravenous (Human)	January 28, 1998	Health care providers	Do
Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products	January 1998	FDA regulated industry	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use	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
Draft Guidance for Industry: Clinical Development of Programs for Drugs, Devices and Biological Products Intended for Treatment of Osteoarthritis (OA)	February 1998	Do	Do
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
Dear Doctor Letter—Standardized Grass Pollen Extracts	May 11, 1998	Health care providers	Do
Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research	May 1998	FDA regulated industry	Do
Draft Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products	May 1998	Do	Do
Draft Guidance for Industry: Electronic Submissions of Case Report Forms (CRFs), Case Report Tabulations (CRTs) and Data to the Center for Biologics Evaluation and Research	May 1998	Do	Do
Draft Guidance for Industry: Electronic Submissions of a Biologics License Application (BLA) or Product License Application (PLA)/ Establishment License Application (ELA) to the Center for Biologics Evaluation and Research	May 1998	Do	Do
Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds	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
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: 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
Draft Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Virus Type 1	July 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft 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 FDA Form 356h ''Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use''	July 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
Draft Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods	July 1998	Do	Do
Dear Colleague Letter—Use of Haemophilus influenzae Conjugate Vaccines in Combination With DTaP in Infants	August 12, 1998	Health care providers	Do
Dear Doctor Letter—Albumin Use in Seriously Ill Patients	August 19, 1998	Do	Do
Draft Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test	August 1998	FDA regulated industry	Do
Draft Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	August 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
Change to the Guidance Entitled ''Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products''—Information Sheet	September 8, 1998	Do	Do
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
CBER's Year 2000 Letter	October 27, 1998	Do	Do
Draft Guidance for Industry: Developing Medical Imaging Drugs and Biologics	October 1998	Do	Do
Dear Blood Bank/Transfusion Service Director Letter: Hepatitis C Virus Risk	November 3, 1998	Do	Do
Dear Doctor Letter—Important Drug Warning: Immune Globulin Intravenous (Human)	November 13, 1998	Health care providers	Do
Draft Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product	November 1998	FDA regulated industry	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft Guidance for Industry: In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis and Recommendations for Dosing and Labeling	November 1998	Do	Do
Draft Document: United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128	December 1997 (released November 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: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing	December 1998	Do	Do
Draft Guidance for Industry: Content and Format of Geriatric Labeling	December 1998	Do	Do
Dear Healthcare Provider: Important Drug Warning: Safety Information Regarding the use of Abbokinase (Urokinase)	January 25, 1999	Health care providers	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	FDA regulated industry	Do
Guidance on Amended Procedures for Advisory Panel Meetings	January 1999	Do	Do
Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations	January 1999	Do	Do
Guidance for Industry: Population Pharmacokinetics	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
Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 1999	Do	Do
Dear Colleague Letter: Voluntary Recall of Tripedia, DTaP Vaccine	February 4, 1999	Health care providers	Do

III. Guidance Documents Issued by the Center for Devices and Radiological Health (CDRH)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance on Medical Device Tracking (Docket No. 98D–0132)	February 19, 1998	Office of Compliance (OC)	Division of Small Manufacturers Assistance, CDRH, Food and Drug Administration, 1–800–638–2041 or 301–827–0111 or (FAX) Facts on Demand at 1–800–899–0381 or Internet at http://www.fda.gov/cdrh
Guidance on Lead Wires and Patient Cables	March 9, 1998	OC	Do
Global Harmonization Task Force: Draft Document on the Essentials Principles of Safety and Performance of Medical Devices on a Global Basis	October 28, 1998	OC	Do
Medical Devices: Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance (Draft)	July 16, 1998	OC	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Letter to Medical Device Manufacturer on Pentium Processors	February 14, 1995	OC	Do
Guideline for Preparing Notices of Availability of Investigational Medical Devices	November 1, 1985	OC/Bioresearch Monitoring (BIMO)	Do
All Diagnostic Ultrasound Manufacturers and Importers-Exemption from Reporting Under 21 CFR 1002	February 24, 1986	OC/Division of Enforcement I (DOEI)	Do
General Principles of Software Validation; Draft Guidance	June 9, 1997	OC/DOEI	Do
Exemption from Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers	September 16, 1981	OC/DOEI	Do
Clarification of Radiation Control Regulations for Diagnostic X-ray Equipment (FDA 89–8221)	March 1, 1989	OC/DOEI	Do
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
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
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
Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and their Major Components	January 1, 1982	OC/DOEI	Do
Guideline for the Manufacture of In Vitro Diagnostic Products	January 10, 1994	OC/DOEI	Do
Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi)	May 17, 1993	OC/DOEI	Do
Manufacturers/Assemblers of Diagnostic X-ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g)	October 13, 1993	OC/DOEI	Do
Retention of Records Required by 21 CFR 1002	August 24, 1981	OC/DOEI	Do
All U.S. Condom Manufacturers, Importers and Repackagers	April 7, 1987	OC/Division of Enforcement II (DOEII)	Do
Letter to Ophthalmologists about Lasers for Refractive Surgery	June 27, 1997	OC/DOEII	Do
Manufacturers and Initial Distributors of Hemodialyzers	May 23, 1996	OC/DOEII	Do
Manufacturers and Users of Lasers for Refractive Surgery	October 10, 1996	OC/DOEII	Do
Shielded Trocars and Needles Used for Abdominal Access During Laparoscopy	August 23, 1996	OC/DOEII	Do
Prospective Manufacturers of Barrier Devices Used During Oral Sex for STD Protection	October 31, 1996	OC/DOEII	Do
Condoms: Inspection and Sampling at Domestic Manufacturers and of all Repackers; Sampling from all Importers (Damaska Memo to Field on 4/8/87)	April 8, 1987	OC/DOEII	Do
Guide for Preparing Product Reports for Lasers and Products Containing Lasers	September 1, 1995	OC/DOEII	Do
Hazards of Volume Ventilators and Heated Humidifiers	September 15, 1993	OC/DOEII	Do
Latex Labeling Letter (Johnson)	March 18, 1993	OC/DOEII	Do
Letter—Condom Manufacturers and Distributors (included in Condom Packet #398)	April 5, 1994	OC/DOEII	Do
Letter to Industry, Powered Wheelchair Manufacturers from R. M. Johnson	May 10, 1993	OC/DOEII	Do
Letter to Manufacturers/Repackers Using Cotton	April 22, 1994	OC/DOEII	Do
Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals	February 3, 1994	OC/DOEII	Do
Compliance Guide for Laser Products (FDA 86–8260)	September 1, 1985	OC/DOEII	Do
Dental Handpiece Sterilization (Dear Doctor Letter)	September 28, 1992	OC/DOEII	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Levels of Exposure	June 23, 1978	OC/DOEII	Do
Letter—Manufacturers, Distributors and Importers of Condom Products (included in Condom Packet #K398)	February 23, 1994	OC/DOEII	Do
Letter—Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt) (included in Condom Packet #398)	February 13, 1989	OC/DOEII	Do
Regulatory Requirements for Medical Gloves—A Workshop Manual FDA Publication No. 96–4257	September 1, 1996	OC/DOEII	Do
Standard Specification for Rubber Contraceptives (Condoms) (included in Condom Packet #398)	October 28, 1983	OC/DOEII	Do
Pesticide Regulation Notice 94–4 Interim Measures for the Registration of Antimicrobial Products/Liquid Chemical Germicides with Medical Device Use Claims	June 30, 1994	OC/DOEII	Do
Open Door Operation of Microwave Ovens as a Result of Oven Miswiring	March 28, 1980	OC/Division of Enforcement III (DOEIII)	Do
Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use	September 1, 1996	OC/DOEIII	Do
Final Design Control Inspectional Strategy	March 1, 1997	OC/DOEIII	Do
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/DOEIII	Do
Design Control Guidance for Medical Device Manufacturers	March 11, 1997	OC/DOEIII	Do
Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products	August 1, 1995	OC/DOEIII	Do
Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device	March 1, 1987	OC/DOEIII	Do
Computerized Devices/Processes Guidance—Application of the Medical Device GMP to Computerized Devices and Manufacturing Processes	May 1, 1992	OC/DOEIII	Do
Guidance for the Submission of Cabinet X–Ray System Reports Pursuant to 21 CFR 1020.40	February 1, 1975	OC/DOEIII	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)	October 1, 1987	OC/DOEIII	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps (replaces FDA 82–8127)	September 1, 1995	OC/DOEIII	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products (replaces FDA 82–8127)	September 1, 1995	OC/DOEIII	Do
Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR 1002)	September 1, 1995	OC/DOEIII	Do
Guide for Preparing Reports on Radiation Safety of Microwave Ovens	March 1, 1985	OC/DOEIII	Do
Guide for Submission of Information on Accelerators Intended to Emit X-Radiation Required Pursuant to 21 CFR 1002.10	April 1, 1971	OC/DOEIII	Do
Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21 CFR 1002.10	April 30, 1974	OC/DOEIII	Do
Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 (FDA 81–8137)	September 1, 1980	OC/DOEIII	Do
Guide for Submission of Information on Industrial X-Ray Equipment Required Pursuant to 21 CFR 1002.10	March 1, 1973	OC/DOEIII	Do
Guide for the filing of Annual Reports for X-Ray Components and Systems	July 1, 1980	OC/DOEIII	Do
Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems	September 1, 1984	OC/DOEIII	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Impact Resistant Lenses: Questions and Answers (FDA 87–4002) (see shelf # 460)	September 1, 1987	OC/DOEIII	Do
Imports Radiation-Producing Electronic Products (FDA 89–8008)	November 1, 1988	OC/DOEIII	Do
Information Requirements for Cookbooks and User and Service Manuals	October 31, 1988	OC/DOEIII	Do
Keeping Medical Devices Safe from Electro-magnetic Interference	July 1, 1995	OC/DOEIII	Do
Keeping Up With the Microwave Revolution (FDA Pub No. 91–4160)	March 1, 1990	OC/DOEIII	Do
Laser Light Show Safety—Who's Responsibility (FDA 86–8262)	May 1, 1986	OC/DOEIII	Do
Letter to All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist	May 28, 1981	OC/DOEIII	Do
Letter to Trade Association: ReUse of Single-use or Disposable Medical Devices	December 27, 1995	OC/DOEIII	Do
Letter: Changes in Regulations Concerning Records and Reports on Radiation-Emitting Electronic Products	October 27, 1995	OC/DOEIII	Do
Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations		OC/DOEIII	Do
Medical Devices and EMI: The FDA Perspective	January 1, 1995	OC/DOEIII	Do
Policy on Lamp Compatibility (sunlamps)	September 2, 1986	OC/DOEIII	Do
Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products	August 21, 1986	OC/DOEIII	Do
Policy on Warning Label Required on Sunlamp Products	June 25, 1985	OC/DOEIII	Do
Quality Assurance Guidelines for Hemodialysis Devices	February 1, 1991	OC/DOEIII	Do
Quality Control Guide for Sunlamp Products (FDA 88–8234)	March 1, 1988	OC/DOEIII	Do
Quality Control Practices for Compliance with the Federal Mercury Vapor Lamp Performance Standard	May 1, 1980	OC/DOEIII	Do
Reporting and Compliance Guide for Television Products including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Information and Guidance	October 1, 1995	OC/DOEIII	Do
Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) (FDA 88–8140)	September 1, 1995	OC/DOEIII	Do
Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR 1002)	September 1, 1995	OC/DOEIII	Do
Reporting of New Model Numbers to Existing Model Families	June 14, 1983	OC/DOEIII	Do
Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (replaces FDA 82–8127)	September 1, 1995	OC/DOEIII	Do
Safety of Electrically Powered Products: Letter To Medical Device and Electronic Product Manufacturers From Lillian Gill & BHB correction memo	September 18, 1996	OC/DOEIII	Do
Suggested State Regulations for Control of Radiation—Volume II Nonionizing Radiation—Lasers (FDA Pub No. 83–8220)	January 1, 1982	OC/DOEIII	Do
Unsafe Patient Lead Wires and Cables	September 3, 1993	OC/DOEIII	Do
Guide for Preparing Annual Reports for Ultrasonic Therapy Products	September 1, 1996	OC/DOEIII	Do
Guide for Preparing Product Reports for Medical Ultrasound Products	September 1, 1996	OC/DOEIII	Do
Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only)	August 1, 1996	OC/DOEIII	Do
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88–8264)	March 1, 1988	OC/DOEI & III	Do
The FDA Export Reform and Enhancement Act of 1996/Export Certification	October 1, 1996	OC/Division of Program Operations (DPO)	Do

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Sec. 300.600 Commercial Distribution with Regard to Premarket Notification (Section 510(k)) (CPG 7124.19)	September 24, 1987	OC/Office of the Director (OD)	Do
Global Harmonization Task Force: Availability of Draft Documents on Adverse Event and Vigilance Reporting of Medical Device Events	August 31, 1998	OC/Office of Surveillance and Biometrics (OSB)	Do
Commercial Distribution/Exhibit Letter (Use instead of Hile letter) (Display)	April 10, 1992	OC/Other (OT)	Do
Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule	July 1, 1995	OC/OT	Do
Guidance for the Medical Device Industry on PMA Shell Development and Modular Review	November 6, 1998	ODE	Do
Medical Devices Containing Materials Derived from Animal Sources (Except In Vitro Diagnostic Devices), Guidance for FDA Reviewers and Industry	November 6, 1998	ODE	Do
Frequently Asked Questions on the New 510(k) Pardigm	October 22, 1998	ODE	Do
Guidance to Industry Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Material, and Priority Review	May 20, 1998	ODE	Do
Convenience Kits Interim Regulatory Guidance	May 20, 1997	ODE	Do
Kit Certification for 510(k)s	July 1997	ODE	Do
Guidance for Industry—Contents of a Product Development Protocol	July 27, 1998	ODE	Do
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (replaces Reviewer Guidance for Computer-Controlled Medical Devices Undergoing 510(k) Review 8/29/91)	May 28, 1998	ODE	Do
New Model Medical Device Development Process	June 3, 1998	ODE	Do
Modifications to Devices Subject to Premarket Approval—the PMA Supplement Decision Making Process	August 6, 1998	ODE	Do
Guidance for Off-the-Shelf Software Use in Medical Devices	August 17, 1998	ODE	Do
PMA/510(k) Expedited Review—Guidance for Industry and CDRH Staff	March 20, 1998	ODE	Do
Guidance on Amended Procedures for Advisory Panel Meetings	March 30, 1998	ODE	Do
'Real-Time' Review Program for Premarket Approval Application (PMA) Supplements	April 22, 1997	ODE	Do
A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications	March 30, 1998	ODE	Do
Freedom of Information/510(K) Process Changes	May 15, 1997	ODE	Do
Guidance for Submitting Reclassification Petition	January 1, 2000	ODE	Do
Product Development Protocol	October 1, 1997	ODE	Do
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—for Use by CDRH and Industry (Docket No. 98D–0079)	February 19, 1998	ODE	Do
Procedures for Class II Device Exemptions from Premarket Notification Guidance for Industry and CDRH Staff (Docket No. 98D–0083)	February 25, 1998	ODE	Do
New section 513(f)(2)—Evaluation of Automatic Class III Designation: Guidance for Industry and CDRH Staff (Docket No. 98D–0082)	February 19, 1998	ODE	Do
SMDA Changes—Premarket Notification; Regulatory Requirements for Medical Devices (510k) Manual Insert	April 17, 1992	ODE	Do
#D95–2, Attachment A (Interagency Agreement between FDA & HCFA)	September 15, 1995	ODE	Do
#D95–2, Attachment B (Criteria for Categorization of Investigational Devices (HCFA)	September 15, 1995	ODE	Do
30–Day Notices and 135–Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH (Docket No. 98D–0080)	February 19, 1998	ODE	Do
510(k) Quality Review Program (blue book memo)	March 29, 1996	ODE	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Distribution and Public Availability of PMA Summary of Safety and Effectiveness Data Packages	October 10, 1997	ODE	Do
Document Review by the Office of the Chief Counsel (Blue Book Memo G96–1))	June 6, 1996	ODE	Do
HCFA Reimbursement Categorization Determinations for FDA-approved IDEs	September 15, 1995	ODE	Do
ODE Executive Secretary Guidance Manual	August 7, 1987	ODE	Do
Determination of Intended Use for 510(k) Devices: Final Document (Docket No. 98D–0081)	February 19, 1998	ODE	Do
Letter—Vascular Graft Industry (Philip Phillips)	November 22, 1995	ODE	Do
Letter to Industry, Powered Wheelchair/Scooter or Accessory/Component Manufacturer from Susan Alpert, Ph.D., M.D.	May 26, 1994	ODE	Do
Preamendments Class III Strategy; SXAlpert	April 19, 1994	ODE	Do
4-of-A-Kind PMA's	October 1, 1991	ODE	Do
Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices	December 1, 1983	ODE	Do
CDRH's 510(k)/IDE/PMA Refuse to Accept/Accept/File Policies (see #D94–1, #K94–1, & #P94–1)	June 30, 1993	ODE	Do
Classified Convenience Kits	April 30, 1993	ODE	Do
Color Additive Petitions (p. II–19 of PMA Manual)	June 1, 1987	ODE	Do
Color Additive Status List (Inspection Operations Manual)	February 1, 1989	ODE	Do
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff, Final Document (Docket No. 98D–0078)	February 19, 1998	ODE	Do
Color Additives for Medical Devices (Snesko)	November 15, 1995	ODE	Do
Deciding When to Submit a 510(k) for a Change to an Existing Device (see CDRH F–O–D #1935)	January 10, 1997	ODE	Do
Device Specific Guidance Documents (List)	May 11, 1993	ODE	Do
FDA Clinical Investigator Information Sheets	May 1, 1989	ODE	Do
FDA Guide for Validation of Biological Indicator Incubation Time (Source: Sterilization Committee; through Virginia Ross; HFZ–332)	January 1, 1986	ODE	Do
FDA Policy For The Regulation Of Computer Products (DRAFT) (See 2099)	November 13, 1989	ODE	Do
Format for IDE Progress Reports	January 1, 2000	ODE	Do
Guidance for Preparation of PMA Manufacturing Information	August 1, 1992	ODE	Do
Guideline for the Monitoring of Clinical Investigations	January 1, 1988	OC/BIMO	Do
Guideline on General Principles of Process Validation	May 1, 1987	ODE	Do
Guideline on Sterile Drug Products Produced by Aseptic Processing	June 1, 1987	ODE	Do
Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test	December 1, 1987	ODE	Do
Indications for Use Statement	January 2, 1996	ODE	Do
Industry Representatives on Scientific Panels	March 27, 1987	ODE	Do
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (see 1198)	April 1, 1996	ODE	Do
Limulus Amebocute Lysate; Reduction of Samples for Testing	October 23, 1987	ODE	Do
Master Files Part III; Guidance on Scientific and Technical Information	June 1, 1987	ODE	Do
Memorandum: Electromagnetic Compatibility for Medical Devices: Issues and Solutions	June 13, 1995	ODE	Do
Methods for Conducting Recall Effectiveness Checks	June 16, 1978	ODE	Do
Necessary Information for Diagnostic Ultrasound 510(k) (Draft)	November 24, 1987	ODE	Do
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)	January 1, 2000	ODE	Do
PMA Review Statistical Checklist	January 1, 2000	ODE	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
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
Preamendment Class III Devices	March 11, 1992	ODE	Do
Premarket Notification [510(k)] Status Request Form, revised	March 7, 1994	ODE	Do
Premarket Submission Coversheet, Instructions, and Survey	January 19, 1995	ODE	Do
Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers (FDA 90–4236)	September 1, 1989	ODE	Do
Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources (include with 926–930)	June 30, 1993	ODE	Do
Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities (see 198)	September 3, 1996	ODE	Do
Shelf Life of Medical Devices	March 1, 1991	ODE	Do
Substantial Equivalence (SE) Decision Making Documentation ATTACHED: 'SE' Decision Making Process (Detailed) i.e. the decision making tree	January 1, 1990	ODE	Do
Suggested Content for Original IDE Application Cover Letter—Version 4	February 27, 1996	ODE	Do
Suggestions for Submitting a Premarket Approval (PMA) Application	April 1, 1993	ODE	Do
Threshold Assessment of the Impact of Requirements for Submission of PMAs for 31 Medical Devices Marketed Prior to May 28, 1976	January 1, 1990	ODE	Do
Guidance on IDE Policies and Procedures	January 20, 1998	ODE	Do
Viable Bacteriophage in Co2 Laser Plume: Aerodynamic Size Distribution	January 1, 2000	ODE	Do
Deciding When to Submit a 510(k) for a Change to an Existing Device (blue book memo #K97–1) (see CDRH F–O–D #935)	January 10, 1997	ODE/blue	Do
Memorandum of Understanding Regarding Patient Labeling Review (blue book memo #G96–3))	August 9, 1996	ODE/blue	Do
Continued Access to Investigational Devices During PMA Preparation and Review (blue book memo)	July 15, 1996	ODE/blue	Do
510(k) Additional Information Procedures (blue book memo #K93–1)	July 23, 1993	ODE/blue/510k	Do
510(k) Refuse to Accept Procedures (blue book memo #K94–1)	May 20, 1994	ODE/blue/510k	Do
510(k) Sign-Off Procedures (blue book memo #K94–2)	June 3, 1994	ODE/blue/510k	Do
510(k) Sterility Review Guidance and Revision of 11/18/1994 (blue book memo #K90–1)	February 12, 1990	ODE/blue/510k	Do
Cover Letter: 510(k) Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices (blue book memo #K95–1)	November 21, 1995	ODE/blue/510k	Do
Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program (blue book memo #K86–3)	June 30, 1986	ODE/blue/510k	Do
Premarket Notification—Consistency of Reviews (blue book memo #K89–1)	February 28, 1989	ODE/blue/510k	Do
Review of 510(k)s for Computer Controlled Medical Devices (blue book memo #K91–1)	August 29, 1991	ODE/blue/510k	Do
Executive Secretaries Guidance Manual ıG87–3	August 7, 1987	ODE/blue/gnrl	Do
Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices (blue book memo #G90–2)	October 19, 1990	ODE/blue/gnrl	Do
Consolidated Review of Submissions for Lasers and Accessories (blue book memo #G90–1)	October 19, 1990	ODE/blue/gnrl	Do
Device Labeling Guidance (blue book memo Γ91–1)	March 8, 1991	ODE/blue/gnrl	Do
Documentation and Resolution of Differences of Opinion on Product Evaluations (blue book memo #G93–1)	December 23, 1993	ODE/blue/gnrl	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
ODE Regulatory Information for the Office of Compliance—Information Sharing Procedures (blue book memo #G87–2)	May 15, 1987	ODE/blue/gnrl	Do
PMA/510(k) Expedited Review (blue book memoG94–2)	May 20, 1994	ODE/blue/gnrl	Do
PMA/510(k) Triage Review Procedures (blue book memo #G94–1)	May 20, 1994	ODE/blue/gnrl	Do
Review of Laser Submissions (blue book memo #G88–1)	April 15, 1988	ODE/blue/gnrl	Do
Toxicology Risk Assessment Committee (blue book memo #G89–1)	August 9, 1989	ODE/blue/gnrl	Do
Use of International Standard ISO–10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing' (blue book memo) (Replaces #G87–1 #8294)	May 1, 1995	ODE/blue/gnrl	Do
Delegation of IDE Actions (blue book memo #D88–1)	April 26, 1988	ODE/blue/ide	Do
Goals and Initiatives for the IDE Program (blue book memo #D95–1)	July 12, 1995	ODE/blue/ide	Do
IDE Refuse to Accept Procedures (blue book memo #D94–1)	May 20, 1994	ODE/blue/ide	Do
Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Att. A Interagency Agreement, Att. B Criteria for Catergorization of Investigational Devices, & Att. C–List (blue book memo #D95–2)	September 15, 1995	ODE/blue/ide	Do
Overdue IDE Annual Progress Report Procedures (blue book memo) #D93–1	July 23, 1993	ODE/blue/ide	Do
Review of IDEs for Feasibility Studies (blue book memo #D89–1)	May 17, 1989	ODE/blue/ide	Do
Assignment of Review Documents (blue book memo #I90–2)	August 24, 1990	ODE/blue/integ	Do
Document Review Processing (blue book memo #I91–1)	February 12, 1992	ODE/blue/integ	Do
Integrity of Data and Information Submitted to ODE (blue book memo #I91–2)	May 29, 1991	ODE/blue/integ	Do
Meetings with the Regulated Industry (blue book memo #I89–3)	November 20, 1989	ODE/blue/integ	Do
Nondisclosure of Financially Sensitive Information (blue book memo #I92–1)	March 5, 1992	ODE/blue/integ	Do
Policy Development and Review Procedures (blue book memo #I90–1)	February 15, 1990	ODE/blue/integ	Do
Telephone Communications Between ODE Staff and Manufacturers (blue book memo #I93–1)	January 29, 1993	ODE/blue/integ	Do
Clinical Utility and Premarket Approval (blue book memo #P91–1)	May 3, 1991	ODE/blue/pma	Do
Criteria for Panel Review of PMA Supplements (blue book memo #P86–3)	January 30, 1986	ODE/blue/pma	Do
Panel Report and Recommendations on PMA Approvals (blue book memo #P86–5)	April 18, 1986	ODE/blue/pma	Do
Panel Review of 'Me-Too' Devices (blue book memo #P86–6)	July 1, 1986	ODE/blue/pma	Do
Panel Review of Premarket Approval Applications (blue book memo #P91–2)	May 3, 1991	ODE/blue/pma	Do
PMA Compliance Program (blue book memo #P91–3)	May 3, 1991	ODE/blue/pma	Do
PMA Filing Decisions (blue book memo #P90–2)	May 18, 1990	ODE/blue/pma	Do
PMA Refuse to File Procedures (blue book memo #P94–1)	May 20, 1994	ODE/blue/pma	Do
PMA Supplements: ODE's letter to manufacturers; identifies situations which may require the submission of a PMA supplement (when PMA Supplements are required) (blue book memo) #P90–1	April 24, 1990	ODE/blue/pma	Do
PMAs Early Review and Preparation of Summaries of Safety and Effectiveness (blue book memo #P86–1)	January 27, 1986	ODE/blue/pma	Do
Premarket Approval Application (PMA) Closure (blue book memo #P94–1)	July 8, 1994	ODE/blue/pma	Do

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Review and Approval of PMAs of Licensees (blue book memo #P86–4)	October 22, 1990	ODE/blue/pma	Do
Review of Final Draft Medical Device Labeling (blue book memo #P91–4)	August 29, 1991	ODE/blue/pma	Do
Distribution and Public Availability of Premarket Approval Application Summary of Safety and Effectiveness Data Packages (P98–1)	October 10, 1997	ODE/blue/pma	Do
PMA Summaries of Safety and Effectiveness and Federal Register Notices of PMA Approvals—Review by the Office of General Counsel (Revised) (P98–1)	June 11, 1993	ODE/blue/pma	Do
PMA Review Schedules (P87–1)	March 31, 1988	ODE/blue/pma	Do
Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material	February 3, 1999	ODE/Division of Clinical Laboratory Devices (DCLD)	Do
Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs	October 30, 1996	ODE/DCLD	Do
Guidance for Submission of Immunohistochemistry Applications to the FDA	June 3, 1998	ODE/DCLD	Do
In Vitro Diagnostic Creatinine Test System	July 2, 1998	ODE/DCLD	Do
In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System	July 6, 1998	ODE/DCLD	Do
In Vitro Diagnostic Chloride Test System	July 6, 1998	ODE/DCLD	Do
In Vitro Diagnostic Glucose Test System	July 6, 1998	ODE/DCLD	Do
In Vitro Diagnostic Potassium Test System	July 6, 1998	ODE/DCLD	Do
In Vitro Diagnostic Sodium Test System	July 6, 1998	ODE/DCLD	Do
In Vitro Diagnostic Urea Nitrogen Test System	July 6, 1998	ODE/DCLD	Do
In Vitro Diagnostic C–Reactive Immunological Test System	July 20, 1998	ODE/DCLD	Do
In Vitro Diagnostic Calibrators	July 20, 1998	ODE/DCLD	Do
Points To Consider For Hematology Quality Control Materials	September 30, 1997	ODE/DCLD	Do
Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to be Used by the Consumer	December 30, 1998	ODE/DCLD	Do
Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) in Vitro Diagnostic Devices (IVDs)	November 6, 1996	ODE/DCLD	Do
Letter to IVD Manufacturers on Streamlined PMA	December 22, 1997	ODE/DCLD	Do
Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification [510(k)] to FDA	September 19, 1996	ODE/DCLD	Do
Review Criteria for Assessment of Rheumatoid Factor (RF) In Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay (EIA), Enzyme Linked Immunosorbent Assay (ELISA), Particle Agglutination Tests, and Laser and Rate Nephgelometry	February 21, 1997	ODE/DCLD	Do
Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use	July 14, 1995	ODE/DCLD	Do
Assessing the Safety/Effectiveness of Home-use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions	October 1, 1988	ODE/DCLD	Do
Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers	June 10, 1996	ODE/DCLD	Do
DCLD Tier/Triage lists (include 931)	May 31, 1996	ODE/DCLD	Do
Draft Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies	August 31, 1995	ODE/DCLD	Do
Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests	July 29, 1992	ODE/DCLD	Do
Draft Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for IVDs	September 30, 1991	ODE/DCLD	Do
Draft Guidance Document for 510(k) Submission of Immunoglobulins A, G, M, D and E Immunoglobulin System In Vitro Devices	September 1, 1992	ODE/DCLD	Do

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Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs using Monoclonal Antibodies	September 26, 1991	ODE/DCLD	Do
Draft Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms	June 14, 1993	ODE/DCLD	Do
Guidance Criteria for Cyclosporine PMAs	January 24, 1992	ODE/DCLD	Do
Draft: Premarketing Approval Review Criteria for Premarket Approval of Estrogen (ER) or Progesterone (PGR) Receptors In Vitro Diagnostic Devices Using Steroid Hormone	September 10, 1992	ODE/DCLD	Do
Points to Consider for Cervical Cytology Devices	July 25, 1994	ODE/DCLD	Do
Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance	September 26, 1994	ODE/DCLD	Do
Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	February 20, 1996	ODE/DCLD	Do
Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices/Cover Letter dated 3/14/1996	February 1, 1996	ODE/DCLD	Do
Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies Using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoasay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA)	February 1, 1994	ODE/DCLD	Do
Review Criteria for Assessment of Alpha-Fetoprotein (AFP) In Vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies	July 15, 1994	ODE/DCLD	Do
Review Criteria for Assessment of Antimicrobial Susceptibility Devices	May 31, 1991	ODE/DCLD	Do
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers	July 15, 1991	ODE/DCLD	Do
Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)	September 27, 1995	ODE/DCLD	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens	January 1, 1992	ODE/DCLD	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. (Tuberculosis (TB))	July 6, 1993	ODE/DCLD	Do
Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter pylori	September 17, 1992	ODE/DCLD	Do
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
Review Criteria for Blood Culture Systems	August 12, 1991	ODE/DCLD	Do
Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases	May 31, 1990	ODE/DCLD	Do
Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe	December 30, 1991	ODE/DCLD	Do
Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents	August 1, 1992	ODE/DCLD	Do
Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic)	February 15, 1996	ODE/DCLD	Do
Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	May 15, 1992	ODE/DCLD	Do
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

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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
Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance	November 19, 1998	ODE/DCRND	Do
Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm)	November 5, 1998	ODE/Division of Cardiovascular, Respiratory and Neurological Devices (DCRND)	Do
Diagnostic ECG Guidance (Including Non-Alarming ST Segment measurement)	November 5, 1998	ODE/DCRND	Do
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/DCRND	Do
Non-Invasive Blood Pressure (NIBP) Monitor Guidance	March 10, 1997	ODE/DCRND	Do
Guidance for Off-the-Shelf Software Use in Medical Devices; Draft Document	June 4, 1997	ODE/DCRND	Do
Draft Percutaneous Transluminal Coronary Angioplasty Package Insert Template	February 7, 1995	ODE/DCRND	Do
Medical Device Labeling—Suggested Format and Content; Draft Document	August 12, 1997	ODE/DCRND	Do
Draft Intravascular Brachytherapy—Guidance for Data to be Submitted to the Food and Drug Administration in Support of Investigational Device Exemption (IDE) Applications	May 24, 1996	ODE/DCRND	Do
510(k) Reviewer Guidelines—Tracheostomy Tubes 868.5800	January 1, 2000	ODE/DCRND	Do
Balloon Valvuloplasty Guidance For The Submission Of an IDE Application and a PMA Application	January 1, 1989	ODE/DCRND	Do
Rechargeable Battery Preliminary Guidance for Data to be Submitted to FDA in Support of Premarket Notification Applications	July 12, 1993	ODE/DCRND	Do
Review Guidance for Anesthesia Conduction Catheter	May 15, 1991	ODE/DCRND	Do
Coronary and Cerebrovascular Guidewire Guidance	January 1, 1995	ODE/DCRND	Do
Draft Guidance: Human Heart Valve Allografts	June 21, 1991	ODE/DCRND	Do
Draft Replacement Heart Valve Guidance	October 14, 1994	ODE/DCRND	Do
Draft Reviewer Guidance for Ventilators	July 1, 1995	ODE/DCRND	Do
Draft Reviewer Guidance on Face Masks and Shield for CPR	March 16, 1996	ODE/DCRND	Do
Draft Version Cardiac Ablation Preliminary Guidance (Data to be Submitted to FDA in Support Investigation Device Exemption Application	March 1, 1995	ODE/DCRND	Do
Draft Version Electrode Recording Catheter Preliminary Guidance (Data to be Submitted to FDA in Support of Premarket Notifications	March 1, 1995	ODE/DCRND	Do
Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch (to be used with EMI standard)	November 1, 1993	ODE/DCRND	Do
General Guidance Document: Non-Invasive Pulse Oximeter	September 7, 1992	ODE/DCRND	Do
Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II	February 1, 1989	ODE/DCRND	Do
Reviewer Guidance for Premarket Notification (510(k)) Submissions—Labeling, Performance and Environmental Testing for Electronic Devices	July 19, 1995	ODE/DCRND	Do
Guidance for Peak Flow Meters for Over-the-Counter Sale	June 1, 1993	ODE/DCRND	Do
Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses	April 1, 1990	ODE/DCRND	Do
Heated Humidifier Review Guidance	August 30, 1991	ODE/DCRND	Do
Implantable Pacemaker Lead Testing Guidance For The Submission of a Section 510(k) Notification	September 1, 1989	ODE/DCRND	Do
Implantable Pacemaker Testing Guidance	January 12, 1990	ODE/DCRND	Do
Policy for Expiration Dating (DCRND RB92–G)	October 30, 1992	ODE/DCRND	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Review Guidelines for Oxygen Generators and Oxygen Equipment	Undated	ODE/DCRND	Do
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	November 9, 1990	ODE/DCRND	Do
Reviewer's Guidance for Oxygen Concentrator	August 30, 1991	ODE/DCRND	Do
Electrocardiograph (ECG) Electrode	February 11, 1997	ODE/DCRND	Do
Electrocardiograph (ECG) Lead Switching Adapter	February 11, 1997	ODE/DCRND	Do
Electrocardiograph (ECG) Surface Electrode Tester	February 11, 1997	ODE/DCRND	Do
Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints	December 1, 1995	ODE/Division of Dental Infection Control and General Hospital Devices (DDIGD)	Do
Guidance for the Preparation of Premarket Notifications for Dental Composites	November 27, 1998	ODE/DDIGD	Do
Neonatal and Neonatal Transport Incubators Premarket Notifications	September 18, 1998	ODE/DDIGD	Do
Reexamination of the Evaluation Process for Liquid Chemical Sterilant and High Level Disinfectants	May 19, 1997	ODE/DDIGD	Do
Further Information on the Regulation of Liquid Chemical Sterilants and High Level Disinfectants	August 5, 1997	ODE/DDIGD	Do
Guidance on the Content and Format of Premarket Notifications [510(k)] Submissions for Liquid Chemical Sterilants and High Level Disinfectants	December 18, 1997	ODE/DDIGD	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Surgical Masks	January 16, 1998	ODE/DDIGD	Do
Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products (Replaces: Guidance on the Content and Format of Premarket Notifications [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products—2/13/98)	January 13, 1999	ODE/DDIGD	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions of Washers and Washer-Disinfectors	August 4, 1998	ODE/DDIGD	Do
Devices for the Treatment and/or Diagnosis of Temporomandibular Joint Dysfunction and/or Orofacial Pain	June 10, 1998	ODE/DDIGD	Do
Dental Impression Materials—Premarket Notification	August 17, 1998	ODE/DDIGD	Do
OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits	August 18, 1998	ODE/DDIGD	Do
Dental Cements—Premarket Notification	August 18, 1998	ODE/DDIGD	Do
Groups Capable of Testing for Latex Skin Sensitization (Addendum to #944)	July 28, 1997	ODE/DDIGD	Do
Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities	September 19, 1995	ODE/DDIGD	Do
Guidance Document on Dental Handpieces	July 1, 1995	ODE/DDIGD/Dental Devices Branch (DDB)	Do
510(k) Guidance for Screw Type Endosseous Implants for Prosthetic Attachment	August 11, 1992	ODE/DDIGD/DDB	Do
510(k) Information Needed for Hydroxyapatite Coated Titanium Endosseous Implants	July 6, 1993	ODE/DDIGD/DDB	Do
510(k) Information Needed for Metallurgical Endosseous Implants	August 12, 1993	ODE/DDIGD/DDB	Do
510(k) Information Needed for Ti-Powder Coated Titanium Endosseous Implants	July 13, 1993	ODE/DDIGD/DDB	Do
Draft Guidance Document for the Preparation of Premarket Notification [510(k)'s] for Dental Alloys	March 3, 1997	ODE/DDIGD/DDB	Do
Guidance Document for the Preparation of Premarket Notifications (510(k)'s) for Temporomandibular Joint Implants	January 23, 1995	ODE/DDIGD/DDB	Do
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application For An Endosseous Implant For Prosthetic Attachment	May 16, 1989	ODE/DDIGD/DDB	Do
Guidance for the Preparation of Premarket Notification [510(k)] for Resorbable Periodontal Barriers	January 1, 2000	ODE/DDIGD/DDB	Do

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Information Necessary for Premarket Notification Submissions for Screw-Type Endossesous Implants	December 9, 1996	ODE/DDIGD/DDB	Do
Outline of Recommended Procedures for a Clinical Investigation of Endosseous Implants Under a 510(k)	January 1, 2000	ODE/DDIGD/DDB	Do
Outline of Recommended Procedures for Animal Laboratory Studies of Endosseous Implants	January 1, 2000	ODE/DDIGD/DDB	Do
Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes	April 1, 1993	ODE/DDIGD/General Hospital Devices Branch (GHDB)	Do
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/GHDB	Do
Guidance on 510(k) Submissions for Implanted Infusion Ports	October 1, 1990	ODE/DDIGD/GHDB	Do
Guidance on Premarket Notification [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters	March 16, 1995	ODE/DDIGD/GHDB	Do
Guidance on the Content of Premarket Notification [510(k)] Submissions for Clinical Electronic Thermometers	March 1, 1993	ODE/DDIGD/GHDB	Do
Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps	March 1, 1993	ODE/DDIGD/GHDB	Do
Guidance on the Content of Premarket Notification [510(k)] Submissions for Hypodermic Single Lumen Needles	April 1, 1993	ODE/DDIGD/GHDB	Do
Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	August 1, 1993	ODE/DDIGD/Infection Control Devices Branch (ICDB)	Do
Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes	August 1, 1993	ODE/DDIGD/ICDB	Do
Guidance on the Content and Format of Premarket Notification 510(k) Submissions for Liquid Chemical Germicides	December 6, 1996	ODE/DDIG/ICDB	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants (and 3/9/94 Addendum)	October 1, 1993	ODE/DDIGD/ICDB	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers	October 1, 1993	ODE/DDIGD/ICDB	Do
Addendum to Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants	March 9, 1994	ODE/DDIGD/ICDB	Do
Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities	March 3, 1993	ODE/Division of General and Restorative Devices (DGRD)	Do
Guidance Document for Powered Suction Pump 510(k)s	September 30, 1998	ODE/DGRD	Do
Guidance Document for Industry and CDRH Staff for the Preparation of Investigational Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices (Replaces: Guidance Document for the Preparation of Investigatinal Device Exemptions and Premarket Approval Applications for Bone Growth Stimulator Devices—8/12/88)	March 18, 1998	ODE/DGRD	Do
Guidance for Content of Premarket Notifications for Esophageal and Tracheal Prostheses	April 28, 1998	ODE/DGRD	Do
Guidance Document for Surgical Lamp 510ks	July 13, 1998	ODE/DGRD	Do
Protocol for Dermal Toxicity Testing for Devices in Contact with Skin (Draft)	January 1, 2000	ODE/DGRD	Do
Guide for 510(k) Review of Processed Human Dura Mater	June 26, 1990	ODE/DGRD	Do
Guide for TENS 510(k) Content (Draft)	August 1, 1994	ODE/DGRD	Do
Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators	January 1, 2000	ODE/DGRD	Do

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Guidance for Studies for Pain Therapy Devices—General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices	May 12, 1988	ODE/DGRD	Do
Galvanic Skin Response Measurement Devices—Draft Guidance for 510(k) Content	August 23, 1994	ODE/DGRD	Do
Draft Version Guide for Cortical Electrode 510(k) Content	August 10, 1992	ODE/DGRD	Do
Draft Version Neuro Endoscope Guidance	July 7, 1994	ODE/DGRD	Do
Draft Version Guidance for Clinical Data to be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators	August 20, 1992	ODE/DGRD	Do
Draft Version 1—Biofeedback Devices—Draft Guidance for 510(k) Content	August 1, 1994	ODE/DGRD	Do
Draft Version—Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model	September 12, 1994	ODE/DGRD	Do
Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	June 1, 1994	ODE/DGRD	Do
Draft Version Cranial Perforator Guidance	July 13, 1994	ODE/DGRD	Do
ORDB 510(k) Sterility Review Guidance	July 3, 1997	ODE/DGRD	Do
Draft Guidance for Testing MR Interaction with Aneurysm Clips	May 22, 1996	ODE/DGRD	Do
Draft 510(k) Guideline for General Surgical Electrosurgical Devices	May 10, 1995	ODE/DGRD/General Surgery Devices Brancch (GSDB)	Do
Draft Guidance for Arthroscope and Accessory 510(k)s	May 1994	ODE/DGRD/GSDB	Do
Guidance for the Preparation of a Premarket Notification for Extended Laparoscopy Devices	August 30, 1994	ODE/DGRD/GSDB	Do
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	June 1, 1995	ODE/DGRD/GSDB	Do
Guidance Document for Testing Bone Anchor Devices	April 20, 1996	ODE/DGRD/Orthopedic Devices Branch (ORDB)	Do
510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants	February 20, 1997	ODE/DGRD/ORDB	Do
Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants	February 21, 1997	ODE/DGRD/ORDB	Do
Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices	March 28, 1995	ODE/DGRD/ORDB	Do
Draft Guidance Document for Femoral Stem Prostheses	August 1, 1995	ODE/DGRD/ORDB	Do
Draft Guidance Document for Testing Acetabular Cup Prostheses	May 1, 1995	ODE/DGRD/ORDB	Do
Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices-The Basic Elements	July 16, 1997	ODE/DGRD/ORDB	Do
Draft Guidance for the Preparation of Premarket Notifications [510(k)s] for Cemented, Semi-Constrained Total Knee Prostheses	April 1, 1993	ODE/DGRD/ORDB	Do
Draft Guideline for Reviewing Spinal Fixation Device Systems	January 9, 1997	ODE/DGRD/ORDB	Do
Draft of Guidance Document for Testing of Orthopedic Implants with Metallic Plasma Sprayed Porous Coatings Subject to Required Post Market Surveillance	October 25, 1995	ODE/DGRD/ORDB	Do
Draft Outline for a Guidance Document for Testing Orthopedic Bone Cement, request for comments by December 10, 1993	November 1, 1993	ODE/DGRD/ORDB	Do
Guidance Document for Testing Biodegradable Polymer Implant Devices	April 20, 1996	ODE/DGRD/ORDB	Do
Guidance Document for Testing Non-Articulating, ''Mechanically Locked'', Modular Implant Components	May 1, 1995	ODE/DGRD/ORDB	Do
Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement	April 28, 1994	ODE/DGRD/ORDB	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament Devices	February 18, 1993	ODE/DGRD/ORDB	Do
Guidance Document for the Preparation of Premarket Notification for Ceramic Ball Hip Systems	January 10, 1995	ODE/DGRD/ORDB	Do
Reviewers Guidance Checklist for Intramedullary Rods	February 21, 1997	ODE/DGRD/ORDB	Do
Reviewers Guidance Checklist for Orthopedic External Fixation Devices	February 21, 1997	ODE/DGRD/ORDB	Do
Electroencephalograph Device Draft Guidance for 510(k) Content	June 25, 1997	ODE/DGRD/Plastic and Reconstructive Surgery Devices Branch (PRSB)	Do
Alternate Suture Labeling Resulting from the January 11, 1993, Meeting with HIMA	January 11, 1993	ODE/DGRD/PRSB	Do
Copy of October 9, 1992 Letter and Original Suture Labeling Guidance		ODE/DGRD/PRSB	Do
Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses	January 18, 1995	ODE/DGRD/PRSB	Do
Draft Guidance for Preparations of FDA Submissions of Silicone Gel-Filled Breast Prostheses	May 11, 1992	ODE/DGRD/PRSB	Do
Draft Guidance for Testing of Alternative Breast Prostheses (nonsilicone gel-filled)	September 1, 1994	ODE/DGRD/PRSB	Do
Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing [510(k)]	March 31, 1995	ODE/DGRD/PRSB	Do
Draft Guidance for the Preparation of IDE Submission for Interactive Wound and Burn Dressing	April 1, 1995	ODE/DGRD/PRSB	Do
Letter: Core Study for Silicone Breast Implants	January 11, 1996	ODE/DGRD/PRSB	Do
Electrical Muscle Stimulator (EMS) Labeling Indications, Contraindications, Warnings, etc.	July 11, 1985	ODE/DGRD/Restorative Devices Branch (REDB)	Do
Technological Reporting for Powered Muscle Stimulator 510k Submissions	January 1, 1992	ODE/DGRD/REDB	Do
Guidance Document for the Preparation of Notification (510(k)) Applications for Therapeutic Massagers and Vibrators	July 26, 1995	ODE/DGRD/REDB	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Beds	July 26, 1995	ODE/DGRD/REDB	Do
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/DGRD/REDB	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Electromyograph Needle Electrodes	July 26, 1995	ODE/DGRD/REDB	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Exercise Equipment	July 26, 1995	ODE/DGRD/REDB	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices	July 26, 1995	ODE/DGRD/REDB	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Immersion Hyudrobaths	July 26, 1995	ODE/DGRD/REDB	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Muscle Stimulators, and Ultrasound Diathermy and Muscle Stimulators	July 26, 1995	ODE/DGRD/REDB	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Powered Tables and Multifunctional Physical Therapy Tables	July 26, 1995	ODE/DGRD/REDB	Do
Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Submerged (Underwater) Exercise Equipment	July 26, 1995	ODE/DGRD/REDB	Do

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Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	July 26, 1995	ODE/DGRD/REDB	Do
Aqueous Shunts—510(k) Submissions	November 16, 1998	ODE/Division of Opthalmics Devices (DOD)	Do
Guidance for Industry—Guidance Document for Nonprescription Sunglasses	October 9, 1998	ODE/DOD	Do
Third Party Review Guidance for Vitreous Aspiration and Cutting Device Premarket Notification (510k)	January 31, 1997	ODE/DOD	Do
Dear Sponsor Letter Concerning the Revocation of 21 CFR Part 813 IOL IDE Regulations	May 20, 1997	ODE/DOD	Do
Retinoscope Guidance	July 8, 1998	ODE/DOD	Do
Opthalmoscope Guidance	July 8, 1998	ODE/DOD	Do
Slit Lamp Guidance	July 8, 1998	ODE/DOD	Do
Revised Procedures for Adding Lens Finishing Laboratories to Approved Premarket Approval Applications for Class III Rigid Gas Permeable Contact Lens for Extended Wear	August 11, 1998	ODE/DOD	Do
Announcement by Dr. Alpert at 7/26/96 Ophthalmic Panel Meeting Concerning Manufacturers & Users of Lasers for Refractive Surgery [excimer	August 26, 1996	ODE/DOD	Do
Announcement: Information for Manufacturers & Users of Lasers for Refractive Surgery [excimer]	September 22, 1997	ODE/DOD	Do
Intraocular Lens (IOL) Guidance Document	October 10, 1997	ODE/DOD	Do
FDA Guidelines for Multifocal Intraocular Lens IDE Studies and PMAs	May 29, 1997	ODE/DOD	Do
Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses	May 12, 1994	ODE/DOD	Do
Contact Lenses: The Better the Care the Safer the Wear—FDA Publication No. (FDA) (91–4220)	April 1, 1991	ODE/DOD	Do
An FDA Survey of U.S. Contact Lens Wearers (Carol L. Herman) Reprinted from Contact Lens Spectrum	July 1, 1987	ODE/DOD	Do
Facts for Consumers from the Federal Trade Commission—Eyeglasses	April 1, 1986	ODE/DOD	Do
Important Information About Rophae Intraocular Lenses	August 20, 1992	ODE/DOD	Do
Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers [excimer]	October 10, 1996	ODE/DOD	Do
Ophthalmic Device Triage List	March 19, 1998	ODE/DOD	Do
Discussion Points for Expansion of the 'Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers' Draft Document	September 5, 1997	ODE/DOD	Do
Letter to Manufacturers and Users of Lasers for Refractive Surgery [excimer]	October 10, 1996	ODE/DOD	Do
Owners Certification of Lasers as PMA Approved Devices [excimer]	September 26, 1996	ODE/DOD	Do
Update on Excimer Lasers for Nearsightedness	May 20, 1996	ODE/DOD	Do
Amendment 1: Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses	June 28, 1994	ODE/DOD	Do
Certification Statement for the Impact Resistance Test	February 3, 1995	ODE/DOD	Do
Premarket Notification 510(k) Guidance for Contact Lens Care Products	May 1, 1997	ODE/DOD	Do
Eye Valve Implant (and all glaucoma drainage devices) manufacturers letter from N. C. Brogdon	November 16, 1995	ODE/DOD	Do
New FDA Recommendations & Results of Contact Lens Study (7-day letter)	May 30, 1989	ODE/DOD	Do
Sunglass Letter including 510(k) format	October 8, 1996	ODE/DOD	Do
Sunglass Package	February 3, 1995	ODE/DOD	Do
Guidance for Industry; Noise Claims in Hearing Aid Labeling	October 21, 1998	ODE/Division of Reproductive, Abdominal, ENT, and Radiological Devices (DRAERD)	Do

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Guidance for the Submission of Premarket Notification for Magnetic Resonance Diagnostic Devices	November 14, 1998	ODE/DRAERD	Do
Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters	November 30, 1998	ODE/DRAERD	Do
Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators	November 20, 1998	ODE/DRAERD	Do
Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems	December 3, 1998	ODE/DRAERD	Do
Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems	February 4, 1999	ODE/-DRAERD	Do
Harmonic Imaging with/without Contrast—Premarket Notification Requirements	November 16, 1998	ODE/DRAERD	Do
Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents	February 5, 1998	ODE/DRAERD	Do
Guidance for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters	February 11, 1997	ODE/DRAERD	Do
Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification	January 14, 1998	ODE/DRAERD	Do
Letter to Manufacturers of Falloposcopes	September 5, 1996	ODE/DRAERD	Do
Letter to Manufacturers of Prescription Home Monitors for Non-Stress Tests	September 6, 1996	ODE/DRAERD	Do
Latex Condoms for Men—Information for 510(k) Premarket Notifications: Use of Consensus Standards for Abbreviated Submissions	July 23, 1998	ODE/DRAERD	Do
Uniform Contraceptive Labeling	July 23, 1998	ODE/DRAERD	Do
Guidance to Industry and CDRH Reviewers—Guidance for the Content of Premarket Notifications for Conventional and Permeability Hemodialyzers (Replaces: Guidelines for Premarket Testing of New Conventional Hemodialyers, High Premeability Hemodialyzers and Hemofilters)	August 7, 1998	ODE/DRAERD	Do
Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures	September 10, 1998	ODE/DRAERD	Do
Guidance for the Technical Content of a Premarket Approval (PMA) Application for an Endolymphatic Shunt Tube with Valve	April 1, 1990	ODE/DRAERD	Do
Letter: Notice to Manufacturers of Bone Mineral Densitometers	September 25, 1997	ODE/DRAERD	Do
Draft Guidance to Hearing Aid Manufacturers for Substantiation of Claims	August 5, 1994	ODE/DRAERD/Ear, Nose, and Throat Devices Branch (ENTB)	Do
Guidance for Submission of a 510(k) Premarket Notification for an Air Conduction Hearing Aid	April 1, 1991	ODE/DRAERD/ENTB	Do
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/DRAERD/ENTB	Do
Guidance for the Content of Premarket Notification for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims	October 21, 1996	ODE/DRAERD/ENTB	Do
Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Adults at Least 18 Years of Age	May 1, 1990	ODE/DRAERD/ENTB	Do
Draft Guidance for Hemodialyzer Reuse Labeling	October 6, 1995	ODE/DRAERD/Gastroenterology and Renal Devices Branch (GRDB)	Do
Draft Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis	May 30, 1997	ODE/DRAERD/GRDB	Do
Condom Packet: 4/13/94 R. J. Rivera Letter, Condom Guidance & 7 Tabs, General Guidance for Modifying Condom Labeling to Include Shelf Life	April 13, 1994	ODE/DRAERD/Obstetrics/Gynecology Devices Branch (OGDB)	Do

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Draft Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions	July 29, 1991	ODE/DRAERD/OGDB	Do
Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons	May 25, 1995	ODE/DRAERD/OGDB	Do
Draft Thermal Endometrial Ablation Devices (Submission Guidance for an IDE)	March 14, 1996	ODE/DRAERD/OGDB	Do
Guidance ('Guidelines') for Evaluation of Fetal Clip Electrode	March 8, 1977	ODE/DRAERD/OGDB	Do
Guidance ('Guidelines') for Evaluation of Hysteroscopic Sterilization Devices	May 10, 1978	ODE/DRAERD/OGDB	Do
Guidance ('Guidelines') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories)	January 1, 2000	ODE/DRAERD/OGDB	Do
Guidance ('Guidelines') for Evaluation of Tubal Occlusion Devices	November 22, 1977	ODE/DRAERD/OGDB	Do
Guidelines for Evaluation of Non-Drug IUDs	September 28, 1976	ODE/DRAERD/OGDB	Do
Hysteroscopes and Gynecology Laparoscopes—Submission Guidance for a 510(k) —includes 00192	March 27, 1996	ODE/DRAERD/OGDB	Do
Hysteroscopes and Laparoscopic Insufflators: Submission Guidance for a 510(k)	August 1, 1995	ODE/DRAERD/OGDB	Do
In-vivo Devices for the Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE Draft Document	June 14, 1997	ODE/DRAERD/OGDB	Do
Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft Document	June 14, 1997	ODE/DRAERD/OGDB	Do
Premarket Testing Guidelines for Falloposcopes	November 20, 1992	ODE/DRAERD/OGDB	Do
Premarket Testing Guidelines for Female Barrier Contraceptive Devices also Intended to Prevent Sexually Transmitted Diseases	April 4, 1990	ODE/DRAERD/OGDB	Do
Premarket Testing Guidelines for Home Uterine Activity Monitors	March 31, 1993	ODE/DRAERD/OGDB	Do
Information for a Latex Condom 510(k) Submission for Obstetrics-Gynecology Branch (draft)	March 1994	ODE/DRAERD/OGDB	Do
Testing Guidance for Male Condoms Made from New Material (Non-Latex)	June 29, 1995	ODE/DRAERD/OGDB	Do
Draft Guidance for Review of Bone Densitometer 510(k) Submissions	November 9, 1992	ODE/DRAERD/Radiology Devices Branch (RDB)	Do
Guidance for Content and Review of a Magnetic Resonance Diagnostic Device 510(k) Application and 10/11/95 MRI Guidance Update for dB/dt	August 2, 1988	ODE/DRAERD/RDB	Do
Guidance for Magnetic Resonance Diagnostic Devices—Criteria for Significant Risk Investigations	September 29, 1997	ODE/DRAERD/RDB	Do
Guidance for the Comment and Review of 510(k) Notifications for Picture Archiving and Communications Systems (PACS) and Related Devices [See 2099]	August 1, 1993	ODE/DRAERD/RDB	Do
Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices	June 1, 1997	ODE/DRAERD/RDB	Do
Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers	September 30, 1997	ODE/DRAERD/RDB	Do
Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems	June 19, 1996	ODE/DRAERD/RDB	Do
Reviewer Guidance for Automatic X-Ray Film Processor 510(k)	February 1, 1990	ODE/DRAERD/RDB	Do
Simplified 510(k) procedures for certain radiology devices: 12/21/93 letter from L. Yin, ODE/DRAERD, to NEMA	December 21, 1993	ODE/DRAERD/RDB	Do
510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments	September 19, 1994	ODE/DRAERD/Urology and Lithrotripsy Devices Branch (ULDB)	Do
Draft Guidance to Firms on Biliary Lithotripsy Studies	August 2, 1990	ODE/DRAERD/ULDB	Do
CDRH Interim Regulatory Policy for External Penile Rigidity Devices	September 10, 1997	ODE/DRAERD/ULDB	Do
Checklist for Mechanical Lithotripters and Stone Dislodgers Used in Gastroenterology and Urology	November 1, 1994	ODE/DRAERD/ULDB	Do

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Draft—510(k) Checklist for Conditioned Response Enuresis Alarms	November 23, 1994	ODE/DRAERD/ULDB	Do
Draft 510(k) Checklist for Condom Catheters	February 23, 1995	ODE/DRAERD/ULDB	Do
Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology	August 16, 1995	ODE/DRAERD/ULDB	Do
Draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology	June 22, 1995	ODE/DRAERD/ULDB	Do
Draft 510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence	June 6, 1995	ODE/DRAERD/ULDB	Do
Draft 510(k) Checklist for Urological Irrigation System and Tubing Set	August 1, 1995	ODE/DRAERD/ULDB	Do
Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)	November 11, 1994	ODE/DRAERD/ULDB	Do
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	February 5, 1992	ODE/DRAERD/ULDB	Do
Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence	November 29, 1995	ODE/DRAERD/ULDB	Do
Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants	March 16, 1993	OD/DRAERD/ULDB	Do
Draft Guidance for Preparation of PMA Applications for Testicular Prostheses	March 16, 1993	ODE/DRAERD/ULDB	Do
Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter)	May 1, 1995	ODE/DRAERD/ULDB	Do
Draft Guidance for the Clinical Investigation of Urethral Stents	November 2, 1995	ODE/DRAERD/ULDB	Do
Draft Guidance for the Content of Premarket Notifications for Endoscopes Used in Gastroenterology and Urology	March 17, 1995	ODE/DRAERD/ULDB	Do
Draft Guidance for the Content of Premarket Notifications for Penile Rigidity Implants	May 30, 1995	ODE/DRAERD/ULDB	Do
Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Catheters	January 24, 1992	ODE/DRAERD/ULDB	Do
Draft Guidance Outline—Points to Consider for Clinical Studies for Vasovasostomy Devices	November 30, 1993	ODE/DRAERD/ULDB	Do
Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements	January 18, 1991	ODE/DRAERD/ULDB	Do
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology	February 10, 1993	ODE/DRAERD/ULDBDo	
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters	September 12, 1994	ODE/DRAERD/ULDB	Do
Guidance for the Content of Premarket Notifications for Ureteral Stents	February 10, 1993	ODE/DRAERD/ULDB	Do
Guidance for the Content of Premarket Notifications for Urine Drainage Bags	June 7, 1994	ODE/DRAERD/ULDB	Do
Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems	July 29, 1994	ODE/DRAERD/ULDB	Do
Guidance to Manufacturers on the Development of Required Postapproval Epidemiologic Study Protocols for Testicular Implants	January 1, 2000	ODE/DRAERD/ULDB	Do
Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy	June 30, 1993	ODE/IDE/blue/	Do
Center for Devices and Radiological Health's Premarket Notification [510(k)] Refuse to Accept Policy—(updated Checklist 3/14/95)	June 30, 1993	ODE/510k/blue/	Do

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Guidance For Request and Issuance of Interim Notice Letters for Mammography Facilities Under the MQSA	October 21, 1998	Office of Health and Industry Programs (OHIP)/Division of Mammography Quality and Radiation Programs (DMQRP)	Do
Continuing Education Credits for Reading/ Writing Articles/Papers and Presenting Courses/Lectures	March 17, 1998	OHIP/DMQRP	Do
Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies	August 13, 1998	OHIP/DMQRP	Do
Additional Mammography Review Policy	March 26, 1998	OHIP/DMQRP	Do
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))	March 26, 1998	OHIP/DMQRP	Do
Guidance for Review of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act (42 U.S.C. 263(b))	March 26, 1998	OHIP/DMQRP	Do
Guidance for Submission of Requests for Reconsideration of Adverse Decisions on Accreditation of Mammography Facilities Under the Mammography Quality Standards Act, 42 U.S.C. 263(b)	March 26, 1998	OHIP/DMQRP	Do
Supplement to The Physician's Continuing Experience Requirement	April 9, 1998	OHIP/DMQRP	Do
Requalification for Interpreting Physician's Continuing Experience	May 28, 1998	OHIP/DMQRP	Do
MQSA Policy Statements in a Question and Answer	June 2, 1998	OHIP/DMQRP	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations	August 27, 1998	OHIP/DMQRP	Do
MQSA Policy Statements for the Interim Regulations	August 6, 1998	OHIP/DMQRP	Do
Policy for Facilities Changing Accreditation Bodies	April 15, 1998	OHIP/DMQRP	Do
Addendum to What a Mammography Facility Should do to Prepare for an MQSA Inspection	July 31, 1996	OHIP/DMQRP	Do
Handbook of Selected Tissue Doses for Fluoroscopic and Cineangiographic Examination of the Coronary Arteries (in SI Units) FDA 95–8289, (Units of milliray (mmmGy) tissue dose and gray (Gy) air kerma)	September 1, 1995	OHIP/DMQRP	Do
What a Mammography Facility Should Do to Prepare for an MQSA Inspection	June 30, 1995	OHIP/DMQRP	Do
Policy Notebook in a Q/A Format (update to existing document)	January 23, 1998	OHIP/DMQRP	Do
Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997	October 30, 1998	OHIP/Division of Small Manufacturer's Assistance (DSMA)	Do
Pages 39.html Exporting Medical Devices and 391.html Foreign Liaison List	June 30, 1998	OHIP/DSMA	Do
Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA)	January 6, 1999	OHIP/DSMA	Do
A Pocket Guide to Device GMP Inspections—Inspections of Medical Device Manufacturers and GMP Regulation Requirements	November 1, 1991	OHIP/DSMA	Do
Medical Device Reporting for Manufacturers	March 1997	OHIP/DSMA	Do
Regulatory Requirement for Devices for the Handicapped (FDA 87–4221)	August 1, 1987	OHIP/DSMA	Do
Comparison Chart: 1996 Quality System Reg vs. 1978 Good Manufacturing Practices Reg vs. ANSI/ISO/ASQC Q9001 and ISO/DI 13485:1996 (include 126)	January 1, 2000	OHIP/DSMA	Do
Small Business Guide to FDA (FDA 96–1092)	January 1, 1996	OHIP/DSMA	Do
Investigational Device Exemptions [IDE] Manual (FDA 96–4159)/DSMA	July 1, 1996	OHIP/DSMA	Do
An Introduction to Medical Device Regulations (FDA 92–4222)	January 1, 1992	OHIP/DSMA	Do

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In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (supersedes FDA 87–4224)	January 1, 1997	OHIP/DSMA	Do
Instructions for Completion of Medical Device Registration and Listing Forms FDA 2891, 2891a and 2892	July 1, 1997	OHIP/DSMA	Do
Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields—Infant Apnea Monitor Standard	September 1, 1993	OHIP/DSMA	Do
Classification Names for Medical Devices and In Vitro Diagnostic Products (FDA Pub No. 95–4246)	March 1, 1995	OHIP/DSMA	Do
Labeling—Regulatory Requirements for Medical Devices (FDA 89–4203)	September 1, 1989	OHIP/DSMA	Do
List of Current CDRH Addresses for Report Submission and Ordering of CDRH Forms	July 30, 1996	OHIP/DSMA	Do
Obtaining CDRH Guidance Documents	May 13, 1998	OHIP/DSMA	Do
Premarket Approval (PMA) Manual (FDA 97–4214)	July 1, 1997	OHIP/DSMA	Do
Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices (FDA 95–4158)	August 1, 1995	OHIP/DSMA	Do
Procedures for Laboratory Compliance Testing of Television Receivers—Part of TV Packet	May 1, 1986	OHIP/DSMA	Do
Regulation of Medical Devices Background Information for Foreign Officials	May 1, 1996	OHIP/DSMA	Do
MDR Documents Access Information	May 10, 1996	OHIP/DSMA	Do
MDR Documents Access Information for CDRH Electronic Docket (ED)	February 29, 1996	OHIP/DSMA	Do
MDR Documents Access Information for CDRH Facts-On-Demand (FOD)	February 29, 1996	OHIP/DSMA	Do
MDR Documents Access Information for Industry Organizations	May 8, 1996	OHIP/DSMA	Do
MDR Documents Access Information for National Technical Information Service (NTIS)	May 10, 1996	OHIP/DSMA	Do
MDR Documents Access Information for World Wide Web (WWW)	February 29, 1996	OHIP/DSMA	Do
Medical Device Quality Systems Manual: A Small Entity Compliance Guide	December 1, 1996	OHIP/DSMA	Do
Overview of FDA Modernization Act of 1997, Medical Device Provisions	February 19, 1998	OHIP/DSMA	Do
Medical Device Appeals and Complaints—Guidance on Dispute Resolutions	February 1, 1998	OHIP/DSMA/Office of the Center Director (OCD)	Do
Medical Device Reporting for User Facilities	April 1996	OHIP/Division of Device User Programs and Systems Analysis (DUPSA)	Do
Human Factors Points to Consider for IDE Devices	January 17, 1997	OHIP/DUPSA	Do
Human Factors Principles for Medical Device Labeling	September 1, 1993	OHIP/DUPSA	Do
Write it Right	August 1, 1993	OHIP/DUPSA	Do
Do It By Design—An Introduction to Human Factors in Medical Devices	December 1, 1996	OHIP/DUPSA	Do
FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of Highest Priority Provisions: Availability	February 6, 1998	OHIP/Regs	Do
Statistical Aspects of Submissions to FDA: A Medical Device Perspective (also includes as Appendix the Article Observed Uses and Abuses of Statistical Procedures in Medical Device Submissions	June 1, 1984	OSB/Division of Biostatistics (DB)	Do
Statistical Guidance for Clinical Trials of Non Diagnostic Medical Devices (Replaces Clincal Study Guidance, formerly 891)	January 1, 1996	OSB/DB	Do
Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads	March 30, 1994	OSB/Division of Postmarket Surveillance (DPS)	Do
Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies	February 19, 1998	OSB/DPS	Do
Guidance on Procedures for Review of Postmarket Surveillance Submissions	February 19, 1998	OSB/DPS	Do
SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance	February 19, 1998	OSB/DPS	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Proposed Draft Guidance to Sponsors Regarding Required Postmarket Surveillance Studies of Plasma-Sprayed Porous-Coated Hip Prostheses	October 7, 1994	OSB/DPS	Do
Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)	June 9, 1993	OSB/DPS	Do
Medical Device Reporting for Distributors	April 1996	OSB/Division of Surveillance Systems (DSS)	Do
Medical Device Reporting: An Overview	April 1996	OSB/DSS	Do
MDR Internet List Server (listserv) Instruction Sheet	August 29, 1996	OSB/DSS	Do
MEDWATCH FDA Form 3500A For Use By User Facilities, Distributors and Manufacturers for Mandatory Reporting	June 1, 1993	OSB/DSS	Do
Instructions for Completing FDA Form 3500A with Coding Manual for Form 3500A (MEDWATCH)	December 15, 1995	OSB/DSS	Do
MDR Policy/Guidance for Endosseus Implant Devices	December 1992	OSB/DSS	Do
MDR Guidance—Blood Loss Policy	December 1995	OSB/DSS	Do
Summary Reporting Approval for Adverse Events	July 31, 1997	OSB/DSS	Do
Common Problems: Baseline Reports and MedWatch Form 3500A (letter to manufacturer—undated)		OSB/DSS	Do
MDR Guidance Document: Remedial Action Exemption—E1996001	July 30, 1996	OSB/DSS	Do
Variance from Manufacturer Report Number Format [MDR letter]	July 16, 1996	OSB/DSS	Do
Instructions for Completing Form 3417: Medical Device Reporting Baseline Report [MDR]	March 31, 1997	OSB/DSS	Do
MDR Guidance Document No. 1—IOL—E1996004	August 7, 1996	OSB/DSS	Do
MDR Guidance Document No. 3—Needlestick & Blood Exposure—E1996003	August 9, 1996	OSB/DSS	Do
MDR Reporting Guidance For Breast Implants—E1996002	August 7, 1996	OSB/DSS	Do
Instructions for Completing Semi-Annual Report, Form 3419 (MDR)	September 24, 1996	OSB/DSS	Do
Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date	May 15, 1998	Office of Standards and Technology (OST)/Division of Electronics and Computer Science (DECS)	Do
Draft Document—A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems	February 7, 1997	OST/Division of Postmarket Surveillance (DPS)	Do
Frequently Asked Questions on Recognition of Consensus Standards	February 19, 1998	OST/OD	Do
Guidance on the Recognition and Use of Consensus Standards	February 19, 1998	OST/OD	Do

IV. Guidance Documents Issued by the Center for Drug Evaluation and Research (CDER)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling	January 12, 1998	Advertising	Drug Information Branch (HFD–210), CDER, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573, or via Internet at http://www.fda.gov/cder/guidance/index.htm
Dissemination of Reprints of Certain Published, Original Data	October 8, 1996	Do	Do
Funded Dissemination of Reference Texts	October 8, 1996	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Consumer-Directed Broadcast Advertisements	August 12, 1997	Advertising draft	Do
Promoting Medical Products in a Changing Healthcare Environment; Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)	January 5, 1998	Do	Do
Alprazolam Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	November 27, 1992	Biopharmaceutic	Do
Bioavailability Policies and Guidelines		Do	Do
Bumetanide Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 15, 1998	Do	Do
Captopril Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 13, 1993	Do	Do
Carbidopa and Levodopa Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 19, 1992	Do	Do
Cefactor Capsules and Suspension In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Cholestyramine Powder In Vitro Bioequivalence	July 15, 1993	Do	Do
Cimetidine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1992	Do	Do
Clozapine (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 15, 1996	Do	Do
Corticosteroids, Dermatologic (topical) In Vivo	June 2, 1995	Do	Do
Diclofenac Sodium (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 6, 1994	Do	Do
Diflunisal Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	Do	Do
Diltiazen Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	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
Flurbiprofen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 8, 1995	Do	Do
Gemfibrozil Capsules or Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 15, 1992	Do	Do
Glipizide (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Guanabenz Acetate Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Hydroxchloroquine Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 28, 1995	Do	Do
Indapamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Ketoprofen (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Leucovorin Calcium (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 4, 1988	Do	Do
Medroxyprogesterone Acetate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 17, 1987	Do	Do
Metaproferenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	June 27, 1989	Do	Do
Metoprolol Tartrate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1992	Do	Do
Nadolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	Do	Do
Naproxen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 8, 1995	Do	Do
Nortriptyline Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1992	Do	Do
Oral Extended (controlled) Release In Vivo Bioequivalence and In Vitro Dissolution Testing	September 9, 1993	Do	Do
Pentoxifyline (extended-release tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 22, 1995	Do	Do
Phenytoin/Phenytoin Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 4, 1994	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Pindolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Piroxicam (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 15, 1992	Do	Do
Potassium Chloride (slow-release tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 6, 1994	Do	Do
Rantidine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Selegiline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 22, 1995	Do	Do
Statistical Procedure for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design	July 1, 1992	Do	Do
Trazodone Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 30, 1988	Do	Do
Antifungal (topical)	February 24, 1990	Biopharmaceutic draft	Do
Antifungal (vaginal)	February 24, 1990	Do	Do
Bioanalytical Methods Validations for Human Studies	January 5, 1999	Do	Do
Food-Effect Bioavailability and Bioequivalence Studies	December 30, 1997	Do	Do
In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches	December 30, 1997	Do	Do
Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies	June 18, 1998	Do	Do
Waiver Policy	March 29, 1993	Do	Do
Glyburide Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Biopharmaceutic testing	Do
Drug Master Files	September 1, 1989	Chemistry	Do
Environmental Assessment of Human Drugs and Biologics Applications	July 27, 1998	Do	Do
FDA's Policy Statement for the Development of New Stereoisomeric Drugs	May 1, 1992	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
Format and Content of the Microbiology Section of an Application	February 1, 1987	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 Packaging for Human Drugs and Biologics	February 1, 1987	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 Supporting Documentation in Testing Drug Applications for the Manufacture of Drug Substances	February 1, 1987	Do	Do
Submitting Samples and Analytical Data for Methods Validation	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: Immediate Release Solid Oral Dosage Forms; Manufacturing Equipment Addendum	October 21, 1997	Do	Do
SUPAC–IR Questions and Answers	February 18, 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
SUPAC–MR: Modified Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation	October 6, 1997	Do	Do
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
BACPAC I: Intermediates in Drug Substance Synthesis (Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation)	November 30, 1998	Chemistry draft	Do
Content and Format of Investigational New Drug Applications (INDs) for Phases 2 and 3 Studies of Drugs, Including Specific Therapeutic Biotechnology-Derived Products—Preliminary Draft	December 10, 1997	Do	Do
Metered Dose Inhalers (MDI) and Dry Powder Inhalers (DPI) Drug Products; Chemistry, Manufacturing, and Controls Documentation	November 19, 1998	Do	Do
NDAs: Impurities in Drug Substances	January 21, 1999	Do	Do
Stability Testing of Drug Substances and Drug Products	June 8, 1998	Do	Do
Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics	July 15, 1997	Do	Do
Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications	November 1, 1991	Do	Do
SUPAC–IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum	April 28, 1998	Do	Do
SUPAC–SS: Nonsterile Semisolid Dosage Forms	January 5, 1999	Do	Do
Tracking of NDA and ANDA Reformulations for Solid, Oral, Immediate Release Drug Products		Do	Do
Acute Bacterial Exacerbation of Chronic Bronchitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Clinical antimicrobial draft	Do
Acute Bacterial Meningitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Acute Bacterial Sinusitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Acute or Chronic Bacterial Prostatitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Acute Otitis Media; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Bacterial Vaginosis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Community Acquired Pneumonia; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Complicated Urinary Tract Infections and Pylonephritis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Empiric Therapy of Febrile Neutropenia; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
General Considerations for Clinical Trials; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Lyme Disease; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Nosocomial Pneumonia; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Secondary Bacterial Infections of Acute Bronchitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Streptococcal Pharyngitis and Tonsillitis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Uncomplicated Gonorrhea—Cervical, Urethral, Rectal, and/or Pharyngeal; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Uncomplicated Urinary Tract Infections; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do

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Uncomplicated and Complicated Skin and Skin Structure Infections; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Vuvlovaginal Candidiasis; Developing Antimicrobial Drugs for Treatment	July 22, 1998	Do	Do
Clinical Evaluation of Antidepressant Drugs	September 1, 1977	Clinical medical	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 Radiopharmaceutical Drugs	October 1, 1981	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 Anti-Anxiety Drugs	September 1, 1977	Do	Do
Clinical Evaluation of Anti-Infective Drugs (Systemic)	September 1, 1977	Do	Do
Clinical Evaluation of Drugs to Prevent, Control and/or Treat Periodontal Disease	November 1, 1978	Do	Do
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs	September 1, 1977	Do	Do
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
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 Superficial Bladder Cancer	June 20, 1989	Do	Do
FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer	January 29, 1991	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 in Infants and Children	September 1, 1977	Do	Do
General Considerations for the Clinical Evaluation of Drugs	December 1, 1978	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
OTC Treatment of Hypercholesterolemia	October 27, 1997	Do	Do
Points to Consider: Clinical Development Programs for MDI and DPI Drug Products	September 19, 1994	Do	Do
Points to Consider in the Clinical Development and Labeling of Anti-Infective Drug Products	October 26, 1992	Do	Do
Points to Consider in the Preclinical Development of Immunomodulatory Drugs for the Treatment of HIV Infection and Associated Disorders	May 1, 1993	Do	Do
Points to Consider in the Preclinical Development of Antiviral Drugs	November 1, 1990	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Postmarketing Adverse Experience Reporting for Human Drugs and Licensed Biological Products; Clarification of What to Report	August 27, 1997	Do	Do
Postmarketing Reporting of Adverse Drug Experiences	March 1, 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
Abuse Liability Assessment	July 1, 1990	Clinical medical draft	Do
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	February 18, 1998	Do	Do
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	March 18, 1998	Do	Do
Clinical Evaluation of Antihypertensive Drugs	May 1, 1988	Do	Do
Clinical Evaluation of Anti-Anginal Drugs	January 1, 1989	Do	Do
Clinical Evaluation of Anti-Arrhythmic Drugs	July 1, 1985	Do	Do
Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure	December 1, 1987	Do	Do
Clinical Evaluation of Drugs for Ulcerative Colitis (3rd draft)		Do	Do
Clinical Evaluation of Lipid-Altering Agents in Adults and Children	September 1, 1990	Do	Do
Clinical Evaluation of Motility-Modifying Drugs		Do	Do
Clinical Evaluation of Weight-Control Drugs	October 1, 1997	Do	Do
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review	November 22, 1996	Do	Do
Developing Medical Imaging Drugs and Biologics	October 13, 1998	Do	Do
Development and Evaluation of Drugs for the Treatment of Psychoactive Substance Use Disorders	February 12, 1992	Do	Do
Evaluating Clinical Studies of Antimicrobials in the Division of Anti-Infective Drug Products	February 18, 1997	Do	Do
Points to Consider for System Inflammatory Response Syndrome (SIRS) 1st Draft		Do	Do
Points to Consider in the Preparation of IND Applications for New Drugs Intended for the Treatment of HIV-Infected Individuals	September 1, 1991	Do	Do
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis	April 1, 1994	Do	Do
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications	September 21, 1998	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
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
General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products	November 30, 1998	Clinical pharmacology draft	o
In Vivo Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling	November 19, 1998	Do	Do
A Review of FDA's Implementation of the Drug Export Amendments of 1986		Compliance	Do
Compressed Medical Gases	December 1, 1989	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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Good Laboratory Practice Regulations Questions and Answers		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
Sterile Drug Products Produced by Aseptic Processing	May 1, 1987	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
Computerized Systems Used in Clinical Trials	June 18, 1997	Compliance draft	Do
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production	September 30, 1998	Do	Do
Manufacture, Processing or Holding of Active Pharmaceutical Ingredients	April 17, 1998	Do	Do
Repackaging of Solid Oral Dosage Form Drug Products	February 1, 1992	Do	Do
ANDAs: Impurities in Drug Products	January 5, 1999	Generic drug draft	Do
ANDAs: Impurities in Drug Substances	July 24, 1998	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	April 18, 1997	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	Generic drug	Do
Letter describing efforts of CDER & 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 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 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 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
Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application	April 7, 1997	Do	Do
Variations in Drug Products that May Be Included in a Single ANDA	January 27, 1999	Do	Do
E5 Ethnic Factors in the Acceptability of Foreign Clinical Data	June 10, 1998	ICH draft guidances efficacy	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances	November 25, 1997	ICH draft guidances—quality	Do
Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products	June 9, 1998	Do	Do
S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)	November 18, 1997	ICH draft guidances safety	Do
E1A 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 guidances—efficacy	Do
E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting	March 1, 1995	Do	Do
E2B Data Elements for Transmission of Individual Case Reports	January 15, 1998	Do	Do
E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	May 19, 1997	Do	Do
E4 Dose-Response Information to Support Drug Registration	November 9, 1994	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
M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	November 25, 1997	ICH guidances—joint safety/efficacy (multidisciplinary)	Do
Q1A Stability Testing of New Drug Substances and Products	September 22, 1994	ICH guidances—quality	Do
Q1B Photostability Testing of New Drug Substances and Products	May 16, 1997	Do	Do
Q1C 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 Impurities in New Drug Products	May 19, 1997	Do	Do
Q3C Impurities: Residual Solvents	December 24, 1997	Do	Do
Q5A Biotechnological/Biological Pharmaceutical Products, Viral Safety Evaluation	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
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
S1A The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals	March 1, 1996	ICH guidances—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
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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals	November 18, 1997	Do	Do
E3 Structure and Content of Clinical Study Reports	July 17, 1996	IHC guidances—efficacy	Do
A Revision in Sample Collection Under the Compliance Program Pertaining to Pre-Approval Inspections	July 15, 1996	Industry letters	Do
Certification Requirements for Debarred Individuals in Drug Applications	July 27, 1992	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	June 1, 1990	Do	Do
Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanisms 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 all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I	October 31, 1986	Do	Do
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	Do
Seventh of a series of letters about the act providing guidance on the ''180-day exclusivity'' provision of section 505(j)(4)(B)(iv) of the FD&C Act	July 29, 1988	Do	Do
Sixth of a series of informal notice letters about the Act discussing the 3- and 5-year exclusivity provisions of sections 505(c)(3)(d) and 505(j)(4)(D) of the FD&C Act	April 28, 1988	Do	Do
Streamlining Initiatives	December 24, 1996	Do	Do
Supplement to 10/11/84 letter about policies, procedures and implementation of the Act (Q & A format)	November 16, 1984	Do	Do
Third of a series of letters regarding the implementation of the Act	May 1, 1985	Do	Do
Regulatory Submissions in Electronic Format; General Considerations	January 28, 1999	Information technology	Do
Regulatory Submissions in Electronic Format; New Drug Applications	January 28, 1999	Do	Do
Acetaminophen, Aspirin and Codeine Phosphate Tablets/Capsules	December 1, 1993	Labeling	Do
Acetaminophen and Codeine Phosphate Oral Solution/Suspension	December 1, 1993	Do	Do
Acetaminophen 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
Barbituate, Single Entity-Class Labeling	March 1, 1981	Do	Do
Butalbital, Acetaminophen, Caffeine and Hydocodone Bitartrate Tablets	September 21, 1997	Do	Do
Butalbital, Acetaminophen and Caffeine Capsules/Tablets USP	September 1, 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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Cisapride Tablets	September 1, 1997	Do	Do
Clindamycin Phosphate Injection USP	September 1, 1998	Do	Do
Clorazepate Dipotassium Capsules/Tablets	March 1, 1993	Do	Do
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	Do
Diltiazem Hydrochloride Extended-Release Capsules	September 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulphate Tablets USP	April 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution USP	April 1, 1995	Do	Do
Dipivefrin Hydrochloride Ophthalmic Solution USP	October 1, 1998	Do	Do
Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%	November 2, 1998	Do	Do
Ergoloid Mesylates Tablets	January 1, 1988	Do	Do
Fludeoxyglucose F18 Injection	January 1, 1997	Do	Do
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	Do
Hypoglycemic Oral Agents—FEDERAL REGISTER	April 1, 1984	Do	Do
Indomethacin Capsules USP	September 1, 1995	Do	Do
Informal Labeling Guidance Texts for Estrogen Drug Products—Patient Labeling	August 1, 1992	Do	Do
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	Do
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	Do
Meclofenamate Sodium Capsules	July 1, 1992	Do	Do
Medroxyprogesterone Acetate Tablets, USP	September 1, 1998	Do	Do
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/ Oral Solution, USP	February 1, 1995	Do	Do
Naphazoline Hydrochloride Ophthalmic Solution	March 1, 1989	Do	Do
Naproxen Sodium Tablets, USP	September 1, 1997	Do	Do
Naproxen Tablets, USP	September 1, 1997	Do	Do
Niacin Tablets	July 1, 1992	Do	Do
Paclitaxel Injection	September 1, 1997	Do	Do
Phendimetrazine Tartrate Capsules/Tablets, and Extended-Release Capsules	February 1, 1991	Do	Do
Phentermine Hydrochloride Capsules/Tablets	August 1, 1988	Do	Do
Promethazine Hydrochloride Tablets	March 1, 1990	Do	Do
Propantheline Bromide Tablets	August 1, 1988	Do	Do
Pyridoxine Hydrochloride Injection	June 1, 1984	Do	Do
Quinidine Sulfate Tablets/Capsules USP	October 1, 1995	Do	Do
Ranitidine Tablets	November 1, 1993	Do	Do
Risperidone Oral Solution	September 1, 1997	Do	Do
Risperidone Tablets	September 1, 1997	Do	Do
Sulfacetamide Sodium Ophthalmic Solution/Ointment	August 1, 1992	Do	Do
Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension and Ointment	January 1, 1995	Do	Do
Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets	February 1, 1992	Do	Do
Sulfamethoxazole and Trimethoprim Tablets and Oral Suspension	August 1, 1993	Do	Do
Theophylline Immediate-Release Dosage Forms	February 1, 1995	Do	Do
Theophylline Intravenous Dosage Forms	September 1, 1995	Do	Do
Thiamine Hydrochloride Injection	February 1, 1988	Do	Do
Tobramycin Sulfate Injection USP	May 1, 1993	Do	Do
Venlafaxine Hydrochloride Tablets	October 1, 1997	Do	Do

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Verapamil Hydrochloride Tablets	October 1, 1991	Do	Do
Vitamin A Capsules	February 1, 1992	Do	Do
Zolpidem Tartrate Tablets	September 1, 1997	Do	Do
Content and Format for Geriatric Labeling	January 21, 1999	Labeling draft	Do
Non-Contraceptive Estrogen Class Labeling	October 15, 1998	Do	Do
Non-Contraceptive Estrogen Drug Products—Physician and Patient Labeling	January 8, 1999	Do	Do
OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)	July 16, 1998	Do	Do
Therapeutic Equivalence Code Placement on Prescription Drug Labels and Labeling	January 28, 1999	Do	Do
Enforcement Policy on Marketing OTC Combination Products		OTC	Do
General Guidelines for OTC Combination Products		Do	Do
Upgrading Category III Antiperspirants to Category I		Do	Do
OTC Nicotine Substitutes	March 1, 1994	OTC draft	Do
Points to Consider for OTC Actual Use Studies	July 22, 1994	Do	Do
Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application	February 1, 1987	Pharmacology/toxicology	Do
Points to Consider in the 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		Do	Do
Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of Non-Life Threatening Disease: Evaluation of Drug Toxicity Prior to Phase I Clinical Studies	February 1, 1989	Do	Do
Single Dose Acute Toxicity Testing for Pharmaceuticals	August 26, 1996	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
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
Implementation of Section 126, Elimination of Certain Labeling Requirements, of the FDA Modernization Act of 1997	July 21, 1998	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	June 29, 1998	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
Submitting Debarment Certification Statements	October 2, 1998	Procedural draft	Do
Classifying Resubmissions in Response to Action Letters	May 14, 1998	User fee	Do
Submitting and Reviewing Complete Responses to Clinical Holds	May 14, 1998	Do	Do

V. Guidance Documents Issued by the Center for Food Safety and Applied Nutrition (CFSAN)

Name of Document	Date of Issuance	Grouped by 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	1996	FDA regulated industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161 (Order No. PB96–920500)
Compliance Programs Guidance Manual	1995	Do	NTIS (Order No. PB95–915499)
Inspection Operations Manual	October 1994	Do	NTIS (Order No. PB95–913399)
Regulatory Procedures Manual	August 1995	Do	NTIS (Order No. PB95–265534)
Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration ''Blue Book''	1997	Do	Superintendent of Documents, Government Printing Office, Washington, DC 20402
FDA Recall Policy	1995	Do	Industry Activities Staff (HFS–565), CFSAN, Food and Drug Administration, 200 C St. SW., Washington, DC 20204
Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed	1995	Food and animal feed industries	Do
Pesticides Analytical Manual	1994	Food Industry	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 & Dairy Foods & Beverages (HFS–306), CFSAN, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681
FDA's Cosmetic Labeling Manual	October 1991	Cosmetic industry	Office of Colors and Cosmetics (HFS–105), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4493
Statement of Policy: Foods Derived from New Plant Varieties	May 29, 1992	Developers of new plant food varieties	Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3100
A Food Labeling Guide	September 1994	Food industry	Superintendent of Documents, Government Printing Office, Washington, DC 20402, 202–512–1800
Appendix I—Model Small Business Food Labeling Exemption Notice	August 7, 1993	Do	Industry Activities Staff (HFS–565), CFSAN, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5251
Food Labeling: Questions and Answers	August 1993	Do	Do
Food Labeling: Questions and Answers: Volume II	August 1995	Do	Superintendent of Documents, Government Printing Office, Washington, DC 20420, 202–512–1800
Fair Packaging and Labeling Act Requirements and Interpretations	June 1978	Do	NTIS (Order No. PB83–222117)
Bacteriological Analytical Manual 7th Edition	1992	FDA regulated industries	AOAC International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2417, 301–924–7077
FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods	1995	Food industry	Industry Activities Staff (HFS–565), CFSAN, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5251
Fabrication of Single Service Containers and Closures for Milk and Milk Products	1995	States	Milk Safety Branch (HFS–626), CFSAN, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–9175
Evaluation of Milk Laboratories	1995	Do	Do
Methods of Making Sanitation Ratings Of Milk Supplies	1995	Do	Do
Dry Milk Ordinance	1995	Do	Do
Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers	1995	Dairy industry	Do
Frozen Dessert Processing Guidelines	1989	Do	Office of Plant and Dairy Foods and Beverages (HFS–302), CFSAN, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–9175
Pasteurized Milk Ordinance	1995	States	Milk Safety Branch (HFS–626), CFSAN, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–9175

Name of Document	Date of Issuance	Grouped by 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	1993	Food industry	Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561
Guidelines for Determining Metric Equivalents of Household Measures	October 1, 1993	Do	Do
List of Food Defect Action Levels (DALS)	1995	Food and Animal Feed Industries Industry Activities Staff (HFS–565), CFSAN, Food and Drug Administration, 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 CPG's)	1995	Do	Do
1997 FDA Food Code	1997	States	NTIS
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, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3150
Fish and Fisheries Products Hazards and Controls Guide	1996	Seafood industry	Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3150
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 (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3100
Guidelines for the Preparation of Petition Submissions	1996	Do	Do
Guidelines for Approval of Color Additives in Contact Lenses Intended as Colors	1996	Color or contact lens industry	Do
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	Do	Do
Recommendations for Chemistry Data for Indirect Food Additive Petitions	June 1995	Do	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	NTIS (Order No. PR–83–170696)
Environmental Assessment Technical Handbook	March 1987	Do	NTIS (Order No. PB87–175345–AS, A–01)
Preparing Environmental Assessments: General Suggestions	August 1990	Do	Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW, Washington, DC 20204, 202–418–3100
Step-by-Step Guidance for Preparing Environmental Assessments	March 1987	Do	Do
Environmental Assessment of Food-Packaging Materials with Enhanced Degradation Characteristics	February 1994	Do	Do
Color Additive Petitions Information and Guidance	1996	Do	Do
Toxological Testing of Food Additives	1983	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
List of Products for Each Product Category	October 8, 1992	Food industry	Office of Food Labeling (HFS–150), 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	Do	Do
Guidance on Labeling of Foods that Need Refrigeration by Consumers	February 24, 1997	Do	Do
Interim Guidance on the Voluntary Labeling of Milk and Milk Products that Have Not Been Treated With Recombinant Bovine Somatropin	February 10, 1994	Do	Do
Guidelines Concerning Notification and Testing of Infant Formula	1985	Infant formula manufacturers	Office of Special Nutritionals (HFS–450), Food and Drug Administration, 200 C St. SW, Washington, DC 20204 202–205–4168
Clinical Testing of Infant Formulas with Respect to Nutritional Suitability for Term Infants	1985	Do	Do
Guidelines for the Evaluation of the Safety and Suitability of New Infant Formulas for Feeding	Infants with Allergic Diseases	1988	Do
Guidelines for the Evaluation of the Safety and Suitability of Infant Formulas for Feeding Infants with Allergic Diseases	1990	Do	Do
Guidelines for the Clinical Evaluation of New Products Used in the Dietary Management of Infants, Children and Pregnant Women with Metabolic Disorders	1987	Do	Do
Guidance Document for Arsenic (Trace Elements in Seafood)	January 1993	States	Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3150 or via Internet: FDA Home Page http://vm.cfsan.fda.gov/list.html
Guidance Document for Cadmium (Trace Elements in Seafood)	January 1993	Do	Do
Guidance Document for Chromium (Trace Elements in Seafood)	January 1993	Do	Do
Guidance Document for Lead (Trace Elements in Seafood)	August 1993	Do	Do
Guidance Document for Nickel (Trace Elements in Seafood)	January 1993	Do	Do
FDA's Policy for Foods Developed by Biotechnology	1995	Food industry	Internet: FDA Home Page http://vm.cfsan.fda.gov
Bovine Spongiform Encephalopathy (BSE) In Products for Human Use	1997	Do	Office of Plant and Dairy Foods and Beverages (HFS–302), CFSAN, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–9175 or via Internet: FDA Home Page http://www.fda.gov/opacom/morechoices/industry/guidance/gelguide.htm
Shellfish Sanitation Model Ordinance	1995	States	Shellfish Program Implementation Branch, Office of Field Programs (HFS–628), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8137
Draft Working Guide to Minimize Microbial Hazards for Fresh Fruits and Vegetables	1998	Farmers and food packers	Food Safety Initiative (HFS–3), Food and Drug Administration, 200 C. St. SW, Washington, DC 20204 or jsaltsman@bangate.fda.gov
Iron-Containing Supplements and Drugs: Label Warning and Unit Dose Packaging; Small Entity Compliance Guide	1997	Dietary supplement manufacturers: small entities	Office of Special Nutritionals (HFS–450), Food and Drug Administration, 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), Food and Drug Administration, 200 C St. SW., Washington, DC 20204
Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food	1998	Do	Do

Name of Document	Date of Issuance	Grouped by 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 Fishery Products Hazards and Controls Guide, 2nd Edition	January 1998	Do	Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204
HACCP Regulations for Fish and Fishery Products: Questions and Answers	1997	Do	Do
Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body	1998	Do	Office of Food Labeling (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099
Small Business Juice Labeling: Questions and Answers	1998	Do	Do
FDA Nutrition Labeling Manual, A Guide for Developing and Using Data Bases	March 1998	Do	Do
HACCP Regulation for Fish and Fishery Products: Questions and Answers, Issue Three, Revised	January 1999	Seafood processors	Office of Seafood (HFS–400), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 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), Food and Drug Administration, 200 C St. SW., Washington, DC 20204
Food Additive Petition Expedited Review	January 1999	FDA personnel and regulated industry	Office of Premarket Approval, Food and Drug Administration, 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	FDA regulated industry	Do—premarkt@cfsan.fda.gov OR http://vm.cfsan.fda.gov//dms/opa-armg.html
Changes to the ''Pesticides and Industrial Chemicals in Domestic Foods'' Compliance Program for FY 99	December 30, 1998	FDA districts	FOI/Domestic Programs Branch (HFS–636), Office of Field Programs, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4771
FY 99 Mycotoxin Collection and Sample Analysis Schedule	November 13, 1998	Do	Do
Revisions to the EHEC Method	November 23, 1998	Do	Do
Vibrio Vulnificus and Vibrio parahaemolyticus in Retail Shell Oysters CFSAN Assignment 98–7	June 17, 1998	Do	Do
Revisions to Att F ''Special Survey Obligations—Dioxins and Furans in Food'' of the Pesticides and Industrial Chemicals Domestic Food Compliance Program for FY99	September 30, 1998	Do	Do
Collection and Analyses of Physical Sample to Support Undeclared Allergen Cases: NLEA and General Labeling Requirements; Domestic Compliance Program	November 30, 1998	Do	Do
Assignment to Assure Unpasteurized Juice Manufacturers and Imported Juice Products Provide Required Label Warnings, Placards, and/or meet the 5 log Pathogen Reduction Requirement	September 21, 1998	Do	Do
Assignment to Assure Unpasteurized Juice Manufacturers and Imported Juice Products Provide Required Label Warnings, Placards, and/or meet the 5 log Pathogen Reduction Requirement	November 3, 1998	Do	Do
Pesticides in Imported Ginseng (Field Assignment)	September 17, 1998	FDA districts	FOI/Imports Branch (HFS–606), Office of Field Programs, Food and Drug Administration, 200 C St. SW., Washington, DC 20204
Radionuclides in Foods	October 2, 1998	Do	Do
Letters to Manufacturers of Prepared Sandwiches	August 21, 1998	Manufacturers of prepared sandwiches	Office of Field Programs (HFS–600), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5194 or JohnThomas@OFP@FDA.CFSAN, FAX 292–260–0133

VI. Guidance Documents Issued by the Center for Veterinary Medicine (CVM)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guideline 3—General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals	July 1994	Animal drug industry	Internet via: http://www.fda.gov/cvm or Communications Staff (HFV–12), CVM, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755, FAX 301–594–1831
Guideline 4—Guidelines for Efficacy Studies for Systemic Sustained Release Sulfonamide Boluses for Cattle		Do	Do
Guideline 5—Stability Guidelines	December 1990	Do	Do
Guideline 6—Guidelines for Submitting NADA's for Generic Drugs Reviewed by NAS/NRC		Do	Do
Guideline 9—Preclearance Guidelines for Production Drugs	October 1975	Do	Do
Guideline 10—Amendment of Section II(G)(1)(b)(4) of the Preclearance Guidelines	October 1975	Do	Do
Guideline 13—Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Free-Choice Feeds	January 1985	Do	Do
Guideline 14—Guideline and Format for Reporting the Details of Clinical Trials Using An Investigational New Animal Drug in FOOD Producing Animals		Do	Do
Guideline 15—Guideline and Format for Reporting the Details of Clinical Trials Using An Investigational New Animal Drug in NON–FOOD Producing Animals	February 1977	Do	Do
Guideline 16—FOI Summary Guideline	May 1985	Do	Do
Guideline 18—Antibacterial Drugs in Animal Feeds: Human Health Safety Criteria		Do	Do
Guideline 19—Antibacterial Drugs in Animal Feeds: Animal Health Safety Criteria		Do	Do
Guideline 20—Antibacterial Drugs in Animal Feeds: Antibacterial Effectiveness Criteria		Do	Do
Guideline 22—Guideline Labeling of Arecoline Base Drugs Intended for Animal Use		Do	Do
Guideline 23—Medicated Free Choice Feeds—Manufacturing Control	July 1985	Do	Do
Guideline 24—Guidelines for Drug Combinations for Use in Animals	October 1983	Do	Do
Guideline 25—Guidelines for the Efficacy Evaluation of Equine Anthelmintics	January 1979	Do	Do
Guideline 29—Guidelines for the Effectiveness Evaluation of Swine Anthelmintics	September 1980	Do	Do
Guideline 31—Guidelines for the Evaluation of Bovine Anthelmintics	July 1981	Do	Do
Guideline 33—Target Animal Safety Guidelines for New Animal Drugs	June 1989	Do	Do
Guideline 35—Bioequivalence Guideline—Final	1996	Do	Do
Guideline 36—Guidelines for Efficacy Evaluation of Canine/Feline Anthelmintics	July 1985	Do	Do
Guideline 37—Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Poultry Feed for Pigmentation	March 1984	Do	Do
Guideline 38—Guideline for Effectiveness Evaluation of Topical/Otic Animal Drugs	August 1984	Do	Do
Guideline 40—Draft Guideline for the Evaluation of the Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry	April 1992	Do	Do
Guideline 41—Draft Guideline: Formatting, Assembling, and Submitting New Animal Drug Applications	June 1992	Do	Do
Guideline 42—Animal Drug Manufacturing Guidelines, 1994	1994	Do	Do
Guideline 43—Guidance on Generic Animal Drug Products Containing Fermentation-Derived Drug Substances	October 1995	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guideline 45—Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle	August 1993	Do	Do
Guideline 48—Guidance for Industry for the Submission of Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products	November 1994	Do	Do
Guideline 49—Guidance Document for Target Animal Safety and Drug Effectiveness Studies for Anti-Microbial Bovine Mastitis Products	April 1996	Do	Do
Guideline 50—Draft Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products	February 1993	Do	Do
Guideline 52—Guidance—Microbiological Testing of Antimicrobial Drug Residues in Food	January 1996	Do	Do
Guideline 53—Guideline for the Evaluation of the Utility of Food Additives in Diets Fed to Aquatic Animals	May 1994	Do	Do
Guideline 54—Draft Guideline for Utility Studies for Anti-Salmonella Chemical Food Additives in Animal Feeds	June 1994	Do	Do
Guideline 55—Supportive Data for Cat Food Labels Bearing ''Reduces Urinary pH Claims: Guideline in Protocol Development''	June 1994	Do	Do
Guideline 56—Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials	November 1994	Do	Do
Guideline 57—Master Files—Guidance for Industry for the Preparation and Submission of Veterinary Master Files	July 1995	Do	Do
Guideline 58—Guidance for Industry for Good Target Animal Study Practices: Clinical Investigators and Monitors	May 1997	Do	Do
Guideline 59—Guidance for Industry: Submitting a Notice of Claimed Investigational Exemption in Electronic Format to CVM via E-Mail	January 1999	Do	Do
Guidance 61—Guidance for Industry—FDA Approval of Animal Drugs for Minor Uses and for Minor Species	January 1999	Do	Do
Guideline 62—Guidance for Industry—Consumer-Directed Broadcast Advertisements	August 1997	Do	Do
Guideline 63—Guidance for Industry—Validation of Analytical Procedures: Definition and Terminology—Draft Guidance	December 1997	Do	Do
Guideline 64—Guidance for Industry—Validation of Analytical Procedures: Methodology—Draft Guidance	December 1997	Do	Do
Guideline 65—Guidance for Industry—Industry-Supported Scientific and Educational Activities	November 1997	Do	Do
Guideline 66—Guidance for Industry—Professional Flexible Labeling of Antimicrobial Drugs—Draft Guidance	January 1998	Do	Do
Guideline 67—Guidance for Industry—Small Entities Compliance Guide for Renderers	February 1998	Do	Do
Guideline 68—Guidance for Industry—Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors	February 1998	Do	Do
Guideline 69—Guidance for Industry—Small Entities Compliance Guide for Feeders of Ruminant Animals With On-Farm Feed Mixing Operations	February 1998	Do	Do
Guideline 70—Guidance for Industry—Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations	February 1998	Do	Do
Guideline 71—Guidance for Industry—Use of Human Chorionic Gonadotropic (HCG) as a Spawning Aid for Fish	April 1998	Do	Do
Guideline 72—Guidance for Industry—GMP's for Medicated Feed Manufacturers Not Required to Register and Be Licensed With FDA	May 1998	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guideline 73—Draft Guidance for Industry—Stability Testing of New Animal Drug Substances and Products	July 1998	Do	Do
Guideline 74—Draft Guidance for Industry—Stability Testing for New Dosage Forms of New Animal Drugs	July 1998	Do	Do
Guideline 75—Guidance for Industry—Stability Testing: Photostability Testing of New Animal Drug Substances and Products: Draft Guidance	July 1998	Do	Do
Guideline 76—Guidance for Industry—Questions and Answers—BSE Feed Regulation	July 1998	Do	Do
Guideline 77—Guidance for Industry—Interpretation of On-Farm Feed Manufacturing and Mixing Operations—Draft Guidance	August 1998	Do	Do
Guideline 78—Guidance for Industry—Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals—Draft Guidance	November 1998	Do	Do

VII. Guidance Documents Issued by the Office of Regulatory Affairs

Name of Document	Date of Issuance	Grouped by 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	August 1996	FDA staff personnel	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161 (Order No. PB96–915499) or via Internet www.fda.gov/ora/compliance—ref/cpg/cpgtc.html
Compliance Policy Guide Medical Device Warning Letter Draft Pilot	August 27, 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 www.fda.gov/ora/compliance—ref/dev—pl.pdf
Compliance Policy Guide-DRAFT Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only	January 5, 1998	Do	Division of Compliance Policy or via Internet at www.fda.gov/cdrh/comp/ivddrfg.html
Compliance Policy Guide 675.400 (CPG 7126.24) REVISION Rendered Animal Feed Ingredients	November 13, 1998	Do	Division of Compliance Policy or via Internet at www.fda.gov/ora/compliance—ref/cpg/cpgvet/cpg675.400.html
Compliance Policy Guide—DRAFT Distributor Medical Device Reporting	August 28, 1998	Do	Division of Compliance Policy or via Internet at www.fda.gov/ora/compliance—ref/cpg—mdr3.txt
Compliance Policy Guide 257.100 NEW Deferral of Source Plasma Donors Due to Red Cell Loss During Collection of Source Plasma by Automated Plasmapheresis	December 21, 1998	Do	Division of Compliance Policy or via Internet at www.fda.gov/ora/compliance—ref/cpg/default.html
FDA/ORA International Inspection Manual and Travel Guide	May 1997	Do	Division of Emergency & Investigational Operations (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 29857 or via Internet www.fda.gov/ora/inspect—ref/itob/itob.html
Glossary of Computerized System and Software Development Terminology	August 1995	Do	NTIS (Order No. PB96–127352) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E-mail, or Internet)
Import Alerts	continuously	Do	Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or via Internet www.fda.gov/ora/fiars/ora—import—alerts.html
Investigations Operations Manual	January 1999	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3276 or via Internet www.fda.gov/ora/inspect—ref/iom/iomtc.html
Investigations Operations Manual-REVISION: Chapter 4—Sampling	July 1998	Do	Do
Investigations Operations Manual-REVISION: Chapter 5—Establishment Inspection	July 1998	Do	Do
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, ATTN: Donna Porter or via Internet www.fda.gov/ora/science—ref/lpm/lpmtc.html
Regulatory Procedures Manual	August 1997	Do	NTIS (Order No. PB97–196182) or via Internet 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, or via Internet www.fda.gov/ora/compliance—ref/rpm/rpmtc.html
Regulatory Procedures Manual: UPDATE Subchapter/Warning Letters	March 1998	Do	Do
Regulatory Procedures Manual: UPDATE/REVISION Subchapter/Import Procedures	April 1998	Do	Do
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	Do	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	Division of Compliance Policy or via Internet at www.fda.gov/ora/compliance—ref/rpm—new2/ch6.html
Regulatory Procedures Manual: UPDATE/REVISION Subchapter/Supervisory Charges	June 1998	Do	Division of Compliance Policy or via Internet at www.fda.gov/ora/compliance—ref/rpm—new2/ch9chgs.html
Regulatory Procedures Manual: NEW Subchapter/ Civil Penalties—Electronic Product Radiation Control	July 1998	Do	Division of Compliance Policy or via Internet at www.fda.gov/ora/compliance—ref/ch6civpen.html
Guide to Inspections of Bulk Pharmaceutical Chemicals	May 1994	Do	NTIS (Order No. PB96–127154) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Pharmaceutical Quality Control Laboratories	July 1993	Do	NTIS (Order No. PB96–127279) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories	July 1993	Do	NTIS (Order No. PB96–127287) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Validation of Cleaning Processes	July 1993	Do	NTIS (Order No. PB96–127246) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Lyophilization of Parenterals	July 1993	Do	NTIS (Order No. PB96–127253) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of High Purity Water Systems	July 1993	Do	NTIS (Order No. PB96–127261) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E-mail, or Internet)
Guide to Inspections of Dosage Form Drug Manufacturers-CGMPs	October 1993	Do	NTIS (Order No. PB96–127212) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation	January 1994	Do	NTIS (Order No. PB96–127345) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Topical Drug Products	July 1994	Do	NTIS (Order No. PB96–127394) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Sterile Drug Substance Manufacturers	July 1994	Do	NTIS (Order No. PB96–127295) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Oral Solutions and Suspensions	August 1994	Do	NTIS (Order No. PB96–127147) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Nutritional Labeling and Education Act (NLEA) Requirements	February 1995	Do	NTIS (Order No. PB96–127378) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Interstate Carriers and Support Facilities	April 1995	Do	NTIS (Order No. PB96–127386) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Dairy Product Manufacturers	April 1995	Do	NTIS (Order No. PB96–127329) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Miscellaneous Foods Vol. I	May 1995	Do	NTIS (Order No. PB96–127220) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Miscellaneous Foods Vol. II	September 1996	Do	NTIS (Order No. PB97–196133) or via Internet 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	NTIS (Order No. PB97–196141) or via Internet 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	NTIS (Order No. PB97–196158) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Cosmetic Product Manufacturers	February 1995	Do	NTIS (Order No. PB96–127238) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Blood Banks	September 1994	Do	NTIS (Order No. PB96–127303) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Source Plasma Establishments	December 1994	Do	NTIS (Order No. PB96–127360) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Infectious Disease Marker Testing Facilities	June 1996	Do	NTIS (Order No. PB96–199476) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Biotechnology Inspections Guide	November 1991	Do	NTIS (Order No. PB96–127402) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Computerized Systems in Drug Processing	February 1983	Do	NTIS (Order No. PB96–127337) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Foreign Medical Device Manufacturers	September 1995	Do	NTIS (Order No. PB96–127311) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Foreign Pharmaceutical Manufacturers	May 1996	Do	NTIS (Order No. PB96–199468) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Mammography Quality Standards Act (MQSA) Auditors Guide	January 1998	Do	NTIS (Order No. PB98–127178) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems	December 1997	Do	NTIS (Order No. PB98–127152) or via Internet www.fda.gov/ora/inspect—ref/igs/iglist.html

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How To Obtain A Hard Copy of The Document (Name and Address, Phone, FAX, E-mail, or Internet)
Guide to Inspections of Grain Product Manufacturers	March 1998	Do	Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3276
Guide to Bioresearch Monitoring Inspections of In Vitro Devices	February 1998	Do	Do
Guide to Inspections of Viral Clearance Processes for Plasma Derivatives	March 1998	Do	Do
Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations	August 1998	Do	Do
Guide to Inspections of Computerized Systems in the Food Processing Industry	August 1998	Do	Do—Internet at www.fda.gov/ora/inspect—ref/igf/iglist.html
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
Computerized Systems Used in Clinical Trials-DRAFT	June 18, 1997	Do	Do
Compliance Program 7348.808: Bioresearch Monitoring; Good Laboratory Practices (Nonclinical)	Revised August 17, 1998	FDA staff personnel	Do—Internet http://www.fda.gov/ora/compliance—ref/bimo/default.html
Compliance Program 7348.810: Sponsors, Contract Research Organizations and Monitors	Revised October 30, 1998	Do	Do
Compliance Program 7348.811: Bioresearch Monitoring; Clinical Investigations	Revised September 2, 1998	Do	Do
Food Laboratory Practice Program (Nonclinical Laboratories) 7348.808A; EPA Data Audit Inspections	October 1, 1991	Do	Division of Compliance Policy
Compliance Program 7348.809; Bioresearch Monitoring; Institutional Review Board	August 18, 1994	Do	Do
Good Laboratory Practice Regulations Management Briefings	August 1979	Do	Do—Internet at www.fda.gov/ora/compliance—ref/bimo/default.html

VIII. Guidance Documents Issued by the Office of the Commissioner and Office of Policy

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, Fax, E-mail or Internet
Draft Guidance for Industry; Exports and Imports under the FDA Export Reform and Enhancement Act of 1996	June 1998	Regulated industry	Internet via www.fda.gov/opacom/fedregister/frexport.html
FDA's Development, Issuance and Use of Guidance Documents	February 1997	FDA personnel and regulated industry	Internet via www.fda.gov/opacom/morechoices/moreindu.html or Office of Policy (301–827–3360)
Industry Supported Scientific and Educational Activities	December 1997	Regulated industry	Internet via www.fda.gov/cder/guidance/index.htm or Office of Policy (301–827–3360)
Draft Guidance on Broadcast Advertisements	February 1997	Do	Do
Direct Final Rule Guidance	November 1997	FDA personnel	Internet via www.fda.gov/opacom/morechoices/industry/guidedc.htm or Lisa Helmanis (301–443–3480)
Small Entities Compliance Guide: 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	Internet via www.fda.gov/opacom/campaigns/tobacco/tobret.htm or 1–888–FDA–4KIDS
Children & Tobacco—Frequently Asked Questions about the New Regulations (Draft)	July 1997	Do	Do
Children & Tobacco—A Retailer's Guide to the New Federal Regulations	October 1997	Do	Do
Children & Tobacco—A Guide to the the New Federal Regulations	October 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, Fax, E-mail or Internet
FDA's Standards Policy	October 1995	FDA personnel and regulated industry	60 FR 53078, October 11, 1995 or Office of Policy (301–827–3360)
Policy & Guidance Handbook for FDA Advisory Committees	1994	FDA personnel	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650 (Order No. PB94–158854)

Dated: June 4, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–14752 Filed 6–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1149]

Draft Guidance for Industry on in Vivo Pharmacokinetics and Bioavailability Studies and in Vitro Dissolution Testing for Levothyroxine Sodium Tablets; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''In Vivo Pharmacokinetics and Bioavailability Studies and in Vitro Dissolution Testing for Levothyroxine Sodium Tablets.'' The draft guidance contains agency recommendations on how to design in vivo pharmacokinetics and bioavailability studies and perform in vitro dissolution testing for levothyroxine sodium tablets.

DATES: Written comments on the draft guidance may be submitted by August 9, 1999. General comments on documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry can be obtained on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments and requests are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michael J. Fossler, Center for Drug Evaluation and Research (HFD–870), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6417.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''In Vivo Pharmacokinetics and Bioavailability Studies and in Vitro Dissolution Testing for Levothyroxine Sodium Tablets.'' This draft guidance contains agency recommendations on how to design in vivo pharmacokinetics and bioavailability studies and perform in vitro dissolution testing for levothyroxine sodium tablets, which were identified as new drugs in a notice published in the **Federal Register** of August 14, 1997 (62 FR 43536).

Levothyroxine sodium was introduced into interstate commerce during the 1950's without approval of new drug applications (NDA's) for the drug products. As a result of concerns about the stability and consistent potency of the products, the agency announced that orally administered drug products containing levothyroxine sodium were new drugs (62 FR 43536). The notice stated that a manufacturer who wished to continue to market orally administered levothyroxine sodium products had to submit an NDA. The agency allowed current manufacturers 3 years to obtain approved NDA's, until August 14, 2000.

A number of firms have contacted FDA for advice regarding how to conduct bioavailability studies and in vitro dissolution testing for levothyroxine sodium tablets. Because of this interest, and the need to provide consistent advice to all firms who intend to submit NDA's for this product, FDA has developed this draft guidance on designing in vivo pharmacokinetics and bioavailability studies and performing in vitro dissolution testing for levothyroxine sodium tablets. The guidance documents FDA's current thinking on this subject. Although the guidance is being submitted in draft for comment, FDA recognizes that sponsors of already marketed levothyroxine sodium products that are required to obtain approved NDA's by August 14, 2000, may already have begun to conduct bioavailability and dissolution studies. The study design described in this guidance may be used for these studies or an alternative approach may be used. In either case, the study designs will be acceptable if scientifically justified. FDA will revise the study designs described in the guidance in accordance with any comments received, if appropriate.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on in vivo pharmacokinetics and bioavailability studies and in vitro dissolution testing for levothyroxine sodium tablets. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

Interested persons may, on or before August 9, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 3, 1999.

Peggy Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–14751 Filed 6–9–99; 8:45 am]

BILLING CODE 4160–01–F