Procedure: On March 23, 1998, from 7:45 a.m. to 4:50 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 16, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. to 8:15 a.m. and between approximately 3:30 p.m. to 4:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 16, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On March 23, 1998, from 4:50 p.m. to 6:20 p.m., the meeting will be closed to review data of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of this information.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 20, 1998.

Michael A. Friedman,

Deputy Commissioner of Operations.

[FR Doc. 98–4964 Filed 2–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0040]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Safety Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 12, 1997 (62 FR 43169), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0345. The approval expires on October 31, 2000.

Dated: February 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–4846 Filed 2–25–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0046]

Comprehensive List of Current Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a comprehensive list of all guidance documents currently in use at the agency. 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, including those documents that were issued prior to the adoption of the GGP's.

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 (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Information on where to obtain single copies of a listed guidance document is provided for each agency center individually in the specific center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: Lisa L. Barclay, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its ''Good Guidance Practices'' (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 a comprehensive list of all guidance documents that are currently in effect. This comprehensive list is maintained on the FDA World Wide Web home page. The list will be updated and published annually in the **Federal Register**. FDA also has committed to publish quarterly a **Federal Register** notice that lists all guidance documents that were issued and withdrawn during that quarter. FDA also has undertaken to publish, on a quarterly basis, a list of all new ''Level 2'' guidance documents issued by the agency under the GGP's. In a separate notice in a future issue of the **Federal Register**, FDA will publish its first quarterly update including a list of Level 2 guidance documents issued during that quarter.

The following list of guidance documents represents all guidances issued by FDA that are currently in effect. The documents 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, and guidance documents that are still in draft form and on which public comment has been requested are so identified.

This cumulative list includes guidance documents that were issued prior to the adoption of the GGP's. At the time such documents are substantively revised, FDA will update them to include the standard guidance elements and nomenclature described in the GGP's.

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 Industries	Office of Communication, Training and Manufacturers Assistance, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–1800 or 1–800–835–4709, FAX Information System: 1–888–CBER–FAX (within U.S.) 301–827–3844 (outside U.S. and local to Rockville, MD) Internet access: 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 Use as a Donor Screen	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
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

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)
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	September 28, 1992	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
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

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)
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, SourcePlasma 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
Guidance for Industry in Designing Clinical Programs for Developing Human Drugs, Medical Devices, or Biological Products Intended for the Treatment of Rheumatoid Arthritis; Availability of Draft Guidance; Notice of Public Workshop on Juvenile Rheumatoid Arthritis	June 24, 1996	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
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

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 Blood Banks, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs	September 1, 1994	Do	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	Do	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-FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	March 13, 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
Guidance for Industry—Screening and Testing of Donors of Human Tissue Intended for Transplantation	July 29, 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—Donor Screening for Antibodies to HTLV–II	August 15, 1997	Do	Do
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
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
Draft Guidance for Industry—For Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products or Animal Plasma or Serum-Derived Products	December 29, 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
Changes to be Reported for Product and Establishment License Applications; Guidance	April 6, 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 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
To Manufacturers of Immune Globulin Products: Testing for Hepatitis C Virus RNA Immunoglobulin	December 27, 1994		
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 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 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, 1985	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
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

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)
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
Draft PTC in Human Somatic Cell Therapy and Gene Therapy	August 27, 1991	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
Draft Addendum to the PTC in Human Somatic Cell and Gene Therapy	January 2, 1996	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
Centerwide Policy on Issuance of and Response to Clinical Hold Letters for Investigational New Drug Applications	August 20, 1996	Do	Do
Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software	January 13, 1997	Do	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)
MDR Reporting Guidance For Breast Implants—E1996002	August 7, 1996	Office of Surveillance and Biometrics (OSB)	Division of Small Manufacturers Assistance, 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
Instructions for Completing Form 3417: Medical Device Reporting Baseline Report [MDR]	March 31, 1987	OSB	Do
MDR Guidance Document No. 1—IOL—E1996004	August 7, 1996	Do	Do
MDR Guidance Document No. 3—Needlestick & Blood Exposure—E1996003	August 9, 1996	Do	Do
Statistical Guidance for Clinical Trials of Non Diagnostic Medical Devices (Replaces Clinical Study Guidance)	January 1, 1996	Do	Do
Medical Device Reporting: An Overview	April 1996	Do	Do
Instructions for Completing FDA Form 3500A with Coding Manual for Form 3500A (MEDWATCH)	December 15, 1995	Do	Do
MEDWATCH FDA Form 3500A for Use by User Facilities, Distributors, and Manufacturers for Mandatory Reporting	June 1, 1993	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)
Amendment to Guidance on Discretionary Postmarket Surveillance on Pacemaker Leads	March 30, 1994	Do	Do
Proposed Draft Guidance to Sponsors Regarding Required Postmarket Surveillance Studies of Plasma—Sprayed Porous-Coated Hip Prostheses	October 7, 1994	Do	Do
Required Postmarket Surveillance Section 522(a) Initial Device Categories Revised	July 31, 1997	Do	Do
MDR Guidance Document: Remedial Action Exemption—E1996001	July 30, 1996	Do	Do
MDR Internet List Server (listserv) Instruction sheet	August 29, 1996	Do	Do
Semi-Annual Report, Form 3419 (MDR)	September 24, 1996	Do	Do
Variance from Manufacturer Report Number Format (MDR letter)	July 16, 1996	Do	Do
Guidance to Manufacturers on the Development of Required Postmarket Surveillance Study Protocols Under Section 522(a)(1) of the Federal Food, Drug, and Cosmetic Act	November 8, 1991	Do	Do
Medical Device Reporting for Distributors	April 1996	Do	Do
Medical Device Reporting for Manufacturers	March 1997	Do	Do
Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)	June 9, 1993	Do	Do
Instructions for Completing Semi-Annual Report, Form 3419 (MDR)	September 24, 1996	Do	Do
Variance from Manufacturer Report Number Format	August 12, 1996	Do	Do
Variance from Manufacturer Report Number Format	July 16, 1996	Do	Do
Statistical Aspects of Submissions to FDA: A Medical Device Perspective (also includes as Appendix the article Observed Uses and Abuses of Statistical Procedures in Medical Device	June 1, 1984	Do	Do
Investigational Device Exemptions [IDE] Manual (FDA 96–4159)/DSMA	June 1, 1996	Office of Health and Industry Programs (OHIP), Division of Small Manufacturer's Assistance (DSMA)	Do
Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields—Infant Apnea Monitor Standard	September 1, 1993	Do	Do
Premarket Approval (PMA) Manual (FDA 93–4214)	April 1, 1993	Do	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)		Do	Do
Obtaining CDRH Guidance Documents	October 21, 1997	Do	Do
Regulatory Requirements for Devices for the Handicapped (FDA 87–4221)	August 1, 1987	Do	Do
Small Business Guide to FDA (FDA 96–1092)	January 1, 1996	Do	Do
MDR Documents Access Information	May 10, 1996	Do	Do
MDR Documents Access Information for CDRH Electronic Docket (ED)	February 29, 1996	Do	Do
MDR Documents Access Information for CDRH Facts-On-Demand (FOD)	February 29, 1996	Do	Do
MDR Documents Access Information for Industry Organizations	May 8, 1996	Do	Do
MDR Documents Access Information for National Technical Information Service (NTIS)	May 10, 1996	Do	Do
MDR Documents Access Information for World Wide Web (WWW)	February 29, 1996	Do	Do
Addendum to What a Mammography Facility Should do to Prepare for an MQSA Inspection	July 31, 1996	OHIP/Division of Mammography Quality and Radiation Programs (DMQRP)/Mammography Quality Standards Act (MQSA)	MQSA
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	September 1, 1995	Do	Do
Policy Statements in Question and Answer Format	October 7, 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)
What a Mammography Facility Should Do to Prepare for an MQSA Inspection	June 30, 1995	Do	Do
Classification Names for Medical Devices and In Vitro Diagnostic Products (FDA Pub No. 95–4246)	March 1, 1995	Do	Do
Import of Medical Devices—A Workshop Manual (FDA 93–4228)	March 1, 1993	Do	Do
Labeling—Regulatory Requirements for Medical Devices (FDA 89–4203)	September 1, 1989	Do	Do
List of Current CDRH Addresses for Report Submission and Ordering of CDRH Forms	July 30, 1996	Do	Do
Premarket Notification: 510(k)—Regulatory Requirements for Medical Devices (FDA 95–4158)	August 1, 1995	Do	Do
Procedures for Laboratory Compliance Testing of Television Receivers—part of TV Packet	May 1, 1986	Do	Do
U.S. Food and Drug Administration Regulation of Medical Devices—Background Information for Foreign Officials	May 1, 1996	Do	Do
Instructions for Completion of Medical Device Registration and Listing Forms FDA 2891, 2891a and 2892	July 1, 1997	Do	Do
In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (supersedes FDA 87–4224)	January 1, 1997	Do	Do
An Introduction to Medical Device Regulations (FDA 92–4222)	January 1, 1992	Do	Do
Do It By Design—An Introduction to Human Factors in Medical Devices	December 1, 1996	OHIP/Division of Device User Programs and Systems Analysis (DDUPSA)	Do
Good Guidance Practices Standard Operating Procedures Manual for the Development and Use of Guidance Documents in CDRH	October 17, 1997	Do	
Human Factors Principles for Medical Device Labeling	September 1, 1993	Do	Do
Medical Device Reporting for User Facilities	April 1996	Do	Do
Write it Right	August 1, 1993	Do	Do
Human Factors Points to Consider for IDE Devices	January 17, 1997	Do	Do
Medical Devices and EMI: The FDA Perspective	January 1, 1995	Office of Compliance	Do
Enforcement Policy; Recalls (Including Product Corrections)—Guidelines on Policy; Procedures; and Industry Responsibilities	June 16, 1978	Do	Do
Sec. 300.600 Commercial Distribution with Regard to Premarket Notification [Section 510(k)] [CPG 7124.19]	September 24, 1987	Do	Do
Procedures for Obtaining FDA Approval to Export Unapproved Medical Devices	January 13, 1995		Do
The FDA Export Reform and Enhancement Act of 1996/Export Certification	October 1, 1996	Do	Do
FDA Regulatory Procedures Manual Chapter 8–10 Warning Letters	May 23, 1991	Do	Do
A Pocket Guide to Device GMP Inspections—Inspections of Medical Device Manufacturers and GMP Regulation Requirements	November 1, 1991	Do	Do
Commercial Distribution/Exhibit Letter (Use instead of Hile letter) (Display)	April 10, 1992	Do	Do
Diagnostic Ultrasound Guidance Update	January 30, 1987	Office of Compliance (OC)/Division of Enforcement I (DOE I)	Do
Doppler Ultrasound Guidance Update	March 7, 1986	Do	Do
Manufacturers/Assemblers of Diagnostic X-ray Systems: Enforcement Policy for Positive-Beam Limitation (PBL) Requirements in 21 CFR 1020.31(g)	October 13, 1993	Do	Do
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	March 1, 1996	Do	Do
A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammographic X–Ray Systems	March 1, 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)
A Guide for the Submission of an Abbreviated Radiation Safety Report on X–Ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use	March 1, 1996	Do	
All Diagnostic Ultrasound Manufacturers and Importers-Exemption from Reporting under 21 CFR 1002	February 24, 1986	Do	Do
Clarification of Radiation Control Regulations for Diagnostic X–Ray Equipment (FDA 89–8221)	March 1, 1989	Do	Do
Guide for the Submission of Initial Reports on Diagnostic X–Ray Systems and their Major Components	January 1, 1982	Do	Do
Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi)	May 17, 1993	Do	Do
Medical Device Tracking: Questions and Answers Based on the Final Rule	August 26, 1993	Do	Do
Guideline for the Manufacture of In Vitro Diagnostic Products	January 10, 1994	Do	Do
Retention of Records Required by 21 CFR 1002	August 24, 1981	Do	Do
Letter to Manufacturers/Repackers Using Cotton	April 22, 1994	OC/Division of Enforcement II (DOE II)	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	Do	Do
Hazards of Volume Ventilators and Heated Humidifiers	September 15, 1993	Do	Do
Compliance Guide for Laser Products (FDA 86–8260)	September 1, 1985	Do	Do
Dental Handpiece Sterilization (Dear Doctor Letter)	September 28, 1992	Do	Do
Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Levels of Exposure	June 23, 1978	Do	Do
GLOVES Information About Medical Gloves	September 1, 1993	Do	Do
Letter—Manufacturers, Distributors and Importers of Condom Products [included in Condom Packet #398]	February 23, 1994	Do	Do
Letter—Manufacturers, Importers, and Repackagers of Condoms for Contraception or Sexually-Transmitted Disease Prevention (Holt) [included in Condom Packet #398]	February 13, 1989	Do	Do
Pesticide Regulation Notice 94–4: Interim Measures for the Registration of Antimicrobial Products/Liquid Chemical Germicides with Medical Device Use Claims Under the	June 30, 1994	Do	Do
Regulatory Requirements for Medical Gloves—A Workshop Manual FDA Publication No. 96–4257	September 1, 1996	Do	Do
Standard Specification for Rubber Contraceptives (Condoms) [included in Condom Packet #398]	October 28, 1983	Do	Do
Sterilization: Questions and Answers from FDA, from Medical Device and Diagnostic Industry for January, 1985, page 132	January 1, 1985	Do	Do
All U.S. Condom Manufacturers, Importers and Repackagers	April 7, 1987	Do	Do
Letter to Ophthalmologists about Lasers for Refractive Surgery	June 27, 1997	Do	Do
Manufacturers and Initial Distributors of Hemodialyzers	May 23, 1996	Do	Do
Manufacturers and Users of Lasers for Refractive Surgery	October 10, 1996	Do	Do
Manufacturers of Laparoscopic Trocars, used for Abdominal Access	August 23, 1996	Do	Do
Prospective Manufacturers of Barrier Devices used during Oral Sex for STD Protection	October 31, 1996	Do	Do
Impact Resistant Lenses: Questions and Answers (FDA 87–4002) [see shelf—# 460]	September 1, 1987	Do	Do
Letter to Industry, Powered Wheelchair Manufacturers from RMJohnson	May 10, 1993	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)
Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals	February 3, 1994	Do	Do
Guide for Preparing Product Reports for Lasers and Products Containing Lasers	September 1, 1995	Do	Do
Letter—Condom Manufacturers and Distributors	April 5, 1994	Do	Do
Suggested State Regulations for Control of Radiation—Volume II Nonionizing Radiation—Lasers (FDA Pub No. 83–8220)	January 1, 1982	OC/Division of Enforcement III (DOE III)	Do
Quality Assurance Guidelines for Hemodialysis Devices	February 1, 1991	Do	Do
Quality Control Guide for Sunlamp Products (FDA 88–8234)	March 1, 1988	Do	Do
Quality Control Practices for Compliance with the Federal Mercury Vapor Lamp Performance Standard	May 1, 1980	Do	Do
Reporting and Compliance Guide for Television Products including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Informational Guidance	October 1, 1995	Do	Do
Policy on Lamp Compatibility (sunlamps)	September 2, 1986	Do	Do
Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products	August 21, 1986	Do	Do
Policy on Warning Label Required on Sunlamp Products	June 25, 1985	Do	Do
Imports Radiation-Producing Electronic Products (FDA 89–8008)	November 1, 1988	Do	Do
Information Requirements for Cookbooks and User and Service Manuals	October 31, 1988	Do	Do
Keeping Up With the Microwave Revolution (FDA Pub No. 91–4160)	March 1, 1990	Do	Do
Laser Light Show Safety—Who's Responsibility (FDA 86–8262)	May 1, 1986	Do	Do
Letter to All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist	May 28, 1981	Do	Do
General Principles of Software Validation; Draft Guidance	June 9, 1997	Do	Do
Reporting Guide for Laser Light Shows and Displays (21 CFR 1002) (FDA 88–8140)	September 1, 1995	Do	Do
Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR 1002)	September 1, 1995	Do	Do
Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (replaces FDA 82–8127)	September 1, 1995	Do	Do
Safety of Electrically Powered Products: Letter To Medical Device and Electronic Product Manufacturers From Lillian Gill & BHB correction memo	September 18, 1996	Do	Do
Unsafe Patient Lead Wires and Cables	September 3, 1993	Do	Do
Design Control Guidance for Medical Device Manufacturers	March 11, 1997	Do	Do
Final Design Control Inspectional Strategy	March 1, 1997	Do	Do
Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use	September 1, 1996	Do	Do
Guide for Preparing Annual Reports for Ultrasonic Therapy Products	September 1, 1996	Do	Do
Guide for Preparing Product Reports for Medical Ultrasound Products	September 1, 1996	Do	Do
Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only)	August 1, 1996	Do	Do
Application for a Variance from 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device	March 1, 1987	Do	Do
Letter to Trade Association: ReUse of Single-use or Disposable Medical Devices	December 27, 1995	Do	Do
Letter: Changes in Regulations Concerning Records and Reports on Radiation-Emitting Electronic Products	October 27, 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)
Medical Device Electromagnetic Interference Issues, Problem Reports, Standards, and Recommendations		Do	Do
Computerized Devices/Processes Guidance—Application of the Medical Device GMP to Computerized Devices and Manufacturing Processes	May 1, 1992	Do	Do
Keeping Medical Devices Safe from Electromagnetic Interference	July 1, 1995	Do	Do
Latex Labeling Letter (Johnson)		Do	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps (replaces FDA 82–8127)	September 1, 1995	Do	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products (replaces FDA 82–8127)	September 1, 1995	Do	Do
Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21 CFR 1002)	September 1, 1995	Do	Do
Abbreviated Reports on Radiation Safety for Microwave Products (Other Than Microwave Ovens)—e.g., Microwave Heating, Microwave Diathermy, RF Sealers, Induction, Dielectric	August 1, 1995	Do	Do
Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products	August 1, 1995	Do	Do
Guidance for the Submission of Cabinet X–Ray System Reports Pursuant to 21 CFR 1020.40	February 1, 1975	Do	Do
Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)	October 1, 1987	Do	Do
Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet (UV) Lamps and Products Containing Such Lamps (21 CFR 1002.10 and 1002.12)	April 1, 1989	Do	Do
Guide for Preparing Reports on Radiation Safety of Microwave Ovens	March 1, 1985	Do	Do
Guide for Submission of Information on Accelerators Intended to Emit X–Radiation Required Pursuant to 21 CFR 1002.10	April 1, 1971	Do	Do
Guide for Submission of Information on Analytical X–Ray Equipment Required Pursuant to 21 CFR 1002.10	April 30, 1974	Do	Do
Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 (FDA 81–8137)	September 1, 1980	Do	Do
Guide for Submission of Information on Industrial X–Ray Equipment Required Pursuant to 21 CFR 1002.10	March 1, 1973	Do	Do
Guide for the Filing of Annual Reports for X–Ray Components and Systems	July 1, 1980	Do	Do
Guide for the Submission of Initial Reports on Computed Tomography X–Ray Systems	September 1, 1984	OC/DOE I and III	Do
Additional Information for Initial Reports	April 9, 1993	Do	Do
All Diagnostic Ultrasound Manufacturers and Importers Exemption from Reporting under 21 CFR 1002	February 24, 1986	Do	Do
Guideline for Preparing Notices of Availability of Investigational Medical Devices	November 1, 1985	OC/Bioresearch Monitoring (BIMO)	Do
Recommended Test Methods Infant Apnea Monitor Standard	September 1, 1993	Office of Standards and Technology (OST)	Do
Draft Document—A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems	February 7, 1997	Do	Do
Letter to Medical Device Manufacturer on Pentium Processors	February 14, 1995	CDRH, Office of the Director (OD)	Do
''Real-Time'' Review Program for Premarket Approval Application (PMA) Supplements	April 22, 1997	Office of Device Evaluation (ODE)	Do
A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications	June 13, 1997	Do	Do
Freedom of Information/510(K) Process Changes	May 15, 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)
Reexamination of the Evaluation Process for Liquid Chemical Sterilant and High Level Disinfectants	May 19, 1997	Do	Do
Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy	June 30, 1993	Do	Do
Center for Devices and Radiological Health's Premarket Notification [510(k)] Refuse to Accept Policy—(updated Checklist 3/14/1995)	June 30, 1993	Do	Do
4-of-A-Kind PMA's	October 1, 1991	Do	Do
Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices	December 1, 1983	Do	Do
Biotechnology and FDA Regulation of Hybridoma In-Vitro Diagnostic Products: List of Current Devices and Guidelines for Manufacturers	January 1, 1986	Do	Do
CDRH's 510(k)/IDE/PMA Refuse to Accept/Accept/File Policies (see #D94–1, #K94–1, & #P94–1)	June 30, 1993	Do	Do
Classified Convenience Kits	April 30, 1993	Do	Do
Color Additive Petitions (p. II–19 of PMA Manual)	June 1, 1987	Do	Do
Color Additive Status List (Inspection Operations Manual)	February 1, 1989	Do	Do
Color Additives for Medical Devices (Snesko)	November 15, 1995	Do	Do
Deciding When to Submit a 510(k) for a Change to an Existing Device [see CDRH F–O–D #1935]	January 10, 1997	Do	Do
Device Specific Guidance Documents (List)	May 11, 1993	Do	Do
FDA Clinical Investigator Information Sheets	May 1, 1989	Do	Do
FDA Guide for Validation of Biological Indicator Incubation Time (Source: Sterilization Committee; through Virginia Ross; HFZ–332)	January 1, 1986	Do	Do
FDA Policy For The Regulation Of Computer Products (DRAFT) [See 2099]	November 13, 1989	Do	Do
Format for IDE Progress Reports		Do	Do
Guidance for Preparation of PMA Manufacturing Information	August 1, 1992	Do	Do
Guide for Establishing and Maintaining a Calibration Constancy Intercomparison System for Microwave Oven Compliance Survey Instruments (FDA 88–8264)	March 1, 1988	Do	Do
Guideline for the Monitoring of Clinical Investigations	January 1, 1988	ODE	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 (LAL) Test as an End-Product Endotoxin Test	December 1, 1987	Do	Do
Indications for Use Statement	January 2, 1996	Do	Do
Industry Representatives on Scientific Panels	March 27, 1987	Do	Do
Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance (see 1198)	April 1, 1996	Do	Do
Limulus Amebocute Lysate; Reduction of Samples for Testing	October 23, 1987	Do	Do
Master Files Part III; Guidance on Scientific and Technical Information	June 1, 1987	Do	Do
Memorandum: Electromagnetic Compatibility for Medical Devices: Issues and Solutions	June 13, 1995	Do	Do
Methods for Conducting Recall Effectiveness Checks	June 16, 1978	Do	Do
Necessary Information for Diagnostic Ultrasound 510(k) (Draft)	November 24, 1987	Do	Do
Perspectives on Clinical Studies for Medical Device Submissions (Statistical)		Do	Do
PMA Review Schedule	March 31, 1988	Do	Do
PMA Review Statistical Checklist		Do	Do
Points to Consider in the Characterization of Cell Lines Used to Produce Biological Products (from John C. Petricciani, M.D.)	June 1, 1984	Do	Do
Preamendment Class III Devices	March 11, 1992	Do	Do

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Premarket Notification [510(k)] Status Request Form, revised	March 7, 1994	Do	Do
Premarket Submission Coversheet, Instructions, and Survey	January 19, 1995	Do	Do
Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers (FDA 90–4236)	September 1, 1989	Do	Do
Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources (include with 926–930)	June 30, 1993	Do	Do
Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	September 3, 1996	Do	Do
Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review	August 29, 1991	Do	Do
Shelf Life of Medical Devices	March 1, 1991	Do	Do
Substantial Equivalence (SE) Decision Making Documentation ATTACHED: ''SE'' Decision Making Process (Detailed) i.e. the decision making tree	January 1, 1990	Do	Do
Suggested Content for Original IDE Application Cover Letter—Version 4	February 27, 1996	Do	Do
Suggestions for Submitting a Premarket Approval (PMA) Application	April 1, 1993	Do	Do
Threshold Assessment of the Impact of Requirements for Submission of PMA's for 31 Medical Devices Marketed Prior to May 28, 1976	January 1, 1990	Do	Do
Viable Bacteriophage in Co2 Laser Plume: Aerodynamic Size Distribution		Do	Do
Drugs of Abuse Screening Test Devices	July 21, 1987	Do	Do
Letter—Vascular Graft Industry (Philip Phillips)	November 22, 1995	Do	Do
Letter to Industry, Powered Wheelchair/Scooter or Accessory/Component Manufacturer from Susan Alpert, Ph.D.,M.D.	May 26, 1994	Do	Do
Preamendments Class III Strategy; SXAlpert	April 19, 1994	Do	Do
Draft Guidance to Firms on Biliary Lithotripsy Studies	August 2, 1990	ODE/Division of Reproductive, Abdominal, ENT, and Radiological Devices (DRAERD)	Do
Letter: Notice to Manufacturers of Bone Mineral Densitometers	September 25, 1997	Do	Do
510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments	September 19, 1994	Do	Do
CDRH Interim Regulatory Policy for External Penile Rigidity Devices	September 10, 1997	Do	Do
Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology	November 1, 1994	Do	Do
Draft—510(k) Checklist for Conditioned Response Enuresis Alarms	November 23, 1994	Do	Do
Draft 510(k) Checklist for Condom Catheters	February 23, 1995	Do	Do
Draft 510(k) Checklist for Endoscopic Electrosurgical Unit (ESU) and Accessories Used in Gastroenterology and Urology	August 16, 1995	Do	Do
Draft 510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology	June 22, 1995	Do	Do
Draft 510(k) Checklist for Non-Implanted Electrical Stimulators Used for the Treatment of Urinary Incontinence	June 6, 1995	Do	Do
Draft 510(k) Checklist for Urological Irrigation System and Tubing Set	August 1, 1995	Do	Do
Draft Guidance for Clinical Investigations of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)	November 11, 1994	Do	Do
Draft Guidance for Information on Clinical Safety and Effectiveness Data for Extracorporeal Shock Wave Lithotripsy of Upper Urinary Tract (Renal Pelvis, Renal)	February 5, 1992	Do	Do
Draft Guidance for Preclinical and Clinical Investigations of Urethral Bulking Agents Used in the Treatment of Urinary Incontinence	November 29, 1995	Do	Do

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Draft Guidance for Preparation of PMA Applications for Penile Inflatable Implants	March 16, 1993	Do	Do
Draft Guidance for Preparation of PMA Applications for Testicular Prostheses	March 16, 1993	Do	Do
Draft Guidance for Preparation of PMA Applications for the Implanted Mechanical/Hydraulic Urinary Continence Device (Artificial Urinary Sphincter)	May 1, 1995	Do	Do
Draft Guidance for the Clinical Investigation of Urethral Stents	November 2, 1995	Do	Do
Draft Guidance for the Content of Premarket Notifications for Endoscopes used in Gastroenterology and Urology	March 17, 1995	Do	Do
Draft Guidance for the Content of Premarket Notifications for Penile Rigidity Implants	May 30, 1995	Do	Do
Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Catheters	January 24, 1992	Do	Do
Draft Guidance Outline—Points to Consider for Clinical Studies for Vasovasostomy Devices	November 30, 1993	Do	Do
Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology	February 10, 1993	Do	Do
Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters	September 12, 1994	Do	Do
Guidance for the Content of Premarket Notifications for Ureteral Stents	February 10, 1993	Do	Do
Guidance for the Content of Premarket Notifications for Urine Drainage Bags	June 7, 1994	Do	Do
Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems	July 29, 1994	Do	Do
Guidance to Manufacturers on the Development of Required Postapproval Epidemiologic Study Protocols for Testicular Implants		Do	Do
510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices	December 1, 1985	Do	Do
Draft Guidance for Review of Bone Densitometer 510(k) Submissions	November 9, 1992	Do	Do
Draft MRI Guidance Update for dB/dt [update, include with 8/2/88 document]	October 11, 1995	Do	Do
Guidance for Magnetic Resonance Diagnostic Devices—Criteria for Significant Risk Investigations	September 29, 1997	Do	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	Do	Do
Guidance for the Submission of 510(k)s for Solid State X–Ray Imaging Devices	June 1, 1997	Do	Do
Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers	April 11, 1997	Do	Do
Information for Manufacturers Seeking Marketing Clearance of Digital Mammography Systems	June 19, 1996	Do	Do
Reviewer Guidance for Automatic X–Ray Film Processor 510(k)	February 1, 1990	Do	Do
Simplified 510(k) procedures for certain radiology devices:3 letters 12/21/93; 1/31/94 and 3/31/94	1994	Do	Do
ORDB 510(k) Sterility Review Guidance	July 3, 1997	Do	Do
Condom Packet: 4/13/94 RJRivera Letter, Condom Guidance & 7 Tabs, General Guidance for Modifying Condom Labeling to Include Shelf Life	April 13, 1994	Do	Do
Draft Guidance for the Content of Premarket Notifications for Loop and Rollerball Electrodes for GYN Electrosurgical Excisions	July 29, 1991	Do	Do
Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons	May 25, 1995	Do	Do
Draft Thermal Endometrial Ablation Devices (Submission Guidance for an IDE)	March 14, 1996	Do	Do
Guidance (''Guidelines'') for Evaluation of Fetal Clip Electrode	March 8, 1977	Do	Do

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Guidance (''Guidelines'') for Evaluation of Hysteroscopic Sterilization Devices	May 10, 1978	Do	Do
Guidance (''Guidelines'') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories)		Do	Do
Guidance (''Guidelines'') for Evaluation of Tubal Occlusion Devices	November 22, 1977	Do	Do
Guidelines for Evaluation of Non-Drug IUD's	September 28, 1976	Do	Do
Hysteroscopes and Gynecology Laparoscopes—Submission Guidance for a 510(k)—includes 00192	March 27, 1996	Do	Do
Hysteroscopes and Laparoscopic Insufflators: Submission Guidance for a 510(k)	August 1, 1995	Do	Do
In-vivo Devices for the Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE Draft Document	June 14, 1997	Do	Do
Intrapartum Continuous Monitors for Fetal Oxygen Saturation and Fetal pH; Submission Guidance for a PMA; Draft Document	June 14, 1997	Do	Do
Premarket Testing Guidelines for Falloposcopes	November 20, 1992	Do	Do
510(k) Diagnostic Ultrasound Guidance4/91 Use of Medical Index in Place of Spatial Peak Intensity in Determining Substantial Equival for Diagnostic Ultrasound Equip/Access/Rel Meas. Dev	February 1993	Do	Do
Premarket Testing Guidelines for Female Barrier Contraceptive Devices also intended to prevent sexually transmitted diseases	April 4, 1990	Do	Do
Premarket Testing Guidelines for Home Uterine Activity Monitors	March 31, 1993	Do	Do
Testing guidance for Male Condoms Made from New Material (Non-Latex)	June 29, 1995	Do	Do
Information for a Latex Condom 510K Subm. for Obstetrics-Gynecology Branch (draft)	March 1994	Do	Do
Guidance for Content and Review of a Magnetic Resonance Diagnostic Device 510(k) Applic.	October 11, 1995	Do	Do
Draft Guidance for Hemodialyzer Reuse Labeling	October 6, 1995	Do	Do
Draft Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis	May 30, 1997	Do	Do
Guidelines for Premarket Testing of New Conventional Hemodialyzers, High Permeability Hemodialyzers, and Hemofilters	March 1, 1982	Do	Do
Draft of Suggested Information for Reporting Extracorporeal Shock Wave Lithotripsy Device Shock Wave Measurements	January 1, 1991	Do	Do
Draft Guidance to Hearing Aid Manufacturers for Substantiation of Claims	August 5, 1994	Do	Do
Guidance for Submission of a 510(k) Premarket Notification for an Air Conduction Hearing Aid	April 1, 1991	Do	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	Do	Do
Guidance for the Content of Premarket Notification for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims	October 21, 1996	Do	Do
Guideline for the Arrangement and Content of a Premarket Approval (PMA) Application for a Cochlear Implant in Adults at Least 18 Years of Age	May 1, 1990	Do	Do
Guidance for the Technical Content of a Premarket Approval (PMA) Application for an Endolymphatic Shunt Tube with Valve	April 1, 1990	Do	Do
Amendment 1: Draft Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses	June 28, 1994	ODE/Division of Opthalmics Devices (DOD)	Do
Certification Statement for the Impact Resistance Test		Do	Do
Draft Premarket Notification 510(k) Guidance for Contact Lens Care Products	May 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)
Eye Valve Implant (and all glaucoma drainage devices) manufacturers letter from NCBrogdon	November 16, 1995	Do	Do
FDA Public Health Advisory: Retinal Photic Injuries from Operating Microscopes During Cataract Surgery	October 16, 1995	Do	Do
New FDA Recommendations & Results of Contact Lens Study (7 day letter)	May 30, 1989	Do	Do
Sunglass Letter including 510(k) format	October 8, 1996	Do	Do
Sunglass Package	February 3, 1995	Do	Do
Third Party Review Guidance for Aspiration and Cutting Device Premarket Notification (510(k))	January 31, 1997	Do	Do
Third Party Review Guidance for Phacofragmentation System Device Premarket Notification (510(k))	January 31, 1997	Do	Do
Announcement by Dr Alpert at 7/26/96 Ophthalmic Panel Meeting concerning Manufacturers & Users of Lasers for Refractive Surgery [excimer]	August 26, 1996	Do	Do
Announcement: Information for Manufacturers & Users of Lasers for Refractive Surgery [excimer]	September 22, 1997	Do	Do
Checklist of Information Usually Submitted in an Investigational Device Exemptions (IDE) Application for Refractive Surgery Lasers [excimer]	October 10, 1996	Do	Do
Discussion Points for Expansion of the ''Checklist of Information Usually Submitted in an Investigational Device Exemption (IDE) Application for Refractive Surgery Lasers''	September 5, 1997	Do	Do
Letter to Manufacturers and Users of Lasers for Refractive Surgery [excimer]	October 10, 1996	Do	Do
Owners Certification of Lasers as PMA Approved Devices [excimer]	September 26, 1996	Do	Do
Update on Excimer Lasers for Nearsightedness	May 20, 1996	Do	Do
Draft Version Guidance for Clinical Data to be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators	August 20, 1992	ODE/Division of General and Restorative Devices (DGRD)	Do
Guidance for the Preparation of Premarket Notifications for Extended Laparoscopy Devices	August 30, 1994	Do	Do
510K Sterility Review Guidance	July 3, 1997	Do	Do
Technological Reporting for Powered Muscle Stimulator 510k Submissions	January 1, 1992	Do	Do
Draft Version Guide for Cortical Electrode 510(k) Content	August 10, 1992	Do	Do
Electrical Muscle Stimulator (EMS) Labeling Indications, Contraindications, Warnings, etc.	July 11, 1985	Do	Do
Galvanic Skin Response Measurement Devices—Draft Guidance for 510 (k) Content	August 23, 1994	Do	Do
Guidance Document for the Preparation for Premarket Notification (510(k)) Applications for Therapeutic Massagers and Vibrators	July 26, 1995	Do	Do
Guidance Document for the Preparation of IDE and PMA Applications for Bone Growth Stimulator Devices	August 12, 1988	Do	Do
Guidance Document for the Preparation of IDE and PMA Applications for Intra-Articular Prosthetic Knee Ligament Devices	February 18, 1993	Do	Do
Guidance Document for the Preparation of Notification (510(k)) Applications for Communication Systems (Powered and Nonpowered) and Powered Environmental Control	July 26, 1995	Do	Do
Guidance Document for the Preparation of Notification (510(k)) Applications for Electromyograph Needle Electrodes	July 26, 1995	Do	Do
Guidance Document for the Preparation of Notification (510(k)) Applications for Heating and Cooling Devices	July 26, 1995	Do	Do
Guidance Document for the Preparation of Notification (510(k)) Applications for Powered Muscle Stimulators and Ultrasound Diathermy and Muscle Stimulator	July 26, 1995	Do	Do

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Guidance Document for the Preparation of Notification (510(k)) Applications for Powered Tables and Multi-function Physical Therapy Tables	July 26, 1995	Do	Do
Guidance Document for the Preparation of Notification (510(k)) Applications for Submerged (underwater) Exercise Equipment	July 26, 1995	Do	Do
Guidance Document for the Preparation of Notification (510(k)) Applications of Immersion Hydrobaths	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Beds	July 26, 1995	Do	Do
Guidance Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles	July 26, 1995	Do	Do
Guidance for Studies for Pain Therapy Devices—Gen. Consid. in the Design of Clinical Studies for Pain-Alleviating Devices	May 12, 1988	Do	Do
Guide for TENS 510(k) Content (Draft)	August 1, 1994	Do	Do
Alternate Suture Labeling Resulting from the January 11, 1993 Meeting with HIMA		Do	Do
Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses	January 18, 1995	Do	Do
Draft Guidance for Preparation of PMA Submissions of Silicone Gel-Filled Breast Prosthesis	May 11, 1992	Do	Do
Draft Guidance for Testing of Alternative Breast Prostheses (Nonsilicone Gel-filled)	September 1, 1994	Do	Do
Draft Guidance for the Preparation of a Premarket Notification for a Non-Interactive Wound and Burn Dressing [510(k)]	March 31, 1995	Do	Do
Draft Guidance for the Preparation of IDE Submission for Interactive Wound and Burn Dressing	April 1, 1995	Do	Do
Guide for 510(k) Review of Processed Human Dura Mater	June 26, 1990	Do	Do
Letter: Core Study for Silicone Breast Implants	January 11, 1996	Do	Do
510(k) Information Needed for Hydroxyapatite Coated Orthopedic Implants	February 20, 1997	Do	Do
Draft Guidance for Preparation of FDA Submissions of Silicone Gel-Filled Breast Prosthesis	May 11, 1992	Do	Do
Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants	February 21, 1997	Do	Do
Draft Data Requirements for Ultrahigh Molecular Weight Polyethylene (Uhmupe) Used in Orthopedic Devices	March 28, 1995	Do	Do
Draft Guidance Document for Femoral Stem Prostheses	August 1, 1995	Do	Do
Draft Guidance Document for Testing Acetabular Cup Prostheses	May 1, 1995	Do	Do
Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Orthopedic Devices-The Basic Elements	September 5, 1996	Do	Do
Draft Guidance for the Preparation of Premarket Notifications [510(k)]s for Cemented, Semi-Constrained Total Knee Prostheses	April 1, 1993	Do	Do
Draft Guideline for Reviewing Spinal Fixation Device Systems	January 9, 1997	Do	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	Do	Do
Draft Outline for a Guidance Document for Testing Orthopedic Bone Cement, request for comments by December 10, 1993	November 1, 1993	Do	Do
Guidance Document for Testing Biodegradable Polymer Implant Devices	April 20, 1996	Do	Do
Guidance Document for Testing Bone Anchor Devices Draft	April 20, 1996	Do	Do

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Guidance Document for Testing Non-Articulating ''Mechanically Locked'' Modular Implant Components	May 1, 1995	Do	Do
Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone Or Bone Cement	April 28, 1994	Do	Do
Guidance Document For The Preparation of Premarket Notification For Ceramic Ball Hip Systems	January 10, 1995	Do	Do
510(k) Sterility Review Guidance	July 3, 1997	Do	Do
Reviewers Guidance Checklist for Intramedullary Rods	February 21, 1997	Do	Do
Reviewers Guidance Checklist for Orthopedic External Fixation Devices	February 21, 1997	Do	Do
Draft 510(k) Guideline for General Surgical Electrosurgical Devices	May 10, 1995	Do	Do
Draft Guidance for Arthroscopes and Accessory 510(k)s	May 1, 1994	Do	Do
Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	June 1, 1994	Do	Do
Draft Version 1—Biofeedback Devices—Draft Guidance for 510(k) Content	August 1, 1994	Do	Do
Draft Version Cranial Perforator Guidance	July 13, 1994	Do	Do
Draft Version Neuro Endoscope Guidance	July 7, 1994	Do	Do
Guidance on the Content and Organization of a Premarket Notification for a Medical Laser	June 1, 1995	Do	Do
Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators		Do	Do
Review of ''YAG'' Lasers for Neurosurgery		Do	Do
Draft Version—Guidance on Biocomatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model	September 12, 1994	Do	Do
Protocol for Dermal Toxicity for Devices in Contact with Skin (Draft)		Do	Do
Addendum to Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants	March 9, 1994	ODE/Division of Dental Infection Control and General Hospital Devices (DDIGD)	Do
Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities	August 1, 1993	Do	Do
Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes	August 1, 1993	Do	Do
Guidance on the Content and Format of Premarket Notification 510(k) Submissions for Liquid Chemical Germicides	December 6, 1996	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants	October 1, 1993	Do	Do
Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers	October 1, 1993	Do	Do
Draft Supplementary Guidance on the Content of Premarket Notification [510(k)] Submissions for Medical Devices with Sharps Injury Prevention Features (Anti-stick)	March 1, 1995	Do	Do
Guidance on 510(k) Submissions for Implanted Infusion Ports	October 1, 1990	Do	Do
Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters	March 16, 1995	Do	Do
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers	March 1, 1993	Do	Do
Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps	March 1, 1993	Do	Do
Guidance on the Content of Premarket Notification [510(K)] Submissions for Hypodermic Single Lumen Needles	April 1, 1993	Do	Do

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Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes	April 1, 1993	Do	Do
510(k) Guidance for Screw Type Endosseous Implants for Prosthetic Attachment	August 11, 1992	Do	Do
510(k) Information Needed for Hydroxyapatite Coated Titanium Endosseous Implants	July 6, 1993	Do	Do
510(k) Information Needed for Metallurgical Endosseous Implants	August 12, 1993	Do	Do
510(k) Information Needed for Ti-Powder Coated Titanium Endosseous Implants	July 13, 1993	Do	Do
Draft Guidance Document for the Preparation of Premarket Notification [510(k)'S] for Dental Alloys	March 3, 1997	Do	Do
Guidance Document for the Preparation of Premarket Notifications (510(k)'s) for Temporomandibular Joint Implants	January 23, 1995	Do	Do
Guidance For The Arrangement and Content of a Premarket Approval (PMA) Application For An Endosseous Implant For Prosthetic Attachment	May 16, 1989	Do	Do
Guidance for the Preparation of Premarket Notification [510(k)] for Resorbable Periodontal Barriers		Do	Do
Information Necessary for Premarket Notification Submissions For Screw-Type Endosseous Implants	December 9, 1996	Do	Do
Outline of Recommended Procedures for a Clinical Investigation of Endosseous Implants Under a 510(k)		Do	Do
Outline of Recommended Procedures for Animal Laboratory Studies of Endosseous Implants		Do	Do
Recommendations of the Dental Products Panel Subcommittee on Dental Lasers		Do	Do
Guidance Document on Dental Handpieces	July 1, 1995	Do	Do
Groups Capable of Testing for Latex Skin Sensitization (Addendum to #994)	July 28, 1997		
Draft Percutaneous Transluminal Coronary Angioplasty Package Insert Template	February 7, 1995	ODE/Division of Cardiovascular, Respiratory and Neurological Devices (DCRND)	Do
Medical Device Labeling—Suggested Format and Content; Draft Document	April 25, 1997	Do	Do
Guidance for Off-the-Shelf Software Use in Medical Devices; Draft Document	June 4, 1997	Do	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	Do	Do
Non-Invasive Blood Pressure (NIBP) Monitor Guidance	March 10, 1997	Do	Do
Draft Guidance for the Content of Preliminary Investigational Device Exemptions (Pre-IDE) Presentations: Teleconferences, Meetings and Written Submissions	August 22, 1995	Do	Do
Electrocardiograph (ECG) Electrode—Version 1.0 Electrocardiograph (ECG) Lead Switching Adapter—Version 1.0	February 11, 1997	Do	Do
Electrocardiograph (ECG) Surface Electrode Tester—Version 1.0	February 11, 1997	Do	Do
Guidance for the Preparation and Content of Applications to the Food and Drug Administration for Ventricular Assist Devices and Total Artificial Hearts (draft)	December 4, 1987	Do	Do
Guidance for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters		Do	Do
Preliminary Guidance for Ambulatory Electrocardiograph for Data to be Submitted to FDA in Support of Premarket Notification Applications	September 1, 1994	Do	Do
Preliminary Guidance for Data to be Submitted in Support of Premarket Notifications for Analyzing ECGs/Interpretive ECGs	December 1, 1994	Do	Do

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Preliminary Guidance for Data to be Submitted to the FDA in Support of Premarket Notification Applications for External Cardioverters and Defibrillators	April 25, 1994	Do	Do
Reviewer Checklist for Monitors: EMC, Battery and Software	January 24, 1996	Do	Do
510(k) Reviewer Guidelines—Tracheostomy Tubes 868.5800		Do	Do
Automated Defibrillators: Operator's Shift Checklist and Manual Defibrillators: Operator's Shift Checklist	August 8, 1991	Do	Do
Balloon Valvuloplasty Guidance For The Submission Of an IDE Application and a PMA Application	January 1, 1989	Do	Do
Battery Guidance (Draft) (Albert Moyal)	July 12, 1993	Do	Do
Catheter Guidance	May 15, 1991	Do	Do
Coronary and Cerebrovascular Guidewire Guidance	January 1, 1995	Do	Do
DCRND—Draft Guidance for Format and Content for Premarket Notification 510(k) [replaces 908] [cardiovascular, respiratory, neurological]	July 19, 1995	Do	Do
Determining Equivalence of Intraaortic Balloon Catheters Under the 510(k) Regulations	January 24, 1989	Do	Do
Draft 510(K) Submission Requirements for Peak Flow Meters	January 13, 1994	Do	Do
Draft Emergency Resuscitator Guidance	April 14, 1993	Do	Do
Draft Guidance for Implantable Cardioverter-Defibrillators	June 19, 1996	Do	Do
Draft Guidance for the Preparation of Research and Marketing Applications for Vascular Graft Prostheses	August 1, 1993	Do	Do
Draft Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular	May 1, 1995	Do	Do
Draft Guidance: Human Heart Valve Allografts	June 21, 1991	Do	Do
Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	June 1, 1994	Do	Do
Draft Replacement Heart Valve Guidance	October 14, 1994	Do	Do
Draft Reviewer Guidance for Ventilators	July 1, 1995	Do	Do
Draft Reviewer Guidance on Face Masks and Shield for CPR	March 16, 1996	Do	Do
Draft Version—Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model	September 12, 1994	Do	Do
Draft Version 1—Biofeedback Devices—Draft Guidance for 510(k) Content	August 1, 1994	Do	Do
Draft Version Cardiac Ablation Preliminary Guidance (Data to be Submitted to the FDA in Support Investigation Device Exemption Application	March 1, 1995	Do	Do
Draft Version Cranial Perforator Guidance	July 13, 1994	Do	Do
Draft Version Electrode Recording Catheter Preliminary Guidance (Data to be Submitted to the FDA in Support of Premarket Notifications	March 1, 1995	Do	Do
Draft Version Guidance for Clinical Data to be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators	August 20, 1992	Do	Do
Draft Version Guide for Cortical Electrode 510(k) Content	August 10, 1992	Do	Do
Draft Version Neuro Endoscope Guidance	July 7, 1994	Do	Do
Excerpts Related to EMI from November 1993 Anesthesiology and Respiratory Devices Branch (to be used with EMI standard)	November 1, 1993	Do	Do
Galvanic Skin Response Measurement Devices—Draft Guidance for 510(k) Content	August 23, 1994	Do	Do
General Guidance Document: Non-Invasive Pulse Oxymeter	September 7, 1992	Do	Do
Guidance for Oxygen Conserving Device 510(k) Review 73 BZD 868.5905 Non-continuous Ventilator Class II	February 1, 1989	Do	Do
Guidance for Peak Flow Meters for Over-the-Counter Sale		Do	Do

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Guidance for Safety and Effectiveness Data Required in Premarket Notification (510(k)) Applications for Blood Oxygenators	March 1, 1983	Do	Do
Guidance for Studies for Pain Therapy Devices—General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices	May 12, 1988	Do	Do
Guidance for the Preparation of the Annual Report to the PMA Approved Heart Valve Prostheses	April 1, 1990	Do	Do
Guide for 510(k) Review of Processed Human Dura Mater	June 26, 1990	Do	Do
Guide for TENS 510(k) Content (Draft)	August 1, 1994	Do	Do
Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators		Do	Do
Heated Humidifier Review Guidance	August 30, 1991	Do	Do
Implantable Pacemaker Lead Testing Guidance For The Submission of a Section 510(k) Notification	September 1, 1989	Do	Do
Implantable Pacemaker Testing Guidance	January 12, 1990	Do	Do
Policy for Expiration Dating (DCRND RB92–G)	October 30, 1992	Do	Do
Protocol for Dermal Toxicity Testing for Devices in Contact with Skin (Draft)		Do	Do
Review Guidelines for Oxygen Generators and Oxygen Equipment		Do	Do
Review of ''YAG'' Lasers for Neurosurgery		Do	Do
Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators	November 9, 1990	Do	Do
Reviewer's Guidance for Oxygen Concentrator	August 30, 1991	Do	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	Do	Do
Assessing the Safety/Effectiv. of Home-use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions	October 1, 1988	ODE/Division of Clinical Laboratory Devices (DCLD)	Do
Review Proposal for Reagents and Analyzer Systems	March 14, 1995	Do	Do
Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagents for Automated Analyzers	June 10, 1996	Do	Do
DCLD Tier/Triage lists (include 931)	May 31, 1996	Do	Do
Draft Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies	August 31, 1995	Do	Do
Draft Document entitled Proposed Format: Package Insert for Immunohistochemistry Products (cover memo dated 5/12/92)	April 28, 1992	Do	Do
Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests	July 29, 1992	Do	Do
Draft Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for IVDs	September 30, 1991	Do	Do
Draft Guidance Document for 510(k) Submission of Immunoglobulins A,G,M,D and E Immunoglobulin System In Vitro Devices	September 1, 1992	Do	Do
Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs using Monoclonal Antibodies	September 26, 1991	Do	Do
Draft Guidance For Submission of Immunohistochemistry Applications to the FDA/ cover letter	April 17, 1995	Do	Do
Draft Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms	June 14, 1993	Do	Do
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	Do	Do
Guidance Criteria for Cyclosporine PMAs	January 24, 1992	Do	Do

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Labeling Requirements for Drugs of Abuse Screening Test Kits	January 27, 1987	Do	Do
Points to Consider & Questions and Answers on Immunohistochemistry Products (cover memo dated 10/18/1993)	October 19, 1993	Do	Do
Points to Consider for Cervical Cytology Devices	July 25, 1994	Do	Do
Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance	September 26, 1994	Do	Do
Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	February 20, 1996	Do	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	Do	Do
Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using Indirect Immunofluorescence Assay (IFA), Indirect	February 1, 1994	Do	Do
Review Criteria for Assessment of Alpha-Fetoprotein (AFP) in vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies	July 15, 1994	Do	Do
Review Criteria for Assessment of Antimicrobial Susceptibility Devices	May 31, 1991	Do	Do
Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers	July 15, 1991	Do	Do
Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)	September 27, 1995	Do	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens	January 1, 1992	Do	Do
Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. [Tuberculosis (TB)]	July 6, 1993	Do	Do
Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter pylori	September 17, 1992	Do	Do
Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology	February 14, 1996	Do	Do
Review Criteria for Blood Culture Systems	August 12, 1991	Do	Do
Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases	May 31, 1990	Do	Do
Review Criteria for Devices Intended for the Detection of Hepatitis B ''e'' Antigen and Antibody to HBe	December 30, 1991	Do	Do
Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents	August 1, 1992	Do	Do
Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and	February 15, 1996	Do	Do
Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	May 15, 1992	Do	Do
Review Criteria for the Assessment of Allergen-Specific Immunoglobulin E (IGE) In-Vitro Diagnostic Devices Using Immunological Test Methodologies	March 2, 1993	Do	Do
Review Criteria for the Assessment of Anti-nuclear Antibodies (ANA) In-Vitro Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA),	September 1, 1992	Do	Do
Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification [510(k)] to FDA	September 19, 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)
Review Criteria for Assessment of Rheumatoid Factor (RF) In Vitro Diagnostic Devices Using Engzyme-Linked Immunoassay (EIA), Enzyme Linked Immunosorbent Assay (ELISA), Particle	February 21, 1997	Do	Do
Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use	July 14, 1995	Do	Do
Clinical Utility and Premarket Approval #P91–1 (blue book memo)	May 3, 1991	ODE	Do
Criteria for Panel Review of PMA Supplements #P86–3 (blue book memo)	January 30, 1986	Do	Do
Panel Report and Recommendations on PMA Approvals #P86–5 (blue book memo)	April 18, 1986	Do	Do
Panel Review of ''Me-Too'' Devices #P86–6 (blue book memo)	July 1, 1986	Do	Do
Panel Review of Premarket Approval Applications #P91–2 (blue book memo)	May 3, 1991	Do	Do
PMA Compliance Program #P91–3 (blue book memo)	May 3, 1991	Do	Do
PMA Filing Decisions #P90–2 (blue book memo)	May 18, 1990	Do	Do
PMA Refuse to File Procedures #P94–1 (blue book memo)	May 20, 1994	Do	Do
PMA Supplements: ODEs letter to manufacturers; identifies situations which may require the submission of a PMA supplement (When PMA Supplements are Required) #P90–1 (blue book memo)	April 24, 1990	Do	Do
PMAs—Early Review and Preparation of Summaries of Safety and Effectiveness #P86–1 (blue book memo)	January 27, 1986	Do	Do
Premarket Approval Application (PMA) Closure #P94–1 (blue book memo)	July 8, 1994	Do	Do
Review and Approval of PMAs of Licensees #P86–4 (blue book memo)	October 22, 1990	Do	Do
Review of Final Draft Medical Device Labeling #P91–4 (blue book memo)	August 29, 1991	Do	Do
Assignment of Review Documents #I90–2 (blue book memo)	August 24, 1990	Do	Do
Document Review Processing #I91–1 (blue book memo)	February 12, 1992	Do	Do
Integrity of Data and Information Submitted to ODE #I91–2 (blue book memo)	May 29, 1991	Do	Do
Meetings with the Regulated Industry #I89–3 (blue book memo)	November 20, 1989	Do	Do
Nondisclosure of Financially Sensitive Information #I92–1 (blue book memo)	March 5, 1992	Do	Do
Policy Development and Review Procedures #I90–1 (blue book memo)	February 15, 1990	Do	Do
Telephone Communications Between ODE Staff and Manufacturers #I93–1 (blue book memo)	January 29, 1993	Do	Do
Delegation of IDE Actions #D88–1 (blue book memo)	April 26, 1988	Do	Do
Goals and Initiatives for the IDE Program #D95–1 (blue book memo)	July 12, 1995	Do	Do
IDE Refuse to Accept Procedures #D94–1 (blue book memo)	May 20, 1994	Do	Do
Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, Att. A Interagency Agreement, Att. B Criteria	September 15, 1995	Do	Do
Overdue IDE Annual Progress Report Procedures #D93–1 (blue book memo)	July 23, 1993	Do	Do
Review of IDEs for Feasibility Studies #D89–1 (blue book memo)	May 17, 1989	Do	Do
Consolidated Review of Submissions for Diagnostic Ultrasound Equipment, Accessories and Related Measurement Devices #G90–2 (blue book memo)	October 19, 1990	Do	Do
Consolidated Review of Submissions for Lasers and Accessories #G90–1 (blue book memo)	October 19, 1990	Do	Do
Device Labeling Guidance #G91–1 (blue book memo)	March 8, 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)
Documentation and Resolution of Differences of Opinion on Product Evaluations #G93–1 (blue book memo)	December 23, 1993	Do	Do
ODE Regulatory Information for the Office of Compliance - Information Sharing Procedures #G87–2 (blue book memo)	May 15, 1987	Do	Do
PMA/510(k) Expedited Review #G94–2 (blue book memo)	May 20, 1994	Do	Do
PMA/510(k) Triage Review Procedures #G94–1 (blue book memo)	May 20, 1994	Do	Do
Review of Laser Submissions #G88–1 (blue book memo)	April 15, 1988	Do	Do
Toxicology Risk Assessment Committee #G89–1 (blue book memo)	August 9, 1989	Do	Do
Use of International Standard ISO-10993, ''Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'' (Replaces #G87–1 #8294) (blue book memo)	May 1, 1995	Do	Do
510(k) Additional Information Procedures #K93–1 (blue book memo)	July 23, 1993	Do	Do
510(k) Refuse to Accept Procedures #K94–1 (blue book memo)	May 20, 1994	Do	Do
510(k) Sign-Off Procedures #K94–2 (blue book memo)	June 3, 1994	Do	Do
510(k) Sterility Review Guidance - and Revision of 11/18/1994 #K90–1 (blue book memo)	February 12, 1990	Do	Do
Cover Letter: 510(k) Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Drugs (blue book #K95–1)	November 21, 1995	Do	Do
Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program #K86–3 (blue book memo)	June 30, 1986	Do	Do
Premarket Notification - Consistency of Reviews #K89–1 (blue book memo)	February 28, 1989	Do	Do
Review of 510(k)s for Computer Controlled Medical Devices #K91–1 (blue book memo)	August 29, 1991	Do	Do
Continued Access to Investigational Devices During PMA Preparation and Review (blue book memo)	July 15, 1996	Do	Do
Use of IEC 60601 Standards Medical Electrical Equipment; Draft Document [blue book memo #G97–X]	October 10, 1997	Do	Do
(blue book memo #K97–1) Deciding When to Submit a 510(k) for a Change to an Existing Device [see CDRH F–O–D #935]	January 10, 1997	Do	Do
Memorandum of Understanding Regarding Patient Labeling Review (blue book memo #G96–3))	August 9, 1996	Do	Do
#D95–2, Attachment A (Interagency Agreement between FDA & HCFA)	September 15, 1995	Do	Do
#D95–2, Attachment B (Criteria for Categorization of Investigational Devices (HCFA)	September 15, 1995	Do	Do
510(k) Quality Review Program (blue book memo)	March 29, 1996	Do	Do
Distribution and Public Availability of PMA Summary of Safety and Effectiveness Data Packages	October 10, 1997	Do	Do
Document Review by the Office of the Chief Counsel (blue book memo G96–1))	June 6, 1996	Do	Do
Draft Guidance for Testing MR Interaction with Aneurysm Clips	May 22, 1996	Do	Do
HCFA Reimbursement Categorization Determinations for FDA-approved IDEs	September 15, 1995	Do	Do
ODE Executive Secretary Guidance Manual	August 7, 1987	Do	Do
Tripartie Biocompatibility Guidance	April 24, 1984	Do	Do
Guidance for Submitting Reclassification Petition		Do	Do
Product Development Protocol	October 1, 1997	Do	Do
Exemption from Reporting and Record keeping Requirements for Certain Sunlamp Product Manufacturers	September 16, 1981	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)
Reporting of New Model Numbers to Existing Model Families	June 14, 1983	Do	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)
Consumer-Directed Broadcast Advertisements	August 12, 1997	Advertising (Draft)	Office of Training and Communications, Drug Information Branch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573 or Internet at http://www.fda.gov/cder/guidance/index.htm
Promoting Med Products (Multicenter)	January 5, 1998	Do	Do
Aerosol Steroid Product Safety Information in Prescript. Drug Advertising and Promotional Labeling DDMAC 2	January 12, 1998	Do	Do
Dissemination of Reprints of Certain Published, Original Data	October 8, 1996	Advertising	Do
Funded Dissemination of Reference Texts	October 8, 1996	Do	Do
Antifungal (topical)	February 24, 1990	Biopharmaceutic (Draft)	Drug Information Branch
Antifungal (vaginal)	February 24, 1990	Do	Do
Food-Effect Bioavailability and Bioequivalence	December 30, 1997	Do	Do
In Vivo Bioequivalence Studies Based on Population and Individual Bioequivalence Approaches	December 30, 1997	Do	Do
Pharmacokinetics and Pharmacodynamics in Patients with Impaired Renal Function: Study Design, Data Analysis, and Impact on Dosing and Labeling	June 16, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Population Pharmacokinetics	September 18, 1997	Do	Do
Waiver Policy	March 29, 1993	Do	Drug Information Branch
Acetohexamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 1, 1988	Biopharmaceutic	Do
Albuterol Inhalation Aerosols (Metered Dose Inhalers) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 27, 1994	Do	Do
Albuterol Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 29, 1987	Do	Do
Allopurinol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 15, 1985	Do	Do
Alprazolam Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	November 27, 1992	Do	Do
Amiloride Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 29, 1985	Do	Do
Aminophylline (suppositories) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 5, 1983	Do	Do
Amitriptyline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 5, 1983	Do	Do
Amoxapine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 5, 1988	Do	Do
Amoxicillin (capsules, tablets and suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 10, 1988	Do	Do
Approaches to Statistical Data Analysis of Bioavailability/Bioequivalence Studies	November 1, 1985	Do	Do
Atenolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 6, 1988	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Baclofen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 5, 1986	Do	Drug Information Branch
Bioavailability Policies and Guidelines		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)
Bumetanide Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Drug Information Branch or Interent at http://www.fda.gov/cder/guidance/index.htm
Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	August 13, 1993	Do	Do
Captopril Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 13, 1993	Do	Do
Carbamazepine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 20, 1988	Do	Drug Information Branch
Carbidopa and Levodopa Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 19, 1992	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Cefaclor Capsules and Suspension In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Cefadroxil (capsules, tablets and suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 7, 1986	Do	Drug Information Branch
Cephalexin (tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 19, 1987	Do	Do
Cephradine (Capsule and Suspension)	September 10, 1986	Do	Do
Chlordiazepoxide (Tablets)	July 5, 1983	Do	Do
Chlordiazepoxide Hydrochloride (Capsules)	July 5, 1983	Do	Do
Chlorpropamide (Tablets)	July 5, 1983	Do	Do
Chlorthalidone (Tablets)	July 5, 1983	Do	Do
Cholestyramine Powder In Vitro Bioequivalence	July 15, 1993	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Cimetidine Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1992	Do	Do
Clindamycin Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 31, 1988	Do	Drug Information Branch
Clofibrate (Capsules)	April 7, 1986	Do	Do
Clonidine Hydrochloride (Tablets)	December 5, 1984	Do	Do
Clorazepate Dipotassium (Capsules and Tablets)	February 17, 1987	Do	Do
Clozapine (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 15, 1996	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Controlled Release Dosage Forms: Issues and Controversies (Conference Report)	September 10, 1985	Do	Drug Information Branch
Corticosteroids, Dermatologic (topical) In Vivo	June 2, 1995	Do	Do
Cyclobenzaprine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 25, 1988	Do	Do
Desipramine Hydrochloride (Tablets)	September 22, 1987	Do	Do
Diazepam (Tablets)	July 8, 1985	Do	Do
Diclofenac Sodium (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 6, 1994	Do	Do
Dicyclomine Hydrochloride (Tablets and Capsules)	August 1, 1984	Do	Do
Diflunisal Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Diltiazem Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	Do	Do
Dipyridamole (Tablets)	September 25, 1987	Do	Drug Information Branch
Disopyramide Phosphate (Capsules)	July 9, 1985	Do	Do
Dissolution Testing (General)	April 1, 1978	Do	Do
Dissolution Testing of Immediate Release Solid Oral Dosage Forms	August 25, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Division Guidelines for the Evaluation of Controlled Release Drug Products	April 18, 1984	Do	Drug Information Branch
Doxepin Hydrochloride (Capsules)	October 9, 1986	Do	Do
Doxycycline Hyclate (Capsules and Tablets)	April 11, 1988	Do	Do
Erythromycin Capsules (Enteric Coated Pellets)	September 21, 1988	Do	Do
Estropipate Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	August 26, 1992	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (BP2)	September 26, 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)
Fenoprofen (capsules and tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	February 3, 1988	Do	Drug Information Branch
Flurazepam Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 15, 1985	Do	Do
Flurbiprofen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 8, 1995	Do	Do
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application*[1]	February 1, 1987	Do	Do
Gemfibrozil Capsules or Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing	June 15, 1992	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Glipizide (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Glyburide 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
Haloperidol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 30, 1987	Do	Drug Information Branch
Hydrochlorothiazide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 28, 1987	Do	Do
Hydroxychloroquine Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 28, 1995	Do	Do
Hydroxyzine Hydrochloride (tablets) (dissolution only)	March 4, 1986	Do	Do
Hydroxyzine Pamoate (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 28, 1987	Do	Do
Indapamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Indomethacin (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 27, 1988	Do	Do
Isopropamide Iodide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 12, 1982	Do	Do
Isosorbide Dinitrate (chewable tablets, oral tablets, and sublingual tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 22, 1987	Do	Do
Isosorbide Dinitrate Controlled Release Products	November 6, 1985	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
Lorazepam (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 16, 1987	Do	Do
Loxapine Succinate (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 10, 1987	Do	Do
Maprotiline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 27, 1987	Do	Do
Meclofenamate Sodium (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 12, 1986	Do	Do
Medroxyprogesterone Acetate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 17, 1987	Do	Do
Megestrol Acetate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 17, 1987	Do	Do
Metaproterenol Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 18, 1988	Do	Do
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	June 27, 1989	Do	Do
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro	June 27, 1989	Do	Do
Methylprednisolone (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1986	Do	Do
Metoclopramide Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 27, 1984	Do	Do
Metoprolol Tartrate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 12, 1992	Do	Do
Minoxidil (Tablets)	June 12, 1986	Do	Do
Nadolol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 16, 1992	Do	Do
Nafcillin Sodium (Capsules and Tablets)	September 10, 1987	Do	Do
Nalidixic Acid (Tablets)	August 19, 1997	Do	Do

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Naproxen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 8, 1995	Do	Do
Nitrofurantion Macrocrystalline (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 10, 1986	Do	Do
Nitroglycerin (Ointment)	December 17, 1986	Do	Do
Norethindrone and Ethinyl Estradiol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 18, 1988	Do	Do
Norethindrone and Mestranol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 13, 1988	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	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Orphenadrine Citrate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 22, 1983	Do	Drug Information Branch
Pentoxifylline (extended-release tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 22, 1995	Do	Do
Perphenazine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 27, 1987	Do	Do
Perphenazine/Amitriptyline (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 27, 1987	Do	Do
Pharmacokinetic Considerations in Drug Studies	N/A	Do	Do
Phenylbutazone Oxyphenbutazone (capsules and tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 28, 1987	Do	Do
Phenytoin/Phenytion Sodium (capsules, tablets, suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 4, 1994	Do	Do
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	May 15, 1987	Do	Do
Prazepam (capsules and tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 26, 1988	Do	Do
Prednisone (tablets) (dissolution only)	July 10, 1985	Do	Do
Probenecid (Tablets)	July 26, 1983	Do	Do
Procainamide Hydrochloride	September 28, 1987	Do	Do
Propoxyphene Napsylate with Acetaminphen (Tablets)	March 26, 1980	Do	Do
Propranolol Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 1, 1984	Do	Do
Propylthiouracil (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 13, 1986	Do	Do
Quinidine Gluconate (tablets, controlled release) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 22, 1987	Do	Do
Ranitidine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 23, 1993	Do	Do
Rifampin (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 8, 1988	Do	Do
Ritodrine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 27, 1987	Do	Do
Selegiline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 22, 1995	Do	Do
Silver Sulfadiazine (cream)	May 7, 1987	Do	Do
Spironolactone (Tablets)	January 1, 1986	Do	Do
Statistical Procedure for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design	July 1, 1992	Do	Do
Submission of Data for Bioequivalence Studies in Computer Format	N/A	Do	Do
Sulfasalazine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 8, 1987	Do	Do
Sulfinpyrazone (Capsules and Tablets)	September 25, 1987	Do	Do
Sulfones (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 7, 1986	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)
Sulindac (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 18, 1988	Do	Do
Temazepam (Capsules)	August 8, 1985	Do	Do
Theophylline (conventional dosage form) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 1, 1984	Do	Do
Timolol Maleate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 9, 1988	Do	Do
Tolazamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 30, 1986	Do	Do
Tolbutamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 1, 1983	Do	Do
Tolmetin Sodium (tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 6, 1994	Do	Do
Trazodone Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	April 30, 1988	Do	Do
Triazolam (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 24, 1992	Do	Do
Trimipramine Maleate (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 18, 1987	Do	Do
Verapamil Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 18, 1985	Do	Do
Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics	July 15, 1997	Chemistry (Draft)	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Submitting Supporting Chemistry Documentation in Radiopharmaceutical Drug Applications*	November 1, 1991	Do	Drug Information Branch
Tracking of NDA and ANDA Reformulations for Solid, Oral, Immediate Release Drug Products (Docket No. 89N–0066)	N/A	Do	Do
Drug Master Files	September 1, 1989	Chemistry	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
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 (CMC 1)	September 1, 1994	Do	Do
Format and Content of the Chemistry, Manufacturing and Controls Section of an Application*	February 1, 1987	Do	Drug Information Branch
Format and Content of the Microbiology Section of an Application* (Docket No. 85D–0245)	February 1, 1987	Do	Do
Reviewer Guidance: Validation of Chromatographic Methods (CMC 3)	November 1, 1994	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Submission of an Environmental Assessment in Human Drug Applications and Supplements (CMC 6)	November 13, 1995	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Submission of Chemistry, Manufacturing and Controls Information for Synthetic Peptide Substances (CMC 4)	November 1, 1994	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Submission of Documentation for Sterilization Process Validation Applications for Human and Veterinary Drug Products (CMC 2)	November 1, 1994	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
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	Drug Information Branch
Submitting Documentation for the Stability of Human Drugs and Biologics*	February 1, 1987	Do	Do
Submitting Samples and Analytical Data for Methods Validation*	February 1, 1987	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances*	February 1, 1987	Do	Do
SUPAC IR–Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (CMC 5)	November 30, 1995	Do	Drug Information Branch or or Internet at http://www.fda.gov/cder/guidance/index.htm

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–IR: Immediate Release Solid Oral Dosage Forms; Manufacturing Equipment Addendum (CMC 9)	October 21, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
SUPAC–IR Questions and Answers	February 18, 1997	Do	Do
SUPAC–MR: Modified Release Solid Oral Dosage Forms: Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (CMC 8)	October 6, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
SUPAC–SS—Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation (CMC 7)	June 13, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Abuse Liability Assessment	July 1, 1990	Clinical (Draft)	Drug Information Branch
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	January 10, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis	April 1, 1994	Do	Drug Information Branch
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 Antihypertensive Drugs	May 1, 1988	Do	Do
Clinical Evaluation of Drugs for the Treatment of Congestive Heart Failure	December 1, 1987	Do	Do
Clinical Evaluation of Drugs for the Treatment of Peripheral Vascular Disease	N/A	Do	Do
Clinical Evaluation of Drugs for Ulcerative Colitis (3rd draft)	N/A	Do	Do
Clinical Evaluation of Motility-Modifying Drugs	N/A	Do	Do
Clinical Evaluation of Weight-Control Drugs	July 12, 1995	Do	Do
Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review (96N–0443)	November 22, 1996	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	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	March 13, 1997	Do	Do
Points to Consider for System Inflammatory Response Syndrome (SIRS) 1st Draft	N/A	Do	Drug Information Branch
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
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products	March 13, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Clinical Evaluation of Analgesic Drugs (FDA 93–3093)	December 1, 1992	Clinical	Drug Information Branch
Clinical Evaluation of Antacid Drugs (FDA 78–3065)	April 1, 1978	Do	Drug Information Branch
Clinical Evaluation of Anti-Infective Drugs (Systemic) (FDA 77–3046)	November 1, 1992	Do	Drug Information Branch
Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children)	May 26, 1993	Do	Drug Information Branch
Clinical Evaluation of Antianxiety Drugs (FDA 77–3043)	N/A	Do	Drug Information Branch
Clinical Evaluation of Antidepressant Drugs (FDA 77–3042)	September 1, 1977	Do	Drug Information Branch
Clinical Evaluation of Antidiarrheal Drugs (FDA 78–3049)	September 1, 1977	Do	Drug Information Branch
Clinical Evaluation of Antiepileptic Drugs (adults and children) (FDA 81–3110)	January 1, 1981	Do	Drug Information Branch
Clinical Evaluation of Bronchodilator Drugs (FDA 79–3073)	N/A	Do	Drug Information Branch
Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy of Postmenopausal Women	March 20, 1995	Do	Drug Information Branch

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)
Clinical Evaluation of Drugs to Prevent, Control and/or Treat Periodontal Disease (FDA 79–3074)	November 1, 1978	Do	Drug Information Branch
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs (FDA 78–3050)	September 1, 1977	Do	Drug Information Branch
Clinical Evaluation of General Anesthetics (FDA 78–3052)	May 1, 1982	Do	Drug Information Branch
Clinical Evaluation of Hypnotic Drugs (FDA 78–3051)	September 1, 1977	Do	Drug Information Branch
Clinical Evaluation of Laxative Drugs (FDA 78–3067)	April 1, 1978	Do	Drug Information Branch
Clinical Evaluation of Lipid-Altering Agents in Adults and Children (FDA 80–3103)	N/A	Do	Drug Information Branch
Clinical Evaluation of Local Anesthetics (FDA 82–3053)	May 1, 1982	Do	Drug Information Branch
Clinical Evaluation of Psychoactive Drugs in Infants and Children (FDA 79–3055)	July 1, 1979	Do	Drug Information Branch
Clinical Evaluation of Radiopharmaceutical Drugs (FDA 81–3120)	October 1, 1981	Do	Drug Information Branch
Content and Format for Pediatric Use Supplements (CLIN 1)	May 24, 1996	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products (CLIN 2)	November 20, 1995	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Development of Vaginal Contraceptive Drugs (NDA) (95D–0004)	April 19, 1995	Do	Drug Information Branch
Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (CLIN 3)	April 7, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer	January 29, 1991	Do	Drug Information Branch
FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer	June 20, 1989	Do	Do
Format and Content of the Clinical and Statistical Sections of New Drug Applications*	July 1, 1988	Do	Drug Information Branch or Internet a http://www.fda.gov/cder/guidance/index.htm
Format and Content of the Summary for New Drug and Antibiotic Applications*	February 1, 1987	Do	Drug Information Branch
Formatting, Assembling and Submitting New Drug and Antibiotic Applications*	February 1, 1987	Do	Do
General Considerations for the Clinical Evaluation of Drugs (FDA 77–3040)	December 1, 1978	Do	Drug Information Branch
General Considerations for the Clinical Evaluation of Drugs in Infants and Children (FDA 77–3041)	N/A	Do	Drug Information Branch
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer	April 13, 1988	Do	Drug Information Branch
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Colon and Rectal Cancer	N/A	Do	Do
OTC Treatment of Hypercholesterolemia (CLIN 5)	October 27, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Points to Consider in the Clinical Development and Labeling of Anti-Infective Drug Products	October 26, 1992	Do	Drug Information Branch
Points to Consider in the Preclinical Development of Antiviral Drugs	November 1, 1990	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: Clinical Development Programs for MDI and DPI Drug Products	September 19, 1994	Do	Do
Postmarketing Adverse Experience Reporting for Human Drugs and Licensed Biological Products; Clarification of What to Report (CLIN 4)	August 27, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Postmarketing Reporting of Adverse Drug Experiences (85D–0249)	March 1, 1992	Do	Drug Information Branch
Preparation of Investigational New Drug Products (Human and Animal)	March 1, 1991	Do	Drug Information Branch

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)
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
Computerized Systems Used in Clinical Trials	June 18, 1997	Compliance (Draft)	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Manufacture, Processing or Holding of Active Pharmaceutical Ingredients	September 20, 1996	Do	Do
Repackaging of Solid Oral Dosage Form Drug Products (92D–0345)	February 1, 1992	Do	Drug Information Branch
Supplements to New Applications, Abbreviated New Drug Applications or Abbreviated Antibiotic Applications for Nonsterile Drug Products (93D–0403)	December 12, 1994	Do	Drug Information Branch
A Review of FDA's Implementation of the Drug Export Amendments of 1986	N/A	Compliance	Drug Information Branch
Compressed Medical Gases	December 1, 1989	Do	Do
Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products (CP 1)	April 22, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (CP 2)	June 27, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
General Principles of Process Validation	May 1, 1987	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Good Laboratory Practice Regulations Questions and Answers	N/A	Do	Drug Information Branch
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
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	Generic Drug (Draft)	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
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	Drug Information Branch
Letter describing efforts by the CDER and the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new and abbreviated drug approval process in order to reduce duplication or redundancy	October 14, 1994	Do	Do
Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy	April 8, 1994	Do	Do
Letter on the provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters	July 1, 1992	Do	Do
Letter on the provision of new procedures and policies affecting the generic drug review process	March 15, 1989	Do	Do
Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions	November 8, 1991	Do	Do
Letter on the response to 12/20/84 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act	March 26, 1985	Do	Do

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 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 (OGD 1)	April 7, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Positron Emission Tomography Questions and Answers 1	October 24, 1996	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Positron Emission Tomography Questions and Answers 2	April 18, 1997	Do	Do
A Revision in Sample Collection Under the Compliance Program Pertaining to Pre-Approval Inspections	July 15, 1996	Industry letters	Drug Information Branch
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 mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required	April 10, 1987	Do	Do
Fourth of a series of letters providing informal notice to 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
In Vivo Bioequivalence Studies of Clozapine	April 22, 1996	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	July 29, 1988	Do	Do
Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act	April 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
Archiving Submissions in Electronic Format—NDAs (IT 1)	September 23, 1997	Information Technology	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
CANDA (Computer Assisted New Drug Application) Guidance Manual (92D–0296)	October 1, 1994	Do	Drug Information Branch
Acetaminophen and Codeine Phosphate Oral Solution/Suspension	December 1, 1993	Labeling	Drug Information Branch
Acetaminophen and Codeine Phosphate Tablets/Capsules	December 1, 1993	Do	Do
Acetaminophen, Aspirin and Codeine Phosphate Tablets/Capsules	December 1, 1993	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Alprazolam Tablets	May 1, 1993	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)
Amiloride Hydrochloride and Hydrochlorothiazide Tablets USP	October 1, 1992	Do	Do
Amlodipine Besylate Tablets (OGD–L–1)	September 1, 1997	Do	Do
Antihistamine Guidance	April 1, 1983	Do	Drug Information Branch
Astemizole Tablets (OGD–L–16)	September 1, 1997	Do	Do
Atenolol Tablets	June 1, 1995	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Barbiturate, Single Entity-Class Labeling	March 1, 1981	Do	Drug Information Branch
Butalbital, Acetaminophen and Caffeine Capsules/Tablets	April 1, 1993	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Butalbital, Acetaminophen, Caffeine and Hydocodone Bitartrate Tablets (OGD–L–6–R1)	September 21, 1997	Do	Drug Information Branch
Butorphanol Tartrate Injection USP	October 1, 1992	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Captopril and Hydrochlorothiazide Tablets	April 1, 1995	Do	Do
Captopril Tablets	February 1, 1995	Do	Drug Information Branch
Carbidopa and Levodopa Tablets	February 1, 1992	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Chlordiazepoxide Hydrochloride Capsules	January 1, 1988	Do	Drug Information Branch
Cimetidine Hydrochloride Injection	September 1, 1995	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Cimetidine Tablets	September 1, 1995	Do	Do
Cisapride Oral Suspension (OGD–L–3)	September 1, 1997	Do	Do
Cisapride Tablets (OGD–L–4)	September 1, 1997	Do	Do
Clindamycin Phosphate Injection USP	May 1, 1992	Do	Do
Clorazepate Dipotassium Capsules/Tablets	March 1, 1993	Do	Drug Information Branch
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	February 1, 1995	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Diltiazem Hydrochloride Extended-Release Capsules (twice a day dosage)	September 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Oral Solution	April 1, 1995	Do	Do
Diphenoxylate Hydrochloride and Atropine Sulfate Tablets	April 1, 1995	Do	Do
Dipivefrin Hydrochloride Ophthalmic Solution, 0.1%	May 1, 1992	Do	Drug Information Branch
Ergoloid Mesylates Tablets	January 1, 1988	Do	Do
Estrogen Class Labeling Guidance	August 1, 1992	Do	Do
Fludeoxyglucose F18 Injection	January 1, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Flurbiprofen Tablets USP	January 1, 1994	Do	Do
Fluroxamine Maleate Tablets (OGD–L–15)	September 1, 1997	Do	Do
Gentamicin Sulfate Ophthalmic Ointment and Solution	April 1, 1992	Do	Do
Heparin Sodium Injection USP	March 1, 1991	Do	Do
Hydrocodone Bitartrate and Acetaminophen Tablets	April 1, 1994	Do	Do
Hydroxyzine Hydrochloride Injection	December 1, 1989	Do	Drug Information Branch
Hydroxyzine Hydrochloride Tablets/Syrup	May 1, 1986	Do	Do
Hypoglycemic Oral Agents—Federal Register	April 1, 1984	Do	Do
Indomethacin Capsules USP	September 1, 1995	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Informal Labeling Guidance Texts for Estrogen Drug Products—Patient Labeling	December 1, 1992	Do	Drug Information Branch
Informal Labeling Guidance Texts for Estrogen Drug Products—Professional Labeling	December 1, 1992	Do	Do
Isoetharine Inhalation Solution	March 1, 1989	Do	Do
Leucovorin Calcium for Injection	N/A	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Leucovorin Calcium Tablets, USP	July 1, 1996	Do	Drug Information Branch

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)
Local Anesthetics—Class Labeling	September 1, 1982	Do	Do
Meclofenamate Sodium Capsules	July 1, 1992	Do	Do
Medroxy-progesterone Acetate Tablets, USP OGD–L–36	November 1, 1997	Do	Do
Metaproterenol Sulfate Inhalation Solution, 5%	May 1, 1992	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Metaproterenol Sulfate Syrup	May 1, 1992	Do	Do
Metaproterenol Sulfate Tablets	May 1, 1992	Do	Do
Metoclopramide Tablets USP/Oral Solution	February 1, 1995	Do	Do
Naphazoline Hydrochloride Ophthalmic Solution	March 1, 1989	Do	Drug Information Branch
Naproxen Sodium Tablets, USP OGD–L–10–R1	September 1, 1997	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Naproxen Tablets, USP OGD–L–9–R1	September 1, 1997	Do	Do
Niacin Tablets	July 1, 1992	Do	Drug Information Branch
Paclitaxel Injection OGD–L–8	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	October 1, 1995	Do	Do
Ranitidine Tablets	November 1, 1993	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Risperidone Oral Solution OGD–L–18	September 1, 1997	Do	Do
Risperidone Tablets OGD–L–17	September 1, 1997	Do	Do
Sulfacetamide Sodium and Prednisolone Acetate Ophthalmic Suspension and Solution	January 1, 1995	Do	Do
Sulfacetamide Sodium Ophthalmic Solution/Ointment	August 1, 1992	Do	Do
Sulfamethoxazole and Phenazopyridine Hydrochloride Tablets	February 1, 1992	Do	Drug Information Branch
Sulfamethoxazole and Trimethoprim Tablets and Oral Suspension	August 1, 1993	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Theophylline Immediate-Release Dosage Forms	February 1, 1995	Do	Drug Information Branch
Theophylline Intravenous Dosage Forms	February 9, 1996	Do	Do
Thiamine Hydrochloride Injection	February 1, 1988	Do	Do
Tobramycin Sulfate Injection	May 1, 1993	Do	Drug Information Branch Internet at http://www.fda.gov/cder/guidance/index.htm
Topical Corticosteroids Class Labeling	N/A	Do	Drug Information Branch
Venlafaxine Hydrochloride Tablets OGD–L–30	October 1, 1997	Do	Do
Verapamil Hydrochloride Tablets	October 1, 1991	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm
Vitamin A Capsules	February 1, 1992	Do	Drug Information Branch
Zolpidem Tartrate Tablets OGD–L–13	September 1, 1997	Do	Do
Points to Consider for OTC Actual Use Studies	July 22, 1994	OTC (Draft)	Do
Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16)	N/A	OTC	Do
General Guidelines for OTC Combination Products (78D–0322)	N/A	Do	Do
OTC Nicotine Sustitutes	March 1, 1994	Do	Drug Information Branch
Upgrading Category III Antiperspirants to Category I (43 FR 46728–46731)	N/A	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	N/A	Do	Drug Information Branch or Internet at http://www.fda.gov/cder/guidance/index.htm

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)
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	Drug Information Branch (REMOVE)

[1] Star (*) indicates that the guidance is one of 13, formerly known as the ''NDA Guidelines,'' or ''Rainbow Pack,'' that are available as a set from the Drug Information Branch.

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, PB96–920500	1996	FDA Regulated Industries	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161
Compliance Programs Guidance Manual, PB95–915499	1995	Do	NTIS
FDA Recall Policy	1995	Do	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204
Inspection Operations Manual, PB–95–913399	October 1994	Do	NTIS
Regulatory Procedures Manual, PB95–265534	August 1995	Do	NTIS
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
Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed, PB96–920500	1995	Food and Animal Feed Industries	Industry Activities Staff
Pesticides Analytical Manual, PB94–911899	1994	Food Industry	NTIS
FDA Advisory for Deoxynivanol (DON) in Finished Wheat Products Intended for Human Consumption and in Grain and Grain By-Products for Animal Feed	September 16, 1993	Food and Animal Feed Industries	Office of Plant and Dairy Foods and Beverages, Food and Drug Administration (HFS–306), 200 C St. SW., Washington, DC 20204, 202–205–4681
FDA's Cosmetic Labeling Manual	October 1991	Cosmetic Industry	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: Notice	May 29, 1992 (57 FR 22984)	Developers of New Plant Food Varieties	Office of Premarket Approval, Food and Drug Administration (HFS–200), 200 C St. SW., Washington, DC 20204, 202–418–3100
A Food Labeling Guide	September 1994	Food Industry	Superintendent of Documents,
Appendix I—Model Small Business Food Labeling Exemption Notice	August 7, 1993	Do	Industry Activities Staff
Food Labeling: Questions and Answers	August 1993	Do	Industry Activities Staff
Food Labeling: Questions and Answers: Volume II	August 1995	Do	Superintendent of Documents
Fair Packaging and Labeling Act Requirements and Interpretations, PB–83–222117	June 1978	Do	NTIS
Bacteriological Analytical Manual, 7th Edition	1992	FDA Regulated Industries	AOAC International, 481 N. Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417, 301–924–7077
FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods	1995	Food Industry	Industry Activities Staff
Fabrication of Single Service Containers and Closures for Milk and Milk Products	1995	States	Milk Safety Branch (HFS–626), Center for Food Safety and Applied Nutrition, 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

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)
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), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204, 202–205–9175
Pasteurized Milk Ordinance	1995	States	Milk Safety Branch
FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases	1993	Food Industry	Office of Food Labeling, Food and Drug Administration (HFS–150), 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
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
Manual of Operations National Shellfish Sanitation	1992	States	Office of Seafood (HFS–407), Shellfish Sanitation Branch, 200 C St. SW., Washington, DC 20204, 202–418–3150
Fish and Fisheries Products Hazards and Controls Guide	1996	Seafood Industry	Office of Seafood, Food and Drug Administration (HFS–400), 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
Guidelines for the Preparation of Petition Submissions	1996	Food Ingredient or Packaging Industry	Do
Guidelines for Approval of Color Additives in Contact Lenses Intended as Colors	1996	Color or Contact Lens Industry	Do
FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs or Cosmetics Use	February 1993	Color Additives Industry	Do
Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations	December 1992	Food Packaging Industry	Do
Recommendations for Submission of Chemical and Technological Data for Direct Food Additive and GRAS Food Ingredient Petitions	May 1993	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	Office of Premarket Approval
Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as Redbook I), PR–83–170696	1982	Petitioners for Food or Color Additives	NTIS
Environmental Assessment Technical Handbook, PB87175345–AS, A–01	March 1987	Do	Do
Preparing Environmental Assessments: General Suggestions	August 1990	Do	Office of Premarket Approval
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	Petitioners for Color Additives	Do
Toxological Testing of Food Additives	1983	Petitioners for Food or Color Additives	Do
List of Products for Each Product Category	October 8, 1992	Food Industry	Office of Food Labeling

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)
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 (62 FR 8248)	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 (59 FR 6279)	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
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	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) or via Internet: FDA Home Page at http://vm.cfsan.fda.gov/list.html
Guidance Document for Cadmium (Trace Elements in Seafood)	January 1993	Do	Office of Seafood (HFS–400) or via Internet: FDA Home Page at http://vm.cfsan.fda.gov
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	Office of Premarket Approval or via Internet: FDA Home Page at http://vm.cfsan.fda.gov
Bovine Spongiform Encephalopathy (BSE) In Products for Human Use	1997	Do	Office of Plant and Dairy Foods and Beverages or via Internet: FDA Home Page at http://www.fda.gov/opacom/morechoices /industry/guidance/gelguide.htm
Shellfish Sanitation Model Ordinance	1995	States	Shellfish Program Implementation Branch, Division of Cooperative Programs, Office of Field Programs (HFS–628), 200 C St. SW., Washington, DC 20204, 202–205–8137

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)
Citizen Petitions: Policy and Procedures (Guide No. 1240.2030)	June 7, 1994	Do	Do
CVM's Implementation of the Agency's Fraud, Untrue Statements of Material Facts, Bribery & Illegal Gratuities Policy (Guide No. 1240.2040)	June 15, 1994	Do	Do
Intra-Agency Relationship (Guide No. 1240.2100)	August 11, 1993	Do	Do
Procedures for Resolving Disagreements within CVM (Guide No. 1240.2110)	April 10, 1991	Do	Do
Product Manager (Guide No. 1240.2120)	August 11, 1993	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)
CVM P & P Manual Utilization and Maintenance (Guide No. 1240.2140)	September 3, 1997	Do	Do
CVM Small Business (Guide No. 1240.2150)	April 10, 1991	Do	Do
CVM Public Affairs Program (Guide No. 1240.2152)	April 7, 1995	Do	Do
Evaluation of Proposed Legislation (Guide No. 1240.2154)	April 7, 1995	Do	Do
Voluntary Compliance (Guide No. 1240.2202)	August 11, 1992	Do	Do
Approval of New Animal Drug Applications and their Supplements (Guide No. 1240.2210)	August 11, 1992	Do	Do
Classification of OTC and Rx Drugs (Guide No. 1240.2220)	January 15, 1985	Do	Do
Processing General Correspondence by Individual Offices in CVM (Guide No. 1240.2300)	June 28, 1993	Do	Do
Routing of Congressional Correspondence (Guide No. 1240.2302)	April 9, 1997	Do	Do
Correspondence to Practicing Veterinarians, Vet Med Associations, and other Scientific Disciplines (Guide No. 1240.2310)	June 28, 1993	Do	Do
Communication and Liaison with other Centers and Agencies (Guide No. 1240.2320)	May 7, 1991	Do	Do
Intercommunication between CVM and Office of Chief Counsel (Guide No. 1240.2322)	June 28, 1993	Do	Do
CVM Guidance on Media Inquiries (Guide No. 1240.2325)	July 1, 1997	Do	Do
Consultative Reviews and Opinions (Guide No. 1240.2330)	May 7, 1991	Do	Do
Freedom of Information Requests (Guide No. 1240.2500)	September 4, 1997	Do	Do
Public Availability of Food Additive Petitions (Guide No. 1240.2501)	June 25, 1993	Do	Do
Advisory Opinions and Informal Requests for Information (Guide No. 1240.2510)	October 23, 1985	Do	Do
Confidentiality of Center Files (Guide No. 1240.2520)	June 25, 1993	Do	Do
Industry Conferences (Guide No. 1240.2600)	June 11, 1990	Do	Do
Meetings with Representatives from Foreign Governments (Guide No. 1240.2601)	September 8, 1994	Do	Do
Trade Media Visits to CVM (Guide No. 1240.2610)	September 8, 1994	Do	Do
New Animal Drugs for Investigational Use (Guide No. 1240.3000)	September 30, 1996	Do	Do
Processing Original Investigational New Animal Drug Applications (Guide No. 1240.3010)	September 30, 1996	Do	Do
Processing Amendments to An Investigational New Animal Drug Application (Guide No. 1240.3020)	September 30, 1996	Do	Do
Non-Routine Invest. New Animal Drugs (Guide No. 1240.3025)	September 30, 1996	Do	Do
Initial Processing of an NADA (Guide No. 1240.3100)	March 25, 1991	Do	Do
Review of Animal Safety and Effectiveness Data (Guide No. 1240.3101)	August 1, 1989	Do	Do
Use of Foreign Non-Clinical and Clinical Data in an NADA (Guide No. 1240.3102)	September 6, 1989	Do	Do
Review of Vet. Med. Guidelines (Guide No. 1240.3103)	November 23, 1993	Do	Do
Specialty Reviews of NADAs (Guide No. 1240.3110)	December 17, 1993	Do	Do
Preparation of NADA Decision Package (Guide No. 1240.3120)	November 23, 1993	Do	Do
Routing of NADA Decision Package (Guide No. 1240.3122)	November 23, 1993	Do	Do
CVM Appeals Procedure Guide (Guide No. 1240.3130)	November 23, 1993	Do	Do
Animal Drug Applications Expedited Review Guideline (Guide No. 1240.3135)	November 23, 1993	Do	Do
Labeling Policy for Animal Drugs that may be Human Carcinogens (Guide No. 1240.3140)	October 13, 1994	Do	Do
NADA Review of Dosage Form Oral Electrolytes (Guide No. 1240.3150)	October 13, 1994	Do	Do
Food Additive Petition Review (Guide No. 1240.3300)	December 7, 1993	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)
Nutritional Ingredients in Animal Drugs and Feeds (Guide No. 1240.3420)	March 23, 1993	Do	Do
New Animal Drug Determination (Guide No. 1240.3500)	July 24, 1989	Do	Do
New Animal Drug Regulation (Guide No. 1240.3502)	September 4, 1991	Do	Do
Drug Experience Reporting Requirements (Guide No. 1240.3510)	November 23, 1993	Do	Do
Additional Sources of Adverse Reaction and Injury Reports (Guide No. 1240.3512)	November 23, 1993	Do	Do
Drug Experience Reporting by Veterinarians (Guide No. 1240.3514)	May 7, 1997	Do	Do
Adverse Reactions as a Basis for Regulatory Action (Guide No. 1240.3520)	November 23, 1993	Do	Do
Animal Health Hazard Evaluation Committee (Guide No. 1240.3521)	March 28, 1986	Do	Do
Review and Evaluation of Drug Experience Reports (Guide No. 1240.3522)	November 23, 1993	Do	Do
Criteria for Veterinary Medical Review of Establishment Inspection Reports (Guide No. 1240.3524)	November 23, 1993	Do	Do
Procedures for Processing Drug Experience Reports (Guide No. 1240.3530)	November 23, 1993	Do	Do
Consumer Complaint Letters (Guide No. 1240.3532)	September 6, 1989	Do	Do
NADAs, Withdrawal of Approvals (Guide No. 1240.3540)	November 23, 1993	Do	Do
Implementation of Causal Reviews (Guide No. 1240.3542)	November 23, 1993	Do	Do
Surveillance at Professional and Trade Meetings (Guide No. 1240.3550)	November 23, 1993	Do	Do
Registration of Producers of Drugs and Listing Of Drugs in Commercial Distribution (Guide No. 1240.3560)	September 9, 1997	Do	Do
Types of Enforcement Activities (Guide No. 1240.3600)	September 9, 1997	Do	Do
Types of Regulatory Actions (Guide No. 1240.3601)	September 9, 1997	Do	Do
Regulating Animal Foods with Drug Claims (Guide No. 1240.3605)	September 9, 1997	Do	Do
Request for CGMP Establishment Inspections (Guide No. 1240.3620)	September 9, 1997	Do	Do
Good Manufacturing Practice Compliance Status (Guide No. 1240.3622)	September 9, 1997	Do	Do
Tissue Residue Reporting (Guide No. 1240.3630)	September 9, 1997	Do	Do
Diversion of Unfit Food to Animal Use (Guide No. 1240.3650)	September 9, 1997	Do	Do
Development of Compliance Policy Guides Affecting Veterinary Products (Guide No. 1240.3660)	September 9, 1997	Do	Do
Preparation of Compliance Programs and Program Circulars (Guide No. 1240.3661)	September 9, 1997	Do	Do
Management of Formal Evidentiary Hearings (Guide No. 1240.3670)	September 9, 1997	Do	Do
Center for Veterinary Medicine Research Activities (Guide No. 1240.3700)	November 3, 1993	Do	Do
Initiation and Approval of Research Projects (Guide No. 1240.3710)	November 3, 1993	Do	Do
Identification/Promotion of NADA Product Approval (Guide No. 1240.4000)	September 10, 1997	Do	Do
Procedure for Center Recommended Labeling Changes (Guide No. 1240.4005)	September 10, 1997	Do	Do
Antibacterials Labeled for Secondary Infections (Guide No. 1240.4010)	September 10, 1997	Do	Do
Uniformity in Labeling (Guide No. 1240.4020)	September 10, 1997	Do	Do
General Policies for Animal Drug Label Review (Guide No. 1240.4021)	September 10, 1997	Do	Do
Therapeutic Use Directions for Medicated Feed and Drinking Water (Guide No. 1240.4025)	September 10, 1997	Do	Do
Established Names (Guide No. 1240.4030)	September 10, 1997	Do	Do
Clinical Investigator Sanctions & the Videotex Method of Obtaining Information on Ineligible Investigators (Guide No. 1240.4040)	September 10, 1997	Do	Do
Criteria for the Approval of Euthanasia Products (Guide No. 1240.4112)	January 5, 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)
Sterility of Ophthalmic Products (Guide No. 1240.4120)	December 7, 1993	Do	Do
Sterility and Pyrogen Requirements for Injectable Drug Products (Guide No. 1240.4122)	November 27, 1989	Do	Do
Overformulation in Animal Drug Products (Guide No. 1240.4130)	January 2, 1992	Do	Do
Continuous Use Production Drugs & Short-Term Therapeutic Treatments in Feeds (Guide No. 1240.4145)	April 16, 1990	Do	Do
Ownership Transfer or Corporate Identity Change of an Application (Guide No. 1240.4150)	January 2, 1992	Do	Do
Policy on Sterilization of New Animal Drug Products and Containers by Irradiation (Guide No. 1240.4160)	September 10, 1997	Do	Do
CVM Medically Necessary Veterinary Drug Product Shortage Management (Guide No. 1240.4170)	June 30, 1994	Do	Do
Drug Use in Aquaculture Enforcement Priorities (Guide No. 1240.4200)	October 29, 1997	Do	Do
Extra-label Use of Approved Drugs in Aquaculture (Guide No. 1240.4210)	October 29, 1997	Do	Do
Drug-Pesticide Issues (Guide No. 1240.4220)	October 29, 1997	Do	Do
Regulation of Fish Identification Products (Guide No. 1240.4230)	October 29, 1997	Do	Do
Safe Levels of Unapproved Drugs in Aquaculture (Guide No. 1240.4240)	October 29, 1997	Do	Do
Classification of Aquaculture Species/Population as Food or Non-Food (Guide No. 1240.4260)	October 29, 1997	Do	Do
Use of Drugs in Outdoor Aquatic Research Facilities (Guide No. 1240.4270)	October 29, 1997	Do	Do
Generic Animal Drug and Patent Term Restoration Act (GADPTRA) Policy Letter 1.—Describes patent and exclusivity information to be submitted to FDA by holders of approved NADAs and NADA applicants	November 23, 1988	Animal drug industry	Communications Staff (HFV–12), FDA/CVM, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755, FAX 301–594–1831
GADPTRA Policy Letter 2.—Describes format and content for suitability petitions, format and content for ANADAs, manufacturing requirements for ANADAs, and environmental review of generic animal drugs	June 7, 1989	Do	Do
GADPTRA Policy Letter 3.—''Exclusivity for human food safety data submitted in supplemental application,'' ''Withdrawal period for generic drugs,'' ''Substitution of an active ingredient in a combination drug or in a feed use combination,'' ''Labeling Requirements for Generic Drugs,'' ''Can a generic animal drug sponsor obtain exclusivity for an innovation approved under a supplement to an ANADA and can the pioneer drug sponsor copy the generic innovation without submitting additional data?''	July 2, 1989	Do	Do
GADPTRA Policy Letter 4.—''Actions concerning ANADAs when a pioneer drug has been withdrawn from sale,'' ''Effect of GADPTRA on approval of pre-62 drugs under the DESI program,'' ''Generic feed use combination drugs''	November 2, 1989	Do	Do
GADPTRA Policy Letter 5.—Bioequivalence Guideline	April 12, 1990	Do	Do
GADPTRA Policy Letter 6.—''Withdrawal period for generic animal drug products,'' ''Eligibiliity of a new salt or ester for a pioneer animal drug''	October 17, 1990	Do	Do
GADPTRA Policy Letter 7.—''Guidance for analytical methods for ANADAs,'' ''ANADAs, NADAs and supplemental approvals for subtherapeutic antibiotics,'' ''Hybrid applications,'' ''Waivers of In Vivo bioequivalence studies for topical products''	March 20, 1991	Do	Do
GADPTRA Policy Letter 8.—Generic copying of certain drugs that were subject to review under the Drug Efficacy Study Implementation (DESI) program	July 23,1991	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)
GADPTRA Policy Letter 9.—''Policy Statement on Environmental Review of Generic Animal Drugs'' (Revision of a policy statement of the same title in Generic Policy Letter #2	June 27, 1995	Do	Do
Guide for Reporting Drug Shipment(s) for Clinical Trials in Non-Food Animals	June 19, 1992	Do	Do
Guide for Reporting The Details of Clinical Trials Using Investigational New Animal Drug(s) in Food-Producing Animals	no date	Do	Do
Aquaculture Drug Use: Answers to Commonly Asked Questions	June 1995	Do	Do Internet via http://www.cvm.fda.gov/
Guideline 3.—General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals	July 1994	Do	Do
Guideline 4.—Guidelines for Efficacy Studies for Systemic Sustained Release Sulfonamide Boluses for Cattle	no date	Do	Do
Guideline 5.—Stability Guidelines	December 1990	Do	Do
Guideline 6.—Guidelines for Submitting NADA's for Generic Drugs Reviewed by NAS/NRC	March 1976	Do	Do
Guideline 9.—Preclearance Guidelines for Production Drugs	October 1975	Do	Communications Staff
Guideline 10.—Amendment of Section II(G)(1)(b)(4) of the Preclearance Guidelines	October 1975	Do	Do Internet at http://www.cvm.fda.gov/
Guideline 13.—Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Free-Choice Feeds (revision of Medicated Block)	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	no date	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	no date	Do	Do
Guideline 19.—Antibacterial Drugs in Animal Feeds: Animal Health Safety Criteria	no date	Do	Do
Guideline 20.—Antibacterial Drugs in Animal Feeds: Antibacterial Effectiveness Criteria	no date	Do	Do
Guideline 22.—Guideline Labeling of Arecoline Base Drugs Intended for Animal Use	no date	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 26.—Guidelines for the Preparation of Data to Satisfy the Requirements of Section 512 of the Act Regarding Animal Safety, Effectiveness, Human Food Safety and Environmental Considerations for Minor Use of New Animal Drugs	April 1986	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)	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

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 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.—Series of four guidelines entitled ''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
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	Communications Staff
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 51.—Points to Consider Guideline—Development of a Pharmacokinetic Guideline Enabling Flexible Labeling of Therapeutic Antimicrobials	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 to Industry Submitting Notices of Claimed Investigational Exemption in Electronic Format to CVM Via E-mail	June 1997	Do	Do
Guideline 60.—Guidance for Industry Animal Proteins Prohibited From Animal Feed, Small Entity Compliance Guide	June 1997	Do	Do
Guideline 61.—Draft Guidance for Industry—FDA Approval of Animal Drugs for Minor Uses and for Minor Species	September 1997	Do	Do
Guideline 62.—Draft Guidance for Industry—Consumer-Directed Broadcast Advertisements	August 1997	Do	Do
NADA Pre-approval Inspections (No. 7368.001)	November 1, 1993	FDA investigators and analysts and regulated industry	Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6310, FAX 301–443–1726
Drug Process and New Animal Drug Inspections (No. 7371.001)	October 8, 1996	Do	Do
Illegal Sales of Veterinary Prescription Drugs (No. 7371.002)	August 17, 1993	Do	Do
Feed Contaminants (No. 7371.003)	November 1, 1993 (July 31, 1996—Partial Revision)	Do	Do
Medicated Feeds (No. 7371.004)	July 7, 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)
Type A Medicated Articles (No. 7371.005)	January 1, 1992	Do	Do
Illegal Drug Residues in Meat and Poultry (No. 7371.006)	September 9, 1996	Do	Do
Imported Bulk New Animal Drugs (No. 7371.007)	October 1, 1991	Do	Do
Center for Veterinary Medicine Public Affairs Specialist Program (No. 7371.826)	May 3, 1996	Do	Do
CVM Initiates Veterinary Drug Listing Verification	February 3, 1994	Public information	Communications Staff, FDA/CVM, 7500 Standish Pl. (HFV–12), Rockville, MD 20855, 301–594–1755, FAX 301–594–1831
FDA Position on the Extra-Label Use of Fluoroquinolones	September 14, 1995	Do	Do
CVM Announces Opinion on Dipyrone Products	December 6, 1995	Do	Do
Regulation of Animal Electronic Identification Products	January 17, 1996	Do	Do
Update on Extra-Label Use of Fluoroquinolones	July 16, 1996	Do	Do Internet via http://www.cvm.fda.gov/
Caution Urged in Using Warbex	October 4, 1996	Do	Do
Revised Labeling for Some Medicated Feed Products	January 30, 1997	Do	Do
Colloidal Silver Not Approved For Treating Animals	February 12, 1997	Do	Do
CVM Policy on Competitive Exclusion Products	February 21, 1997	Do	Do
Updated Policy on the Use of Animal Electronic Identification Products in Swine	March 14, 1997	Do	Do
Human Drug Product not Equivalent to Veterinary Ceftiofur	July 16, 1997	Do	Do
FDA Requests That Ball Clay Not be Used in Animal Feeds	October 14, 1997	Do	Do

VII. Guidance Documents Issued by the 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)
FDA's Development, Issuance and Use of Guidance Documents	February 1997	Internal FDA 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 Consumer Directed Broadcast Advertisements	February 1997	Do	Do
Direct Final Rule Guidance	November 1997	Internal FDA	Internet via www.fda.gov/opacom/morechoices/industry/preguide.htm or Marquita Steadman 301–443–3480
Small Entities Compliance Guide On: Regulations to Restrict the Sale and Distribution of Cigarettes and Smokeless Tobacco in Order to Protect Children and Adolescents (21 CFR Part 897)	February 1997	Regulated industry	Internet via www.fda.gov/opacom/campaigns/tobacco/tobret.htm or 1–888–FDA–4KIDS
Children and Tobacco—Frequently Asked Questions About the New Regulations-Draft Guidance	July 1997	Do	Internet via www.fda.gov/opacom/campaigns/tobacco/tobret.htm or 1–888–FDA–4KIDS
Children & Tobacco—A Retailer's Guide to the New Federal Regulations	October 1997	Do	Internet via www.fda.gov/opacom/campaigns/tobacco/tobret.htm or 1–888–FDA–4KIDS
Children & Tobacco—A Guide to the New Federal Regulations	October 1997	Do	Internet via www.fda.gov/opacom/campaigns/tobacco/tobret.htm or 1–888–FDA–4KIDS
FDA's Standards Policy	October 1995	Internal FDA and regulated industry	60 FR 53078, October 11, 1995 or Office of Policy 301–827–3360

VIII. 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 (PB96–915499)	August 1996	FDA Staff Personnel	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161 or via Internet at www.fda.gov/ora/compliance—ref/cpg/cpgtc.html
FDA/ORA International Inspection Manual and Travel Guide	May 1997	Do	FDA, Division of Emergency and Investigational Operations (HFC–130), 5600 Fishers Lane, Rockville, MD 20857 or via Internet at www.fda.gov/ora/inspect—ref/itob/itob.html
Glossary of Computerized System and Software Development Terminology (PB96–127352)	August 1995	Do	NTIS or via Internet at www.fda.gov/ora/inspect—ref/igs/iglist.html
Import Alerts	continuously	Do	FDA, Freedom of Information Staff (HFI–35), 5600 Fishers Lane, Rockville, MD 20857, or via Internet at www.fda.gov/ora/fiars/ora—import—alerts.html
Investigations Operations Manual (PB96–913399)	May 1996	Do	NTIS or via Internet at www.fda.gov/ora/inspect—ref/iom/iomtc.html
Laboratory Procedures Manual	June 1994	Do	FDA, Division of Field Science (HFC–141), 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857, ATTN: Denise I. Jones or via Internet at www.fda.gov/ora/science—ref/lpm/lpmtc.html
Regulatory Procedures Manual (PB97–196182)	August 1997	Do	NTIS or via Internet at www.fda.gov/ora/compliance—ref/rpm/rpmtc.html
Guide to Inspections of Bulk Pharmaceutical Chemicals (PB96–127154)	May 1994	Do	NTIS or via Internet at www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Pharmaceutical Quality Control Laboratories (PB96–127279)	July 1993	Do	Do
Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories (PB96–127287)	July 1993	Do	Do
Guide to Inspections of Validation of Cleaning Processes (PB96–127246)	July 1993	Do	Do
Guide to Inspections of Lyophilization of Parenterals (PB96–127253)	July 1993	Do	Do
Guide to Inspections of High Purity Water Systems (PB96–127261)	July 1993	Do	Do
Guide to Inspections of Dosage Form Drug Manufacturers-CGMPs (PB96–127212)	October 1993	Do	Do
Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation (PB96–127345)	January 1994	Do	Do
Guide to Inspections of Topical Drug Products (PB96–127394)	July 1994	Do	Do
Guide to Inspections of Sterile Drug Substance Manufacturers (PB96–127295)	July 1994	Do	Do
Guide to Inspections of Oral Solutions and Suspensions (PB96–127147)	August 1994	Do	Do
Guide to Inspections of Nutritional Labeling and Education Act (NLEA) Requirements (PB96–127378)	February 1995	Do	Do
Guide to Inspections of Interstate Carriers and Support Facilities (PB96–127386)	April 1995	Do	Do
Guide to Inspections of Dairy Product Manufacturers (PB96–127329)	April 1995	Do	Do
Guide to Inspections of Miscellaneous Foods Vol. I (PB96–127220)	May 1995	Do	Do
Guide to Inspections of Miscellaneous Foods Vol. II (PB97–196133)	September 1996	Do	Do
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 1—Administrative Procedures/Scheduled Processes (PB97–196141)	November 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)
Guide to Inspections of Low Acid Canned Foods Manufacturers, Part 2— Processes/Procedures (PB97–196158)	April 1997	Do	Do
Guide to Inspections of Cosmetic Product Manufacturers (PB96–127238)	February 1995	Do	Do
Guide to Inspections of Blood Banks (PB96–127303)	September 1994	Do	Do
Guide to Inspections of Source Plasma Establishments (PB96–127360)	December 1994	Do	Do
Guide to Inspections of Infectious Disease Marker Testing Facilities (PB96–199476)	June 1996	Do	Do
Biotechnology Inspections Guide (PB96–127402)	November 1991	Do	Do
Guide to Inspections of Computerized Systems in Drug Processing (PB96–127337)	February 1983	Do	Do
Guide to Inspections of Foreign Medical Device Manufacturers (PB96–127311)	September 1995	Do	Do
Guide to Inspections of Foreign Pharmaceutical Manufacturers (PB96–199468)	May 1996	Do	Do

IX. International Conference on Harmonization Guidances (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)
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	Do	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 Safety Reports	October 1, 1996	Do	Do
E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs	May 19, 1997	Do	Do
E3 Structure and Content of Clinical Study Reports	July 17, 1996	Do	Do
E4 Dose-Response Information to Support Drug Registration	November 9, 1994	Do	Do
E5 Ethnic Factors in the Acceptability of Foreign Clinical Data	July 31, 1997	Do	Do
E6 Good Clinical Practices; 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	May 30, 1997	Do	Do
E9 Statistical Principles for Clinical Trials	May 9, 1997	Do	Do
M3 Timing of Nonclinical Studies for the Conduct of Human Clinical Trials for Pharmaceuticals	May 2, 1997	Do	Do
Q1A Stability Testing of New Drug Substances and Products	September 22, 1994	Do	Do
Q2A Text on Validation of Analytical Procedures	March 1, 1995	Do	Do
Q3A Impurities in New Drug Substances	January 4, 1996	Do	Do
Q5A Biotechnological/Biological Pharmaceutical Products; Viral Safety Evaluation	May 10, 1996	Do	Do
Q6A Specifications; Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products Chemical Substances	November 25, 1997	Do	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
Q2B Validation of Analytical Procedures: Methodology	May 19,1997	Do	Do
Q3B Impurities in New Drug Products	May 19, 1997	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
Q3C Impurities: Residual Solvents	May 2, 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)
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	May 2, 1997	Do	Do
S1A The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals	March 1, 1996	Do	Do
S3A Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies	March 1, 1995	Do	Do
S5A Detection of Toxicity to Reproduction for Medicinal Products	September 22, 1994	Do	Do
S1C Dose Selection for Carcinogenicity Studies of Pharmaceuticals	March 1, 1995	Do	Do
S1C (R) Carcinogenicity Studies of Pharmaceuticals: Addendum to Dose Selection	April 2, 1997	Do	Do
S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals	April 24, 1996	Do	Do
S3B Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies	March 1, 1995	Do	Do
S2B Genotoxicity: Standard Battery Testing	April 3, 1997	Do	Do
S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity)	November 18, 1997	Do	Do
S5B Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility	April 5, 1996	Do	Do
S6 Preclinical Testing of Biotechnology-Derived Pharmaceuticals	April 4, 1997	Do	Do

Dated: February 20, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–339]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Provider Cost Report Reimbursement Questionnaire and Supporting Regulations in 42 CFR 405.465, 405.481, 413.20, and 413.24; *Form No.:* HCFA–339 (OMB# 0938–0301); *Use:* The Medicare Provider Cost Report Reimbursement Questionnaire must be completed by all providers to assist in preparing an acceptable cost report, to ensure proper Medicare reimbursement, and to minimize subsequent contact between the provider and its fiscal intermediary; *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local and tribal government; *Number of Respondents:* 30,607; *Total Annual Responses:* 30,607; *Total Annual Hours:* 1,239,584.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room C2–26–17, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 18, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–4865 Filed 2–25–98; 8:45 am]

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