
SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees” dated March 2006. The guidance is intended to assist sponsors of clinical trials in determining when a DMC is needed for study monitoring, and how such committees should operate. The guidance addresses the roles, responsibilities, and operating procedures of DMCs.

In the Federal Register of November 20, 2001 (66 FR 58151), FDA announced the availability of the draft guidance entitled “Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees” dated November 2001. FDA received a number of comments on the draft guidance and considered those comments carefully as the guidance was finalized. The final guidance also incorporates editorial and clarifying changes.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0581.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see ADDRESSES) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access


Dated: March 17, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. E6–4428 Filed 3–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998N–0046]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing its annual comprehensive list of all guidance documents currently in use at the agency. This list is being published under FDA’s good guidance practices (GGPs) regulations. It is intended to inform the public of the existence and availability of all of our current guidance documents. It also provides information on guidance documents that have been added or withdrawn in the past year.

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

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. For information on a specific guidance or to obtain a hard copy of any of the guidance currently in use, contact the appropriate Center listed in the SUPPLEMENTARY INFORMATION section of this document.

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

SUPPLEMENTARY INFORMATION:

I. Background

FDA’s GGPs were published in the Federal Register of September 19, 2000 (65 FR 56468), and became effective October 19, 2000. GGPs (§ 10.115 (21 CFR 10.115)) are intended to ensure involvement of the public in the development of guidance documents, and to enhance understanding of the availability, nature, and legal effect of such guidance. In § 10.115(m)(2), FDA stated that it intended to publish an annual comprehensive list of guidance documents. The list in this document updates a comprehensive list that was published January 5, 2005 (70 FR 824).

This year FDA has adopted a new format for its annual comprehensive guidance list. This new format is intended to increase the timeliness of the annual comprehensive list. For information on a specific guidance or to obtain a hard copy, please refer to the heading of each Center’s section (sections II through VIII of this document). The list of guidance documents that have been withdrawn is for those guidance documents that have been withdrawn from January 5, 2005, to January 5, 2006. The list of current guidance documents is a reprint of FDA’s Web site as of January 31, 2006 or February 1, 2006. You are encouraged to use FDA’s Web site as the most up-to-date source for all current guidance documents in use by the agency, as the Web site is updated on a daily basis.

In accordance with the agency’s general policy on guidances, you may comment on this list and on any FDA guidance document at any time.

We have organized the documents by the issuing Center or Office within FDA. The dates in the list refer to the date we issued the guidance or, where applicable, the last date we revised a document. Because each issuing Center or Office maintains its own database, there are slight variations in the way in which they provide the information in this document.

II. Center for Biologics Evaluation and Research (CBER)

The following is a list of CBER guidance documents that have been withdrawn from January 5, 2005, to January 5, 2006.

<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Date of Issuance</th>
<th>Date of Withdrawal</th>
</tr>
</thead>
</table>

The following is a copy of the list of current CBER guidance documents obtained from the FDA Web site on March 14, 2006.

CBER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)

2006

FDA Initiative Helps Expedite Development of Seasonal and Pandemic Flu Vaccines—3/2/2006
Guidance for Industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications—2/13/2006
Guidance for Industry: Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format—1/18/2006
Guidance for Industry: Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format—1/18/2006
Draft Guidance for Industry: INDs—Approaches to Complying with CGMP During Phase 1—1/12/2006
Appendix 2
Appendix 3—CDER MAPP 6020.3, CBER SOPP 8405
Appendix 4

2005

Draft Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees—12/30/2005
FEDERAL REGISTER: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees—12/30/2005
Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)—11/30/2005
Draft Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies—10/19/2005
International Conference on Harmonisation (ICH); Guidance for Industry: E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs—10/19/2005
International Conference on Harmonisation (ICH); Guidance for Industry: ST2 Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals—10/19/2005
International Conference on Harmonisation (ICH); Guidance for Industry: Granularity Document Annex to M4: Organization of the CTD—10/18/2005
Draft Guidance for Industry and FDA Staff: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices—10/7/2005
Draft Guidance for Industry and FDA Staff: Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices—6/19/2003
Draft Guidance for Industry and FDA Staff: Collection of Platelets by Automated Methods—9/30/2005
International Conference on Harmonisation (ICH); Guidance for Industry: E2B(R) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports—9/30/2005
Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials—9/19/2005
Guidance for Industry, FDA Staff, and FDA-Accredited Third Parties: Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002—9/15/2005
Draft Guidance for Industry: How to Comply with the Pediatric Research Equity Act—9/7/2005
International Conference on Harmonisation (ICH); Draft Guideline: M5 Data Elements and Standards for Drug Dictionaries—9/2/2005
International Conference on Harmonisation (ICH); Draft Consensus Guideline: Q9 Quality Risk Management—8/5/2005
Draft Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV–1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry—7/19/2005
FEDERAL REGISTER: Guidance for Industry: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection; Withdrawal of Guidance—6/30/2005
International Conference on Harmonisation (ICH); Guidance for Industry: Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process—6/29/2005
Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices—5/12/2005
Draft Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials—4/29/2005
Guidance for Industry and FDA Staff: Application User Fees for Combination Products—4/20/2005
Draft Guidance for Industry: Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics—4/1/2005
International Conference on Harmonisation (ICH); Guidance for Industry: E2E Pharmacovigilance Planning—3/31/2005
Guidance for Industry: Pharmacogenomic Data Submissions—3/22/2005
Attachment to Guidance on Pharmacogenomic Data Submissions—3/22/2005
Draft Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications—2/17/2005
Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications—12/27/1996
FEDERAL REGISTER: Annual Comprehensive List of Guidance Documents at the Food and Drug Administration; Correction—2/11/2005
FEDERAL REGISTER: Annual Comprehensive List of Guidance Documents at the Food and Drug Administration—1/5/2005
International Conference on Harmonisation (ICH); Draft Guidance on Q8 Pharmaceutical Development—2/8/2005
International Conference on Harmonisation (ICH); Draft Guidance on S8 Immunotoxicity Studies for Human Pharmaceuticals—2/7/2005

2004

International Conference on Harmonisation (ICH); Guidance for Industry: M-4: CTD—Efficacy: Questions and Answers (Revision 3)—12/22/2004
International Conference on Harmonisation (ICH); Guidance for Industry: M4: The CTD—General: Questions and Answers (Revision 3)—12/22/2004
Guidance for Industry and FDA Staff: Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use—11/30/2004
Guidance for Industry and FDA Staff: Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFA—11/17/2004
BER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components (including Source Plasma and Source Leukocytes) to Adequately and Appropriately Reduce the Risk of Transmission of HIV—1 and HCV—10/21/2004


Guidance for Industry: Computerized Systems Used in Clinical Trials—5/10/1999


Guidance on Research Involving Coded Private Information or Biological Specimens—8/30/2004


Guidance for Industry: FDA Export Certificates (Corrected to update the Medical Devices contact phone number 4/27/2005)—7/12/2004

International Conference on Harmonisation (ICH); Guidance for Industry: Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV—7/2/2004


Part 1: Conducting Safety Assessments

Part 2: Clinical Indications

Part 3: Design, Analysis, and Interpretation of Clinical Studies


International Conference on Harmonisation (ICH); Guidance for Industry: Q1E Evaluation of Stability Data—6/7/2004


Guidance for Industry and FDA Staff: User Fees and Refunds for Premarket Notification Submissions (510(k))—5/28/2004


Draft Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)—5/20/2004

Questions and Answers for Roll-Out of Donor Eligibility Final Rule and Draft Guidance


Example of Fictional Highlights of Prescribing Information (Based on Proposed Physician Labeling Rule)—2/4/2004


Draft Guidance for Industry: “Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms—2/4/2004

Draft Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Revision 1)—1/26/2004

Draft Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions—3/18/2002

Guidance for Industry: IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (Revision 1)—1/16/2004


2003


Guidance for Industry and FDA Staff: User Fees and Refunds for Premarket Approval Applications—11/21/2003

Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission—11/21/2003


International Conference on Harmonisation (ICH); Guidance for Industry: Q1A(R2) Stability Testing of New Drug Substances and Products—11/20/2003

International Conference on Harmonisation (ICH); Guidance for Industry: Q3B(R) Impurities in New Drug Products—11/13/2003

International Conference on Harmonisation (ICH); Guidance for Industry: Q3C—Tables and List—11/12/2003


Guidance for Industry and FDA Staff: Premarket Approval Application Modular Review—10/31/2003
CBER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus—10/30/2003
Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion—9/22/2003
Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS—9/16/2003
Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS—4/17/2003
Question and Answer on FDA Guidance Entitled “Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Suspected and Probable Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS”—Since Publication of this guidance, CDC issued a health alert for travelers arriving from Toronto Canada, and updated their case definition. As discussed in the guidance under section II.B.3., Updated Information on Case Definitions in Areas Affected by SARS, the FDA indicated that you should consult with the CDC website and phone number for updates. Phone (888) 246-2675.
Draft Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices—7/24/2003
Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices—7/3/2003
Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients—12/30/2002—(Corrected 2/4/2003)
Questions and Answers on FDA Guidance Entitled “Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients”—1/20/2002

2002

Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals—9/6/2002
Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)—6/14/2002
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Questions and Answers—5/13/2002
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation—7/7/1999
Draft Guidelines for Ensuring the Quality of Information Disseminated to the Public—5/2/2002—HHS Guideline
Electronic IND Demo
Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff—1/11/2002
Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products—1/9/2002
Questions and Answers on "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products"

2001

Draft Guidance for Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees—11/15/2001
International Conference on Harmonisation (ICH); Guidance on M4 Common Technical Document—10/16/2001—
M4: Organization of the CTD
M4E: The CTD—Efficacy
M4Q: The CTD—Quality
M4S: The CTD—Safety
M4S: The CTD—Safety Appendices
Guidance for Industry: Content and Format of Geriatric Labeling—10/5/2001
Guidance for Industry: Cancer Drug and Biological Products—Clinical Data in Marketing Applications—10/5/2001
Draft Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research—8/22/2001
Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis—8/22/2001
Draft Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components—8/10/2001
Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture—8/7/2001
Guidance for FDA Reviewers: Premarket Notification Submissions for Transfer Sets (Excluding Sterile Connecting Devices)—7/19/2001
Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors—7/11/2001
Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing and Controls Information—5/25/2001
Draft Guidance for Industry: Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—5/14/2001
Draft Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research—2/15/2001
PHS Guideline on Infectious Disease Issues in Xenotransplantation—1/19/2001

2000

Guidance for Industry: Toxin-Neutralizing Monoclonal Antibodies in Clinical Investigations of New Drugs—1/12/1999
Guidance for Industry: Q & A Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products—10/3/2000
Guidance for Industry: Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products—11/1995
Guidance for Industry: Use of Plant Derived Materials as Excipients or Drug Substances—10/18/2000
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use—2/10/2000

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Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immuno-deficiency Viruses Types 1 and 2—12/14/1999
REVISION Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—10/28/1999
Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)—7/15/1999
ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing); Availability—6/25/1999
Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Reactively Screened Testing for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV)—6/17/1999
FEDERAL REGISTER Notice of Availability—6/22/1999
Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Reactively Screened Testing for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV—2/28/1999
Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls Information and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h “Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use”—5/10/1999
Guidance for Industry On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test—4/23/1999
Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans—4/6/1999
Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product—3/8/1999
Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls Information and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products—2/17/1999
Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products for the Treatment of Rheumatoid Arthritis (RA)—2/17/1999
Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products—2/3/1999
CBER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product—1/5/1999

1998

Draft Guidance for Industry: General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products—11/30/1998
Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV—9/23/1998
ICH Guidance on Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products—9/21/1998
ICH Guidance on Statistical Principles for Clinical Trials—9/16/1998

1997

Guidance for Industry—Donor Screening for Antibodies to HTLV—II—8/15/1997
Guidance for Industry—Changes to an Approved Application: Biological Products—7/24/1997
Guidance for Industry—Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products—7/24/1997
Proposed Approach to Regulation of Cellular and Tissue-Based Products—2/28/1997

1996

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—8/1996
Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated ex vivo and Intended for Structural Repair or Reconstruction—5/1996
CBER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

FDAs Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products—4/1996
International Conference on Harmonisation: Final Guideline on Quality of Biotechnical Products: Analysis of the Expression Construct in Cells Used for the Production of r-DNA Derived Protein Products—2/1996

1995 and earlier

Points to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived from Transgenic Animals—1995
Guidance on Alternatives to Lot Release for Licensed Biological Products—7/14/1993
Draft Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (1993)—7/12/1993
Supplement to the Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability—4/6/1992
Guideline for the Determination of Residual Moisture in Dried Biological Products—1/1/1990
Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers (“High Risk” Donors)—10/26/1989

Points to Consider in the Collection, Processing, and Testing of Ex-Vivo Activated Mononuclear Leukocytes for Administering to Humans—8/22/1999
Draft Points to Consider in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus Type 1—8/8/1989
Revised Guideline for the Collection of Platelets, Pheresis—10/7/1988
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—12/1987
Guideline on General Principles of Process Validation—5/1987
Guideline for the Uniform Labeling of Blood and Blood Components—8/1985
Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology—4/10/1985

III. Center for Drug Evaluation and Research (CDER)


The following is a list of CDER guidance documents that have been withdrawn from January 5, 2005, to January 5, 2006.

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<th>Title of Document</th>
<th>Date of Issuance</th>
<th>Date of Withdrawal</th>
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<tr>
<td>Preclinical Development of Antiviral Drugs</td>
<td>11/1/1990</td>
<td>7/6/2005</td>
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<td>Conjugated Estrogens, USP: LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence</td>
<td>3/9/2000</td>
<td>8/12/2005</td>
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<tr>
<td>Phenytion/Phenytoin Sodium Capsules, Tablets and Suspension In Vivo Bioequivalence and In Vitro Dissolution Testing</td>
<td>3/4/1994</td>
<td>9/6/2005</td>
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<tr>
<td>Organization of an Abbreviated New Drug Application</td>
<td>3/2/1999</td>
<td>11/18/2005</td>
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The following is a copy of a list of current CDER guidance documents obtained from the FDA Web site as of March 14, 2006.

CDER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)

Guidance Agenda: Guidances CDER is Planning to Develop During Calendar Year 2006 (03/01/2006)
CDER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued


Advertising

Questions and Answers (Posted 8/6/1999)

Advertising Draft

Labeling Example
Labeling Example: Consumer-Friendly Version
“Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (Issued 1/26/2004, Posted 2/4/2004)

Biopharmaceutics

Cholesteryramine Powder in Vitro Bioequivalence (Interim Guidance)
Statistical Approaches to Establishing Bioequivalence (Issued 2001, Posted 2/1/2001)

Biopharmaceutics (Draft)

Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence. Withdrawn per August 12, 2005, Federal Register notice.

CGMPs (Pharmaceutical CGMPs for the 21st Century)

Questions and Answers on Current Good Manufacturing Practices (cGMP) for Drugs (Posted 8/4/2004)

CGMPs (Pharmaceutical CGMPs for the 21st Century)—Draft

Current Good Manufacturing Practice for Combination Products (Posted 9/29/2004)
INNs—Approaches to Complying with CGMP’s for Phase 1 Drugs (Issued 1/12/2006; Posted 1/12/2006)

Chemistry

Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products (Issued 7/1997, Posted 7/28/1997)
Changes to an Approved NDA or ANDA (Issued 4/2004, Posted 4/7/2004)
Changes to an Approved NDA or ANDA: Questions and Answers (Issued 1/2001, Posted 1/22/2001)
Changes to an Approved NDA or ANDA; Specifications—Use of Enforcement Discretion for Compendial Changes (Issued 11/19/2004, Posted 11/19/2004)
CDER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

The Use of Clinical Holds Following Clinical Investigator Misconduct

Clinical/Medical (Draft)

Acne Vulgaris: Developing Drugs for Treatment (Issued 9/16/2005, Posted 9/16/2005)
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (Issued 7/07/1999, Posted 7/14/1999)
Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (Issued 4/1/2005, Posted 4/1/2005)
Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (Issued 9/6/2002)
Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommendations for Clinical Evaluation (Issued 1/2003, Posted 1/30/2003)
Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children (Posted 11/6/2001)
Exercise-Induced Bronchospasm (EIB)—Development of Drugs to Prevent EIB (Issued 2/2002, Posted 2/19/2002)
Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention (Issued June 24, 2005, Posted June 27, 2005)
PEDIATRIC ONCOLOGY STUDIES IN RESPONSE TO A WRITTEN REQUEST (ISSUED 6/2000, POSTED 6/19/2000)
Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)) (Posted 12/1/2000)

Clinical Pharmacology

Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application (Issued 2/18/97, Posted 2/3/1998)
Population Pharmacokinetics (Issued 2/1999, Posted 2/10/1999)

Clinical Pharmacology (Draft)

Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling (Issued 2/7/05, Posted 2/8/05)
General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products (Issued 11/1998, Posted 11/12/1998)

Combination Products (Drug/Device/Biologic)

Draft and Final guidances can be found on the Office of Combination Products web site.

Compliance

General Principles of Process Validation
Good Laboratory Practice Regulations Questions and Answers (Posted 3/2/1998)
Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities—FDA Public Health Advisory (Issued andPosted 4/5/2001
Guideline for Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices (Posted 3/2/1998)
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment (Posted 3/2/1998)
Compliance (Draft)

Computerized Systems Used in Clinical Trials (Posted 9/29/2004)
Current Good Manufacturing Practice for Medical Gases (Posted 5/6/2003)

Drug Safety


Drug Safety Draft


Questions and Answers (Qs & As)

Electronic Submissions

Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. To ensure you have the most recent versions of the specifications referenced in this document, check the appropriate center’s guidance Web page. For CBER, this Web site is http://www.fda.gov/cber/esub/esub.htm. For CDER, this Web site is http://www.fda.gov/cder/regulatory/ersr/ectd.htm. (Issued 10/18/2005, Posted 10/18/2005)
Regulatory Submissions in Electronic Format; General Considerations (Issued 1/1999, Posted 1/27/1999)
Regulatory Submissions in Electronic Format; New Drug Applications (Issued 1/1999, Posted 1/27/1999)

Electronic Submissions Draft

Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs (Posted 8/27/2003)

Generics

180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day (Issued 7/2003, Posted 7/31/2003)
Alternate Source of the Active Pharmaceutical Ingredient in Pending ANDAs (Posted 12/12/2000)
ANDAs: Impurities in Drug Substances (Issued 11/1999, Posted 12/2/1999)
Handling and Retention of BA and BE Testing Samples (5/25/2004)
Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past. (Posted 3/2/1998)
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 in the process (Posted 3/2/1998)
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 (Posted 3/2/1998)
Letter on the provision of new procedures and policies affecting the generic drug review process (Posted 3/2/1998)
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 (Posted 3/2/1998)
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 (Posted 3/2/1998)
Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria and bioequivalence requirements (Posted 3/2/1998)
Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications (Issued 12/2001, Posted 12/20/2001)
Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing (Issued 10/25/2005; Posted 10/25/2005)
Variations in Drug Products that May Be Included in a Single ANDA (Issued 12/1999, Posted 1/26/1999)
CDER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Generics (Draft)


Good Review Practices (GRPs)

Pharmacology/Toxicology Review Format (Posted 5/9/2001)

Good Review Practices (GRPs) (Draft)

Industry Letters

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 (Posted 3/2/1998)
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 (Posted 3/2/1998)
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 II (Posted 3/2/1998)
Implementation Plan USP Injection nomenclature (Posted 3/2/1998)
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 (Posted 3/2/1998)
Supplement to 10/11/1984 letter about policies, procedures and implementation of the Act (Q&A format) (Posted 3/2/1998)
Third of a series of letters regarding the implementation of the Act (Posted 3/2/1998)
Year 2000 Letter from Dr. Janet Woodcock (10/19/98)

International Conference on Harmonisation

Safety
S1A The Need for Long-term Rodent Carcinogenicity Studies of Pharmaceuticals
S1C Dose Selection for Carcinogenicity Studies of Pharmaceuticals
S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals
S3A The Assessment of Systemic Exposure in Toxicity Studies
S3B Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies
S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing) Posted 6/25/99
S5B Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility
S7A Safety Pharmacology Studies for Human Pharmaceuticals (Issued 7/1/2001, Posted 7/12/2001)
S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals (Issued 10/19/2005, Posted 10/19/2005)

Joint Safety/Efficacy (Multidisciplinary)

M2 eCTD Specification Questions and Answers and Change Requests (Posted 3/14/05)
M4 Common Technical Document for the Registration of Pharmaceuticals for Human Use (Posted 10/15/2001)
M4 Organization of the CTD
M4: The CTD—Quality
M4: The CTD—Efficacy
M4: The CTD—Safety
M4: The CTD—Safety Appendices

Efficacy
E1A The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions
E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
CDER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

| E2C Addendum to ICH E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (Posted 2/5/2004) |
| E2E Pharmacovigilance Planning (Issued 3/31/05; Posted 3/31/05) |
| E3 Structure and Content of Clinical Study Reports |
| E4 Dose-Response Information to Support Drug Registration |
| E5 Ethnic Factors in the Acceptability of Foreign Clinical Data |
| E8 General Considerations for Clinical Trials (Issued 12/1997, Posted 12/17/1997) |
| E9 Statistical Principles for Clinical Trials (9/1/1998) |
| E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Issued 10/19/2005, Posted 10/19/2005) |

**Quality**

| Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV, revision 1 (7/1/2004) |
| Q2A Text on Validation of Analytical Procedures |
| Q3C Impurities: Residual Solvents or Adobe Acrobat version (Issued 12/24/1997, Posted 12/30/1997) |
| Q3C Tables and List (Posted 11/12/2003) |
| Appendix 4, Appendix 5, and Appendix 6 (Appendices were issued with the Q3C draft guidance documents) |
| Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin (Posted 9/1998) |
| Q5B Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products |
| Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products |
| Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products; Availability (Issued 9/21/1998, Posted 9/21/1998) |
| Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (Issued 8/1999, Posted 12/14/2001) |

**International Conference on Harmonisation (Draft)**

| E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting (Posted 9/12/2003) |
| Joint Safety/Efficacy (Multidisciplinary) (Draft) |
| Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (Issued 9/2001, Posted 9/5/2001) |

**Quality**

| Q9 Quality Risk Management (Issued 8/5/2005, Posted 8/5/2005) |

**Safety**

| S8 Immunotoxicity Studies for Human Pharmaceuticals (Issued 2/7/05, Posted 2/8/05) |

**Investigational New Drug Applications**

| Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs |

**Labeling**

| Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (Issued 1/18/2006; Posted 1/18/2006) |
| Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products—Content and Format (Issued 1/18/2006; Posted 1/18/2006) |
| Content and Format for Geriatric Labeling (Issued 10/2001, Posted 10/4/2001) |
CDER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Labeling (Draft)

Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements (Issued 1/18/2006; Posted 1/18/2006)
Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format (Issued 1/18/2006; Posted 1/18/2006)

Microbiology

Format and Content of the Microbiology Section of an Application

Modernization Act of 1997

Changes to an Approved NDA or ANDA (Issued 4/2004, Posted 4/7/2004)
Appendix 2: Appendix 3 consisting of Mapp 6020.3 and SOPP 8405; and Appendix 4 [Appendices are scanned copies, which will be replaced by final versions] (Issued 11/17/1998, Posted 11/17/1998)

Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Issued 3/2002, Posted 3/18/2002)

Modernization Act of 1997 (Draft)

Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Issued 1/2004, Posted 1/27/2004)
PET Drug Applications—Content and Format for NDAs and ANDAs (Issued 3/7/2000, Posted 3/7/2000)
Sample formats for chemistry, manufacturing, and controls sections
Sample formats for labeling
Sample formats for Form FDA 356h
Sample formats for user fee Form FDA 3397

Over-the-Counter (OTC) Guidelines

Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16) (Posted 3/2/1998)
General Guidelines for OTC Combination Products (Posted 3/2/1998)
Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs
Example Drug Facts Labels
  Acetaminophen 120 mg in a Suppository Dosage Form
  Acetaminophen 325 mg in a Suppository Dosage Form
  Acetaminophen 650 mg in a Suppository Dosage Form
  Cimetidine 200 mg in a Tablet Dosage Form
  Clemastine Fumarate 1.34 mg in a Tablet Dosage Form
  Doxylamine Succinate 25 mg Tablet Dosage Form
  Ibuprofen 200 mg in a Tablet/Capsule Dosage Form
  Loperamide HCl in a Liquid Dosage Form
  Loperamide HCl in a Tablet/Caplet Dosage Form
  Miconazole Nitrate Vaginal Products
  Minoxidil Topical Solution 2% for Men and Women
  Minoxidil Topical Solution 5% for Men
  Naproxen Sodium 220 mg in a Tablet/Caplet/Gelcap Dosage Form
  Pseudoephedrine HCl Extended-Release Tablets 120 mg

Sample formats for Form FDA 3397
Sample formats for chemistry, manufacturing, and controls sections
Sample formats for labeling
Sample formats for Form FDA 356h
CDER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued


Over-the-Counter (OTC) Draft

Labeling OTC Human Drug Products Questions and Answers (Issued 1/2005, Posted 1/12/05)
Labeling OTC Human Drug Products Updating Labeling in ANDAs (2/21/2001)
  Additional examples 1 (3/19/2001)
  Additional examples 2 (3/26/2001)
  Additional examples 3 (3/26/2001)

Pharmacology/Toxicology

Carcinogenicity Study Protocol Submissions (Issued 5/22/2002)
Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products
Developing Medical Imaging Drug and Biological Products
Exploratory IND Studies (Issued 1/12/2006; Posted 1/12/2006)
Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application* (Posted 3/2/1998)
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
Nonclinical Safety Evaluation of Pediatric Drug Products (Issued 2/14/2006, Posted 2/14/2006)
Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients (Issued 05/18/2005, Posted 05/18/2005)
Recommended Approaches to Integration of Genetic Toxicology Study Results (Issued 1/3/2006, Posted 1/3/2006).
Reference Guide for the Nonclinical Toxicology Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease Evaluation of Drug Toxicity Prior to Phase I Clinical Studies (Posted 3/2/1998)
Single Dose Acute Toxicity Testing for Pharmaceuticals

Pharmacology/Toxicology Draft

Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities (Issued 11/2001, Posted 11/9/2001)
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals (Issued 6/17/2005; Posted 6/17/2005)
Nonclinical Safety Evaluation of Drug Combinations (Issued 1/26/05, Posted 1/26/05)

Procedural

Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under PDUFA (Posted 10/1/2003)
Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA (Posted 10/1/2003)
Fast Track Drug Development Programs—Designation, Development, and Application Review (Posted 1/12/2006)
Appendix 2 ; Appendix 3 consisting of Mapp 6020.3 and SOPP 8405; and Appendix 4 [Appendices are scanned copies, which will be replaced by final versions 11/18] (Issued 11/17/1998,Posted 11/17/1998)
Financial Disclosure by Clinical Investigators (3/27/2001)
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997—Advisory Committees (Issued 10/1998, Posted 11/02/98)
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Issued 3/2002, Posted 3/18/2002)
Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act (Issued 11/2001)
Lethal Thyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications (Issued 7/2001, Posted 7/12/2001)
CDER GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (Issued 12/2001, Posted 12/10/2001)
Reduction of Civil Money Penalties for Small Entities (Issued 3/20/2001)
Refusal to File (Issued 7/12/1993, Posted 11/26/99)
Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (Issued 2/15/2006; Posted 2/15/2006)

Procedural Draft

Applications Covered by Section 505(b)(2) (Issued 10/2000, Posted 12/7/1999)
Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000 (Issued 12/1999, Posted 12/22/1999)
Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees (2/14/2002)
Emergency Use Authorization of Medical Products; Availability (Issued 7/5/2005; Posted 7/5/2005)
Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution (5/14/2001)
How to Comply with the Pediatric Research Equity Act (Posted 9/7/2005)
Independent Consultants for Biotechnology Clinical Trial Protocols (Posted 5/7/2003)
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Issued 1/2004, Posted 1/27/2004)
PET Drug Applications—Content and Format for NDAs and ANDAs (Issued 3/7/2000, Posted 3/7/2000)
Sample formats for chemistry, manufacturing, and controle sections
Sample formats for labeling
Sample formats for Form FDA 356h
Sample formats for user fee Form FDA 3397
Submitting Debarment Certification Statements (Issued 10/2/98, Posted 10/2/98)
Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (Issued 12/1999, Posted 12/22/1999)

Small Entity Compliance Guides

Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation—Small Entity Compliance Guide (Posted 11/7/2001)

Small Entity Compliance Guides (Draft)


User Fees

Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act (Issued 11/2001)

User Fees (Draft)


Also see Current Good Manufacturing Practice Regulations
Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations (Posted 8/11/1997)

IV. Center for Devices and Radiological Health (CDRH)

The following is a list of CDRH guidance documents that have been withdrawn from January 5, 2005, to January 5, 2006.

- Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (Issued 2/15/2006; Posted 2/15/2006)
<table>
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<tr>
<td>Guidance for Industry; In Vitro Diagnostic C-Reactive Protein Immunological Test System</td>
<td>July 20, 1998</td>
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<td>Guidance for Over-the-Counter (OTC) Ovulation Predictor 510(k)s</td>
<td>July 22, 2000</td>
<td>September 7, 2005</td>
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<td>Draft Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms</td>
<td>June 14, 1993</td>
<td>December 8, 2005</td>
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<td>CDRH Interim Regulatory Policy for External Penile Rigidity Devices</td>
<td>September 10, 1997</td>
<td>January 2005</td>
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<tr>
<td>Guidance for Neurological Embolization Devices</td>
<td>November 1, 2000</td>
<td>January 2005</td>
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<tr>
<td>Class II Special Controls Guidance Document; Dental Bone Grafting Material Devices</td>
<td>Draft of this document was issued on June 30, 2004</td>
<td>Final issued on: April 28, 2005</td>
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<tr>
<td>Class II Special Controls Guidance Document; Vascular and Neurovascular Embolization Devices</td>
<td>Draft of this document was issued on February 25, 2004</td>
<td>Final issued on: December 29, 2004</td>
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<tr>
<td>Class II Special Controls Guidance Document; External Penile Rigidity Devices</td>
<td>Draft of this document was issued March 17, 2004</td>
<td>Final issued on: December 28, 2004</td>
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The following is a copy of a list of current CDRH guidance documents obtained from the FDA Web site as of March 14, 2006.

**CDRH GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)**

(2) Abbreviated Reports on Radiation Safety of Non-Medical Ultrasonic Products 951 08/01/1995
(3) Compliance Program for Field Compliance Testing of Cabinet X-Ray Equipment (CP 7386.004); Final Guidance for Industry and FDA Staff 57 02/26/2001
(6) Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21-CFR 1020.40 241 02/01/1975
(8) Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use 399 09/01/1996
(9) Guide for Preparing Annual Reports for Ultrasonic Therapy Products 261 09/01/1996
(10) Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 243 10/01/1987
(11) Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 263 09/01/1995
(12) Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 262 09/01/1995
(13) Guide for Preparing Product Reports for Medical Ultrasound Products 960 09/01/1996
(14) Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only) 249 08/01/1996
(15) Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21-CFR 1002) 279 09/01/1995
(16) Guide for Preparing Reports on Radiation Safety of Microwave Ovens 239 03/01/1985
(17) Guide for Submission of Information on Accelerators Intended to Emit X-Radiation Required Pursuant to 21-CFR 1002.10 235 04/01/1971
(20) Guide for Submission of Information on Industrial X-Ray Equipment Required Pursuant to 21-CFR 1002.10 237 03/01/1973
(21) Information Requirements for Cookbooks and User and Service Manuals 697 10/31/1988
(22) Keeping Up With the Microwave Revolution (FDA Pub No. 91–4160) 356 03/01/1990
(23) Laser Light Show Safety—Who’s Responsibility (FDA 86–8262) 13 05/01/1986
(24) Laser Products—Conformance with IEC 60825–1, Am.2 and IEC 60601–2–22; Final Guidance for Industry and FDA (Laser Notice 50) 1546 07/28/2001
(25) Letter to All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist 231 05/28/1981
(26) Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products 342 08/21/1986
(27) Quality Control Guide for Sunlamp Products (FDA 88–8234) 270 03/01/1988
(28) Quality Control Practices for Compliance with the Federal Mercury Vapor Lamp Performance Standard 349 05/01/1980
CDRH GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEBSITE ON MARCH 14, 2006)—Continued

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<td>(190) Application of the Device Good Manufacturing Practice (GMP) Regulation to the Manufacture of Sterile Devices</td>
<td>ODE 267 12/01/1983</td>
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<td>(191) Assignment of Review Documents #190–2 (blue book memo)</td>
<td>ODE 366 08/24/1990</td>
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<tr>
<td>(192) Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff</td>
<td>ODE 1341 07/18/2001</td>
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<td>(193) Center for Devices and Radiological Health’s Investigational Device Exemption (IDE) Refuse to Accept Policy</td>
<td>ODE 4859 06/30/1993</td>
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<tr>
<td>(194) Center for Devices and Radiological Health’s Premarket Notification [510(k)] Refuse to Accept Policy—(updated Checklist 3/14/1995)</td>
<td>ODE 3859 06/30/1993</td>
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<td>(195) Changes or Modifications During the Conduct of a Clinical Investigation; Final Guidance for Industry and CDRH Staff</td>
<td>ODE 1337 05/29/2001</td>
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<td>(196) Classified Convenience Kits</td>
<td>ODE 789 04/30/1993</td>
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<td>(199) Continued Access to Investigational Devices During PMA Preparation and Review (Blue Book Memo) (D96–1)</td>
<td>ODE 872 07/15/1996</td>
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<td>(200) Convenience Kits Interim Regulatory Guidance ODE 562 05/20/1997</td>
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<td>(202) Deciding When to Submit a 510(k) for a Change to an Existing Device (K97–1)</td>
<td>ODE 895 01/10/1997</td>
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<tr>
<td>(203) Deciding When to Submit a 510(k) for a Change to an Existing Wireless Telemetry Medical Device; Final Guidance for FDA Reviewers and Industry</td>
<td>ODE 1073 11/30/2000</td>
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<tr>
<td>(204) Determination of Intended Use for 510(k) Devices; for CDRH Staff</td>
<td>ODE 857 12/03/2002</td>
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<tr>
<td>(206) Distribution and Public Availability of PMA Summary of Safety and Effectiveness Data Packages</td>
<td>ODE 563 10/10/1997</td>
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<tr>
<td>(207) Document Review Processing #191–1 (blue book memo)</td>
<td>ODE 446 02/12/1992</td>
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<tr>
<td>(209) Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff</td>
<td>ODE 310 02/28/2001</td>
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<td>(210) Format for IDE Progress Reports</td>
<td>ODE 311 06/01/1996</td>
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<td>(211) Frequently Asked Questions on the New 510(k) Paradigm; Final ODE 2230 10/22/1998</td>
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<td>(212) Goals and Initiatives for the IDE Program #D95–1 (blue book memo)</td>
<td>ODE 405 07/12/1995</td>
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<td>(213) Guidance for Industry; General/Specific Intended Use; Final ODE 499 11/04/1998</td>
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<td>(214) Guidance for Off-the-Shelf Software Use in Medical Devices; Final ODE 585 09/09/1999</td>
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<td>(215) Guidance for Submitting Reclassification Petition ODE 609 01/01/1997</td>
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<td>(216) Guidance on Amended Procedures for Advisory Panel Meetings; Final ODE 413 07/22/2000</td>
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<tr>
<td>(217) Guidance on IDE Policies and Procedures; Final ODE 882 01/20/1998</td>
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<tr>
<td>(218) Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—for Use by CDRH and Industry; Final ODE 322 02/19/1998</td>
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<tr>
<td>(221) Guidance on the Use of Standards in Substantial Equivalence Determinations; Final ODE 1131 03/12/2000</td>
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<td>(222) Guidance to Industry Supplements to Approved Applications for Class III Medical Devices: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review; Final ODE 380 05/20/1998</td>
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<td>(223) Guideline on General Principles of Process Validation ODE 425 05/01/1987</td>
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<td>(224) Guideline on Validation of the Limulus Amebocyte Lysate (LAL) Test as an End-Product Endotoxin Test ODE 427 12/01/1987</td>
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<td>(225) HCFA Reimbursement Categorization Determinations for FDA-approved IDEs ODE 4106 09/15/1995</td>
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(311) Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA ODE/DAGID/GHDB 1326 03/12/2001
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(315) Guidance on the Content of Premarket Notification [510(k)] Submissions for Clinical Electronic Thermometers ODE/DAGID/GHDB 822 03/01/1993
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(319) Medical Devices with Shars Injury Prevention Features—Guidance for Industry and FDA Staff ODE/DAGID/GHDB 934 08/09/2005
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(324) Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes ODE/DAGID/INCB 888 08/01/1993
(325) Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants and High Level Disinfectants; Final ODE/DAGID/INCB 397 01/03/2000
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(327) Premarket Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon’s Glove—Guidance for Industry and FDA Staff ODE/DAGID/INCB 1230 04/13/2004
(328) Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA ODE/DAGID/INCB 891 03/02/2001
(329) Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA ODE/DAGID/INCB 1388 03/07/2002
(330) Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Natural Rubber Products; Final ODE/DAGID/INCB 944 01/13/1999
(331) Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers ODE/DAGID/INCB 05/21/2001
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(335) Balloon Valvuloplasty Guidance For The Submission Of an IDE Application and a PMA Application ODE/DCD 370 01/01/1989
(336) Battery Guidance ODE/DCD 873 01/01/1994
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(338) Cardiac Ablation Catheters Generic Arrhythmia Indications for Use; Guidance for Industry ODE/DCD/CEMB 1382 07/01/2002
(340) Clinical Study Designs for Percutaneous Catheter Ablation for Treatment of Atrial Fibrillation—Guidance for Industry and FDA Staff ODE/ DCD/CEMB 1229 01/09/2004
(341) Coronary and Peripheral Arterial Diagnostic Catheters—Guidance for Industry and FDA Staff ODE/DCD/CEMB 1228 07/15/2003
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(345) Investigational Device Exemption (IDE) Study Enrollment for Cardiac Ablation of Typical Atrial Flutter; Final Guidance for Industry and FDA Reviewers ODE/DCD/CEMB 1199 11/08/2000
(347) Non-Invasive Blood Pressure (NIBP) Monitor Guidance ODE/DCD/CEMB 123 03/10/1997
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CDRH GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

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(355) Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm); Final ODE/DCD/PDLB 2233 11/05/1998

(356) Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement); Final ODE/DCD/PDLB 2232 11/05/1998

(357) Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions ODE/DCD/PDLB 372 11/01/2000

(358) Implantable Pacemaker Testing Guidance ODE/DCD/PDLB 383 01/12/1990


(361) Guidance for Cardiovascular Intravascular Filter 510(k) Submissions ODE/DCD/PVDB 24 11/26/1999

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(365) Guidance Document for Surgical Lamp 510(k)s; Final ODE/DGRND/GSDB 1244 07/13/1998

(366) Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Electromyograph Needle Electrodes ODE/ DGRND/GSDB 325 07/26/1995


(368) Guidance on the Content and Organization of a Premarket Notification for a Medical Laser ODE/DGRND/GSDB 386 06/01/1995

(369) Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators ODE/DGRND/ GSDB 593 02/01/1997

(370) Premarket Notification [510(k)] Submissions for Chemical Indicators—Guidance for Industry and FDA Staff ODE/DGRND/INCB 1420 12/19/2003

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(372) Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemnted or Uncemented Prosthesis ODE/DCD/ ORDB 1328 04/30/2002

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(376) Clinical Data Presentations for Orthopedic Device Applications—Guidance for Industry and FDA Staff ODE/DGRND/ORDB 1542 12/02/2004


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(384) Guidance Document For The Preparation of Premarket Notification For Ceramic Hip Systems ODE/DGRND/ORDB 355 01/10/1995

(385) ORDB 510(k) Sterility Review Guidance Document ODE/DGRND/ORDB 659 07/03/1997

(386) Reviewers Guidance Checklist for Intramedullary Rods ODE/DGRND/ORDB 956 02/21/1997

(387) Reviewers Guidance Checklist for Orthopedic External Fixation Devices ODE/DGRND/ORDB 829 02/21/1997

(388) Spinal System 510(k)s—Guidance for Industry and FDA Staff ODE/DGRND/ORDB 636 05/03/2004

(389) Class II Special Controls Guidance Document: Human Dura Mater; Guidance for Industry and FDA Staff ODE/DGRND/PRSB 54 12/18/2003

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(391) Cyanoacrylate Tissue Adhesive for the Topical Approximation of Skin—Premarket Approval Applications (PMAs)—Guidance for Industry and FDA Staff ODE/DGRND/PRSB 1233 02/13/2004


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(396) Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA ODE/DGRND/PRSB 1354 02/11/2003


(398) Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Final ODE/DGRND/PRSB 2247 03/02/1999

(399) Low Energy Ultrasound Wound Cleaner: Class II Special Controls Guidance Document—Guidance for Industry and FDA Staff ODE/ DGRND/PRSB 1302 11/07/2005

(400) Saline, Silicone Gel, and Alternative Breast Implants—Draft Guidance for Industry and FDA Staff ODE/DGRND/PRSB 1239 01/13/2004

(401) Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA ODE/ DGRND/REDB 855 06/02/2003

(402) Guidance Document for Powered Muscle Stimulator 510(k)s; Final ODE/DGRND/REDB 2246 06/09/1999

(403) Guidance Document for the Preparation of Notification (510(k)) Applications for Therapeutic Massagers and Vibrators ODE/DGRND/REDB 818 07/26/1995
(451) Class II Special Controls Guidance Document for Contraceptive Spermicides; Final ODE/DRARD/OGDB 1398 07/03/2000
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(459) Class II Special Controls Guidance Document for Clitoral Enlargement Devices ODE/DRARD/OGDB 1144 07/03/2000
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(462) Guidance ('Guidelines') for Evaluation of Fetal Clip Electrode ODE/DRARD/OGDB 244 03/08/1977
(464) Guidance ('Guidelines') for Evaluation of Laparoscopic Bipolar and Thermal Coagulators (and Accessories) ODE/DRARD/GRDB 232 05/01/1978
(467) Guidance for Industry and FDA Staff—Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) ODE/DRARD/OGDB 166 07/27/2005
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(470) Hysteroscopes and Gynecology Laparoscopes—Submission Guidance for a 510(k) ODE/DRARD/OGDB 907 03/07/1996
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(480) Bone Sonometers—Class II Special Controls Guidance Document—Draft Guidance for Industry and FDA Staff ODE/DRARD/RDB 1547 02/15/2006
(481) 510(k) Checklist for Sterile Lubricating Jelly Used With Transurethral Surgical Instruments ODE/DRARD/ULDB 892 09/19/1994
(482) Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology ODE/DRARD/ULDB 98 11/01/1994
(484) Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi ODE/DRARD/ULDB 1226 08/09/2000
(485) Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology ODE/DRARD/ULDB 482 02/10/1993
(486) Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters ODE/DRARD/ULDB 97 09/12/1994
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(488) Guidance for the Content of Premarket Notifications for Penile Rigidty Implants; Final ODE/DRARD/ULDB 177 01/16/2000
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(490) Guidance for the Content of Premarket Notifications for Urine Drainage Bags ODE/DRARD/ULBD 96 06/07/1994
(492) Analyte Specific Reagents; Small Entity Compliance Guidance; Guidance for Industry OIVD 1205 02/26/2003
(494) Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff OIVD 857 12/03/2002
(495) Guidance for Administrative Procedures for CLIA Categorization OIVD 1143 08/14/2000
(496) Guidance for Industry—Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final OIVD 1247 02/22/1999
(497) Guidance for Industry and FDA Staff; Replacement Reagent and Instrument Family Policy OIVD 950 12/11/2003
(498) Guidance on Labeling for Laboratory Tests; Draft OIVD 1352 06/24/1999
(499) Guideline for the Manufacture of In Vitro Diagnostic Products OIVD 918 01/10/1994
(500) Letter to IVD Manufacturers on Streamlined PMA; Final OIVD 1395 12/22/1997
(501) Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance OIVD 95 09/26/1994
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(503) Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft OIVD 553 02/01/1996
(504) Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications—Draft Guidance for Industry and FDA Staff OIVD 1171 09/07/2005
(506) Format for Traditional and Abbreviated 510(k)s—Guidance for Industry and FDA Staff OIVD 1567 08/12/2005

CDRH GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued
V. Center for Food Safety and Applied Nutrition (CFSAN)


No CFSAN guidance documents were withdrawn from January 5, 2005, to January 5, 2006.

The following is a copy of a list of current CFSAN guidance documents obtained from the FDA Web site as of March 14, 2006.

Recent Published Guidance

March 1, 2006: Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (Added to Produce)

March 1, 2006: Frequently Asked Questions about FDA’s Regulation of Infant Formula (Updated in Infant Formula)

February 17, 2006: Whole Grain Label Statements (Added to Food Labeling)

January 30, 2006: Redbook 2000—Chapter IV.C.6: Carcinogenicity Studies with Rodents (Updated in Food and Color Additives)

December 30, 2005: Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006 (Added to Food Labeling)

December 22, 2005: Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy (Added to Chemical and Pesticide Contaminants)

December 14, 2005: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2) (Added to Food Labeling)

General Publications

Compliance Policy Guides Manual (August 2000; Updated April 2001) Consolidates the Administrative Guidelines Manual. Lists levels of contamination at which regulatory actions will be invoked. Print version available from NTIS. Their order numbers are: Foods and Cosmetics Order No. PB96–920500 Drugs and Biologics Order No. PB96–920500 Veterinary Medicine Order No. PB96–920800 Medical and Radiological Devices Order No. PB96–920900 Source: National Technical Information Service


FDA Recall Policy (2002) Explains the three classes of recalls and discusses FDA’s role in the recall process. Source: Industry Activities Staff

Guidance for FDA Staff: The Leveraging Handbook; An Agency Resource for Effective Collaborations


Chemical and Pesticide Contaminants Publications

Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy (December 22, 2005)

Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations (May 2005)

FDA Advisory for Deoxynivalenol (DON) in Finished Wheat Products Intended for Human Consumption and in Grain and Grain By-Products for Animal Feed (September 16, 1993) Office of Plant & Dairy Foods & Beverages Food and Drug Administration (HFS–306) 5100 Paint Branch Parkway College Park, MD 20740 (301) 436–2367 See also: Compliance Policy Guides—Guidance for FDA Staff on Guidance Levels for Radionuclides in Domestic and Imported Foods July 2004

Cosmetic Publications


Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance (December 17, 2003)
CFSAN GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients (January 10, 2005)

Dietary Supplements Publications

A Dietary Supplement Labeling Guide (April 2005)
Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (November 2004)
Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003)
Interim Evidence-based Ranking System for Scientific Data (July 10, 2003)
Structure/Function Claims: Small Entity Compliance Guide (January 9, 2002)
Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (July 1998)

Food and Color Additives Publications

Providing Regulatory Submissions in Electronic Format—General Considerations (October 2003)
Providing Food and Color Additive Petitions in Electronic Format (July 2001)
Electronic Submission Forms (July 2001)
FDA’s Policy for Foods Developed by Biotechnology (1995)
Partial List of Enzyme Preparations That are Used in Foods (2001)
Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food (2001)
Use of Antibiotic Resistance Marker Genes in Transgenic Plants (September 1998)
Enzyme Preparations: Chemistry Recommendations For Food Additive and GRAS Affirmation Petitions (January 1993)
Submitting Requests under 21 CFR 170.39 Threshold of Regulation for Substances used in Food Contact Articles (April 2005)
Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations (December 1992)
Frequently Asked Questions about Generally Recognized as Safe (GRAS) (December 2004)
How to Submit a GRAS Notice (April 17, 1997)
Recommendations for Submission of Chemical and Technological Data for Direct Food Additive and GRAS Food Ingredient Petitions (May 1993)
Recommended guidelines for the testing of substances intended for use in food contacting articles, plastic, rubber, and paper that contact food (January 2004)
Pre-petition Consultations for Food Additives and Color Additives (April 2005)
Guidelines for Approval of Color Additives in Contact Lenses Intended as Colors (1996) Source: Office of Premarket Approval
FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs or Cosmetics Use (January 1997)
Estimating Exposure to Direct Food Additive and Chemical Contaminants in the Diet (September 1995)
Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as Redbook I) (1982) Source: National Technical Information Service (NTIS)
Toxicological Principles for the Safety of Food Ingredients (Redbook 2000) (July 7, 2000; Updated October 2001, November 2003, January 2006) The Agency is in the process of updating the Redbook and is now making Redbook 2000 chapters available electronically. The Redbook 2000 chapters now substitute for, or supplement, guidance available in the 1982 Redbook I (see above) and in the 1993 Draft Redbook II, which can be obtained from the Office of Food Additive Safety. As additional chapters of Redbook 2000 are completed they will become available electronically.
Templates for Reporting Toxicology Data (March 2004)
Draft Guidance: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (September 17, 2003)
Guidance on Consultation Procedures Foods Derived From New Plant Varieties (October 1997)
Recommendations for the Early Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (November 2004)
Bovine Spongiform Encephalopathy (BSE) in Products for Human Use (1997) Executive Secretariat (HF–40) Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857
Antimicrobial Food Additives—Guidance (July 1999) Source: Office of Premarket Approval
Preparation of Premarket Notifications for Food Contact Substances (Food Contact Notifications (FCN)); Administrative Recommendations (May 2002)
Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations (April 2002) Source: Office of Food Additive Safety
CFSAN GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations (April 2002) Source: Office of Food Additive Safety

Food Labeling Publications

A Food Labeling Guide (May 1997) Booklet. This booklet is a summary of the required statements that must appear on food labels. Source: Industry Activities Staff


Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006 (December 30, 2005)

Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003)

Interim Evidence-based Ranking System for Scientific Data (July 10, 2003)

Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements (December 18, 2002)

Draft Guidance: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (January 2001)

Small Business Food Labeling Exemption (June 1996) Information sheet and sample small business exemption application form. Source: Industry Activities Staff

Food Labeling: Questions and Answers Volume I, (August 1994) Booklet. Provided to facilitate the advice to retail businesses process of developing or revising labels for foods other than dietary supplements. Source: Industry Activities Staff


Structure/Function Claims: Small Entity Compliance Guide (January 9, 2002)

Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (July 1998) Source: Office of Food Labeling


Guidelines for Determining Metric Equivalents of Household Measures (October 1, 1993) Source: Office of Food Labeling

Food Labeling—Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution Small Entity Compliance Guide (July 2001)

Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction (October 7, 2002)

Food Labeling—Serving Sizes Reference Amount for Baking Powder, Baking Soda, Pectin; Small Entity Compliance Guide (July 2001)

Whole Grain Label Statements (February 2006)

Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2) (December 14, 2005)

Food Processing Publications


Bacteriological Analytical Manual Online (2001)

Food and Cosmetic Security Publications

Entry Types and Entry Identifiers—Prior Notice of Imported Food (April 7, 2005)


Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2) (November 10, 2005)

What You Need to Know About Establishment and Maintenance of Records (December 2004)

What You Need to Know About Administrative Detention of Foods (November 2004)


Questions and Answers Regarding Registration of Food Facilities (Edition 4) (August 6, 2004)


Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance (December 17, 2003)

Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance (December 17, 2003)

What You Need to Know About Registration of Food Facilities (November 25, 2003)

What You Need to Know About Prior Notice of Imported Food Shipments (November 25, 2003)

Necessity of the Use of Food Product Categories in Registration of Food Facilities (July 17, 2003)

Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance (July 11, 2003)


See also: Compliance Policy Guides—Guidance for FDA Staff on enforcement of Registration of Food Facilities December 2003, Last Revised November 2004 and Prior Notice of Imported Foods December 2003, Last Revised November 2005

Imports and Exports Publications
CFSAN GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators (August 26, 2004) HTS Codes Revision History
What You Need to Know About Prior Notice of Imported Food Shipments (November 25, 2003)
Guidance for Industry and FDA: Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile (June 22, 2005)
Guidance for Industry: FDA Export Certificates (2002) (also available in PDF)
Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers (June 13, 1995)
See also: Compliance Policy Guides—Guidance for FDA Staff on Guidance Levels for Radionuclides in Domestic and Imported Foods July 2004

Infant Formula Publications

Frequently Asked Questions about FDA’s Regulation of Infant Formula (March 1, 2006)

Juice Publications

Letter to State Regulatory Agencies and Firms That Produce Treated (but not Pasteurized) and Untreated Juice and Cider (September 22, 2005)
Recommendations to Processors of Apple Juice or Cider on the Use of Ozone for Pathogen Reduction Purposes (November 2004)
The Juice HACCP Regulation: Questions and Answers (September 4, 2003)
Standardized Training Curriculum for Application of HACCP Principles to Juice Processing (June 2003)
Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices (April 24, 2002)
Juice HACCP Small Entity Compliance Guide (April 4, 2003)
Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction (October 7, 2002)
Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin (October 2001)
The Juice HACCP Regulation: Questions & Answers (August 31, 2001)
Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide (September 18, 1998)

Low-Acid and Acidified Foods Publications


Milk Sanitation Publications

Grade “A” Pasteurized Milk Ordinance 2003 Revision (March 2, 2004)
Grade “A” Pasteurized Milk Ordinance 2001 Revision (May 15, 2002)
Importation of PMO Defined Dairy Products (M–I–00–4) (April 11, 2000)
Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers (1999) Provides procedures for a national reciprocity milk program. Includes by-laws and constitution of the National Conference on Interstate Milk Shipments and the Memorandum of Understanding between the National Conference and FDA. Source: Milk Safety Branch
Dry Milk Ordinance (1995) Source: Milk Safety Branch
Pasteurized Milk Ordinance (1999) Source: Milk Safety Branch

Natural Toxins Publications

Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin (October 2001)
Fumonisin Levels in Human Foods and Animal Feeds (November 9, 2001)

Nutrition and Food Science Publications

FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases (March 1998) Generic instructions for developing and preparing an acceptable data base when valid estimates of nutrient content and variation are not available for the food (single or mixed products) to be labeled. Source: Office of Food Labeling
CFSAN GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

Guidelines for Determining Metric Equivalents of Household Measures (October 1, 1993) Source: Office of Food Labeling
List of Products for Each Product Category (October 8, 1992) Source: Office of Food Labeling
Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers (June 10, 1996) Source: Office of Food Labeling
Guidance on Labeling of Foods that Need Refrigeration by Consumers (February 24, 1997) 62 FR 8248 Source: Office of Food Labeling
Interim Guidance on the Voluntary Labeling of Milk and Milk Products that have not been treated with Recombinant Bovine Somatotropin (February 10, 1994) 59 FR 6279 Source: Office of Food Labeling

Produce Publications

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (October 26, 1998) (Also available in French, Spanish, Portuguese and Arabic) Source: Food Safety Initiative Staff
Draft Guidance: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (March 1, 2006)
Reducing Microbial Food Safety Hazards For Sprouted Seeds (October 1999) Source: Office of Plant and Dairy Foods and Beverages
Sampling And Microbial Testing Of Spent Irrigation Water During Sprout Production (October 1999) Source: Office of Plant and Dairy Foods and Beverages

Retail Food Protection Publications

A Notice from the Food and Drug Administration to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products on Decontamination of Transport Vehicles (October 7, 2005)
Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance (December 17, 2003)
Food Labeling—Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution Small Entity Compliance Guide (July 2001)

Sanitation Publications

Foods—Adulteration Involving Hard or Sharp Foreign Objects (February 1999) Compliance Policy Guide Chapter 5 Subchapter 555 Section 555.425
Defect Action Levels (DALS) (1995; Revised March 1997 and May 1998) Booklet. This list is compiled from FDA’s Compliance Policy Guides on established “current levels for natural or unavoidable defects in food for human use that present no health hazards.” Source: Industry Activities Staff
Action Levels for Poisonous or Deleterious Substances in Human Food and Feed (2000) Source: Industry Activities Staff

Seafood Publications

Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products (July 2001) Source: Office of Seafood
Letter to Various Seafood Trade Associations Regarding the Labeling of Catfish (February 28, 2003)

Small Entity Compliance Guides Publications

What You Need to Know About Establishment and Maintenance of Records (December 2004)
What You Need to Know About Registration of Food Facilities (November 25, 2003)
What You Need to Know About Prior Notice of Imported Food Shipments (November 25, 2003)
Juice HACCP Small Entity Compliance Guide (April 4, 2003)
Structure/Function Claims: Small Entity Compliance Guide (January 9, 2002)
Food Labeling—Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution Small Entity Compliance Guide (July 2001)

VI. Center for Veterinary Medicine (CVM)

For information on a specific guidance document or to obtain a hard copy, contact: Communications Staff, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–3800, http://www.fda.gov/cvm/guidance/published.htm. The following is a list of CVM guidance documents that have been withdrawn from January 5, 2005, to January 5, 2006.
The following is a copy of a list of current CVM guidance documents obtained from the FDA Web site as of March 14, 2006.

CVM GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)

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<th>Title of Document</th>
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<tr>
<td>#78 Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals</td>
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1. Anticoccidial Guidelines replaced by Guideline #40
3. General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals 06/21/05
5. Stability Guidelines 12/90
6. Guidelines for Submitting NADA’s for Generic Drugs Reviewed by NAS/NRC 10/20/71; rev. 03/19/76
7. Guidelines for Toxicological Investigations replaced by Guideline number 3
8. Preclinical Guidelines for Production Drugs Withdrawn pending revisions
9. Amendment of Section II(G)(1)(b)(4) of the Preclearance Guidelines 10/75
10. Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Free-Choice Feed revision of Medicated Block 01/85
13. FOI Summary Guideline 05/85
14. Working Guidelines for Assigning Residue Tolerances replaced by Guideline #3
16. 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
17. Guidelines for the Efficacy Evaluation of Swine Anthelmintics 09/80
18. Guidelines for the Effectiveness Evaluation of Topical/Otic Animal Drugs 03/84
19. Guidelines for Threshold Assessment replaced by Guideline number 3
22. Bioequivalence Guideline revised 10/09/02
23. Guidelines for Efficacy Evaluation of Canine/Feline Anthelmintics 07/85
24. Guidelines for Efficacy Evaluation of Poultry Feed for Pigmentation 03/84
25. Guidelines for Efficacy Evaluation of Topical/Otic Animal Drugs 03/84
32. Guideline for Threshold Assessment replaced by Guideline number 3
33. 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
34. New Animal Drug Determinations (see Policy and Procedures Guide 1240.3500) 07/89
36. Guidelines for the Effectiveness Evaluation of Bovine Anthelmintics 07/81
37. Guidelines for the Evaluation of Bovine Anthelmintics 07/81
38. Guidelines for the Evaluation of Bovine Anthelmintics 07/81
39. 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
40. Draft Guideline for the Evaluation of the Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry 04/92
42. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
43. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
44. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
45. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
46. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
47. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
48. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
49. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
50. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
51. Draft Guideline 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 (superseded by Guidance #61) 04/86; see also Guideline 61, below.
CVM GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

59. Guidance for Industry: How to Submit a Notice of Claimed Investigational Exemption in Electronic Format by E-Mail 01/17/06
60. Guidance For Industry: Animal Proteins Prohibited From Animal Feed; Small Entity Compliance Guide Replaced by Guidance 67, 68, 69, and 70
61. Guidance For Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species 04/99
66. Withdrawal of Guidance Document on Professional Flexible Labeling of Antimicrobial Drugs 01/02
67. Guidance for Industry: Small Entities Compliance Guide for Blender, Feed Manufacturers, and Distributors 02/98
68. Guidance for Industry: Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors 02/98
69. Guidance for Industry: Withdrawal of Guidance Document on Professional Flexible Labeling of Antimicrobial Drugs 01/02
70. Guidance for Industry: Small Entities Compliance Guide for Feeders of Ruminant Animals without On-Farm Feed Mixing Operations 02/98
71. Guidance for Industry: Use of Human Chorionic Gonadotropin (HCG) as a Spawning Aid for Fish Rescinded
72. Guidance For Industry: GMP’S For Medicated Feed Manufacturers Not Required to Register and be Licensed with FDA 05/98
76. Guidance For Industry: Questions and Answers BSE Feed Regulations 07/98
77. Guidance for Industry: Interpretation of On-Farm Feed Manufacturing and Mixing Operations: DRAFT GUIDANCE Withdrawn 06/12/03
78. Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals Replaced by Guidance 152
79. Guidance for Industry #79—Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM)—Final Guidance July 2005
80. Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds 11/21/02
81. Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs—Final Guidance 10/28/02
82. Guidance for Industry: Chemistry, Manufacturing, and Controls Changes to an Approved NADA or ANADA—DRAFT GUIDANCE 06/99
84. Guidance for Industry: Good Clinical Practices: VICH GL9, Final Guidance 05/09/01
86. Guidance for Industry—How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format by E-Mail 1/17/06
87. Guidance for Industry—How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format by E-Mail 01/17/06
88. Guidance for Industry—How to Submit a Request for a Meeting or Teletconference in Electronic Format by E-Mail 01/17/06
89. Guidance for Industry—Environmental Impact Assessments (EIA’s) For Veterinary Medicinal Products (VMP’s)—Phase I, VICH GL6: Final Guidance 03/07/01
91. Guidance for Industry—International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal products (VICH); Final Guidance on Stability Testing for Medicated Premixes (VICH GL8); Availability 03/00
92. Guidance for Industry #92: Impurities in New Veterinary Drug Substances (Revision), VICH GL10 ( R) , Draft Revised Guidance, January 5, 2006 01/05/06
93. Guidance for Industry #93—Impurities in New Veterinary Medicinal Products (Revised), Draft Revised Guidance—VICH GL11 ( R), January 10, 2006 01/10/05
94. Guidance for Industry: Efficacy Of Anthelmintics: Specific Recommendations for Bovines: VICH GL12, Final Guidance 03/26/01
95. Guidance for Industry: Efficacy Of Anthelmintics: Specific Recommendations for Ovines: VICH GL13, Final Guidance 03/26/01
96. Guidance for Industry: Efficacy Of Anthelmintics: Specific Recommendations for Caprines: VICH GL14, Final Guidance 03/26/01
97. Dioxin In Anti-Caking Agents Used In Animal Feed And Feed Ingredients Revised 04/14/00
98. Guidance for Industry: Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products—VICH GL17—Final Guidance 03/26/01
100. Guidance for Industry: Manufacture and Distribution of Unapproved Piperazine Products”—Revised 08/99
101. Guidance for Industry: Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports For Submission to the Division of Therapeutic Drugs for Non-Food Animals 07/10/01
102. Draft Guidance for Industry: Computerized Systems Used in Clinical Trials, Revision 1, Erratum, September 2004 09/04
103. The Use of Published Literature in Support of New Animal Drug Approval 08/31/00
104. Guidance for Industry: How to Submit a Protocol in Electronic Format by E-Mail 01/17/06
105. Guidance for Industry: How to Submit Information in Electronic Format by E-Mail 01/17/06
106. Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Equine—VICH GL15—Final Guidance 06/27/02
108. Guidance for Industry: Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports For Submission to the Division of Therapeutic Drugs for Non-Food Animals 07/10/01
110. Guidance for Industry: Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients: VICH GL18, Final Guidance 05/15/01
111. Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Canine—VICH GL19—Final Guidance 06/27/02
112. Guidance For Industry: Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM)—Final Guidance July 2005
113. Guidance for Industry: How to Submit Information in Electronic Format by E-Mail 01/17/06
114. Guidance for Industry: Efficacy Of Anthelmintics: Specific Recommendations for Poultry-Gallus Gallus—VICH GL21—Final Guidance 06/19/02
CVM GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

115. Guidance for Industry: Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies—VICH GL22—Final Guidance 01/03/02
116. Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Genotoxicity Testing—VICH GL23—Final Guidance 01/03/02
117. Guidance for Industry: Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)—VICH GL45—DRAFT GUIDANCE 12/12/00
118. Guidance for Industry: Mass Spectrometry for Confirmation of the Identity of Animal Drug Residues—Final Guidance 05/01/03
119. Guidance for Industry and Reviewers: How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug—Final Guidance 08/29/02
120. Guidance for Industry #120—Veterinary Feed Directive Regulation 03/01/01
121. Guidance for Industry #121: Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims 03/06/01
123. Guidance for Industry 123—Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-steroidal Anti-Inflammatory Drugs (NSAIDS) for Use in Animals, Final, January 5, 2006 01/05/06
124. Guidance for Industry # 124: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Biotechnology—Draft 01/17/01
127. Guidance for Industry: Validation of Analytical Procedures for Type C Medicated Feeds, Final 11/07/05
128. Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing, VICH GL28, Final Guidance 05/24/04
129. CVM Guidance for Industry #142: Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)—VICH GL29—Draft Guidance 12/12/01
130. CVM Guidance for Industry #143: Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms—VICH GL30—Draft Guidance 02/01/02
131. Guidance for Industry: Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food-Producing Animals with Respect to Antimicrobial Resistance—VICH GL27, Final Guidance 04/27/04
132. Bioanalytical Method Validation 05/01
133. Guidance for Industry 147—Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (90-Day) Toxicity Testing—VICH GL31, 11/12/03
134. Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Developmental Toxicity Testing—VICH GL32 Final Guidance 03/19/04
135. Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Testing VICH GL33 05/18/04
136. Guidance for Industry: Status of Clove Oil and Eugenol for Anesthesia of Fish 06/11/02
137. Guidance for Industry: FDA Export Certificates 07/04
139. Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals 09/02
142. Draft Guidance for Industry: Comparability Protocols—Chemistry, Manufacturing, and Controls Information; Availability 02/03
143. Guidance for Industry: Part 11, Electronic Records, Electronic Signatures—Scope and Application 08/03
144. Guidance for Industry—Use of Material from Deer and Elk in Animal Feed 09/15/03
145. Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI—VICH GL—36, Final Guidance 02/10/05
146. Guidance for Industry—Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Repeat-Dose (Chronic) Toxicity Testing, VICH GL—37—Final Guidance 02/07/05
147. Draft Guidance for Industry—Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information 09/03
150. Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations 10/03
151. Guidance for Industry—Environmental Impact Assessments (EIA’s) for Veterinary Medicinal Products (VMPs), Phase II, Final Guidance, VICH GL38, 01/09/06
152. Guidance for Industry: Prior Notice of Imported Food Questions and Answers 12/12/03
156. Guidance for Industry on Waivers of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles; Availability (Notice) 02/16/06
157. Guidance for Industry #172—Use of unapproved hormone implants in veal calves, April 2, 2004 Withdrawn 07/15/04
158. Guidance for Industry—Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA) Appendix 02/07/05
159. Guidance for Industry—Use of Material from BSE Positive Cattle in Animal Feed 09/30/03
VII. Office of the Commissioner/Office of Policy (OC/OP)

For information on a specific guidance document or to obtain a hard copy, contact:


No OC/OP guidance documents were withdrawn from January 5, 2005, to January 5, 2006.

The following is a copy of a list of current OC/OP guidance documents obtained from the FDA Web site as of March 14, 2006.

OC/OP GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)

Office of the Commissioner:

Draft Guidance: Using Electronic Means to Distribute Certain Product Information
Draft Guidance: Emergency Use Authorization of Medical Products
Conflict of Interest Disclosure Guidance
Small Business Guide to FDA
FDA Guidance—Financial Disclosure by Clinical Investigators, March 20, 2001
Guidance for FDA and Industry: Direct Final Rule Procedures (Federal Register Nov. 21, 1997)

Guidances and Information Sheets on Good Clinical Practice in FDA-Regulated Clinical Trials

Guidances
FDA Information Sheet Guidelines for Institutional Review Boards, Clinical Investigators, and Sponsors
Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection
Guidance for Industry: Acceptance of Foreign Clinical Studies
Guidance for Industry: Available Therapy
Guidance for Industry: Computerized Systems Used in Clinical Trials
Guidance for Industry: Development and Use of Risk Minimization Action Plans
Guidance for Industry Exploratory IND Studies
Guidance for Industry: Financial Disclosure by Clinical Investigators
Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies
Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
Guidance for Industry: Guideline for the Monitoring of Clinical Investigators
Guidance for Industry: Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs
Guidance for Industry on Handling and Retention of Bioavailability and Bioequivalence Testing Samples; Availability
Guidance for Industry: IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer
Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions
Guidance for Industry: IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations
Guidance for Industry on Part 11, Electronic Records—Electronic Signatures—Scope and Application
Guidance on Pharmacogenomic Data Submissions
Guidance for Premarketing Risk Assessment
Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
Guidance for Industry and Clinical Investigators on the Use of Clinical Holds Following Clinical Investigator Misconduct

ICH Guidances

ICH E3: Guideline for Industry Structure and Content of Clinical Study Reports
ICH E5: Ethnic Factors in the Acceptability of Foreign Clinical Data
ICH E6: Good Clinical Practice: Consolidated Guidance
ICH E10: Choice of Control Group and Related Issues in Clinical Trials

VIII. Office of Regulatory Affairs (ORA)

For information on a specific guidance document or to obtain a hard copy, contact: Office of Executive Operations, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, http://www.fda.gov/ora.

The following is a list of ORA guidance documents that have been withdrawn from January 5, 2005, to January 5, 2006.

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<td>CPG—Sec. 355.100 Cellutron Machine (CPG 7124.03)</td>
<td>May 31, 1990</td>
<td>March 10, 2005</td>
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<tr>
<td>CPG—Sec. 460.700 Controlled Release Dosage Form Drugs—Rate of Release of Active Ingredients (CPG 7132a.02)</td>
<td>January 1, 1973</td>
<td>August 19, 2005</td>
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**ORA GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)**

**Industry Assistance Reference**

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**ORA Science Reference**

Information related to the locations of the components, ORA laboratory, laboratory procedures, new techniques and useful analytical findings in support of FDA regulatory activities. ORA Science References are available for the following:

**TOTAL DIET AND PESTICIDE RESEARCH CENTER**—Information and materials relating to the FDA Total Diet Study Research.

**LABORATORY MANUAL 2004**—Agency policy for testing consumer products, training of laboratory staff, report writing, safety, research, review of private laboratory reports and court testimony. (Formerly: Laboratory Procedure Manual)

**LABORATORY INFORMATION BULLETINS**—Samples of collection of more than 3,000 bulletins describing new techniques and useful analytical findings by ORA laboratories in support of FDA regulatory activities.

**PRIVATE LABORATORIES**—Information concerning private laboratories and activities are included in this section.

**Revisions and Update List**

Recent:

<table>
<thead>
<tr>
<th>Date</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/08/2006</td>
<td>Revised list to add 1 new member, Restricted List for Clinical Investigators</td>
</tr>
<tr>
<td>02/09/2006</td>
<td>Updated the program contact person(s) information on the following pages: <a href="http://www.fda.gov/ora/compliance_ref/bimo/de-fault.htm">http://www.fda.gov/ora/compliance_ref/bimo/de-fault.htm</a> <a href="http://www.fda.gov/ora/compliance_ref/bimo/background.html">http://www.fda.gov/ora/compliance_ref/bimo/background.html</a> <a href="http://www.fda.gov/ora/compliance_ref/bimo/comparison_chart/pref-ace.html">http://www.fda.gov/ora/compliance_ref/bimo/comparison_chart/pref-ace.html</a></td>
</tr>
<tr>
<td>01/19/2006</td>
<td>Change in classification (Class)—Pine Acres Research Facility, Norton, MA</td>
</tr>
<tr>
<td>01/11/2006</td>
<td>Updated list to remove restriction for 1 member. Restricted List for Clinical Investigators</td>
</tr>
<tr>
<td>12/29/2005</td>
<td>Revised Restricted List for Clinical Investigators to add 1 new member</td>
</tr>
<tr>
<td>12/21/2005</td>
<td>Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990. Updated December 09, 2005 Edited list to correct typographical error in the initial of Dr. Farber on Disqualified/Totally Restricted List for Clinical Investigators Updated “FDA AIP Contacts List” (December 2005) on the Application Integrity Policy Information page</td>
</tr>
<tr>
<td>12/12/2005</td>
<td>Revised CPG Sec. 230.150—Blood Donor Classification Statement, Paid or Volunteer Donor Revised CPG Sec. 300.750—Class III Devices Subject to 515(b) Requirements (CPG 7124.18) Revoked CPG Sec. 460.700—Controlled Release Dosage Form Drugs—Rate of Release of Active Ingredients (CPG 7132a.02)</td>
</tr>
<tr>
<td>12/06/2005</td>
<td>Updated list to remove restriction for 1 member, 11/23/2005: Restricted List for Clinical Investigators</td>
</tr>
<tr>
<td>12/01/2005</td>
<td>Updated “FDA AIP Contacts List” (August 2005) on the Application Integrity Policy Information page</td>
</tr>
<tr>
<td>11/29/2005</td>
<td>Edited Compliance Policy Guides Sec. 160.100 and 118 pages in Chapter 5 to reflect FDA organization and contact changes.</td>
</tr>
<tr>
<td>11/18/2005</td>
<td>Added on-line link for compliance program 7385.014, Mammography Facility Inspections. Revised list to add 1 new member on Disqualified/Totally Restricted List for Clinical Investigators</td>
</tr>
<tr>
<td>11/14/2005</td>
<td>Revised list to add 1 new member, Disqualified/Totally Restricted List for Clinical Investigators</td>
</tr>
<tr>
<td>11/10/2005</td>
<td>Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002</td>
</tr>
<tr>
<td>11/03/2005</td>
<td>Revised list to remove one member from the Application Integrity Policy List</td>
</tr>
<tr>
<td>10/31/2005</td>
<td>Revised <a href="http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm">http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm</a> to add one person and update the list contact person. Also, the contact person was updated on: <a href="http://www.fda.gov/ora/compliance_ref/bimo/ausurlist.htm">http://www.fda.gov/ora/compliance_ref/bimo/ausurlist.htm</a> <a href="http://www.fda.gov/ora/compliance_ref/bimo/restlist.htm">http://www.fda.gov/ora/compliance_ref/bimo/restlist.htm</a></td>
</tr>
<tr>
<td>09/15/2005</td>
<td>Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990 Updated September 15, 2005</td>
</tr>
<tr>
<td>09/13/2005</td>
<td>Revised list to remove one member on the Application Integrity Policy List</td>
</tr>
<tr>
<td>08/08/2005</td>
<td>Revoked by Federal Register notice on 09/24/1998 (63 FR 51074), CPG Sec. 615.100 Extra-Label Use of New Animal Drugs in Food-Producing Animals (CPG 7125.06)</td>
</tr>
<tr>
<td>08/02/2005</td>
<td>Table for Veterinary Medicine compliance programs is updated to reflect on-line documents and/or information now supplied by the Center for Veterinary Medicine</td>
</tr>
<tr>
<td>07/18/2005</td>
<td>Re-numbered existing biologics compliance program 7341.002 “Inspection of Tissue Establishments” to 7341.002A and added new biologics compliance program 7341.002 “Inspection of Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps).”</td>
</tr>
<tr>
<td>5/31/2005</td>
<td>Draft revised CPG Sec. 480–200—Expiration Dating of Unit-Dose Repackaged Drugs (CPG 7132b.11) Notice of Availability Draft Guidance</td>
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<tr>
<td>05/20/2005</td>
<td>Revised list to add 1 new member, Restricted List for Clinical Investigators</td>
</tr>
<tr>
<td>05/19/2005</td>
<td>Revised CPG Sec. 315.100 Illegal Interstate Commercial Shipment of Dentures (CPG 7124.07)</td>
</tr>
<tr>
<td>05/17/2005</td>
<td>Revised list to add 1 new member, Restricted List for Clinical Investigators</td>
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</tbody>
</table>
ORA GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

05/05/2005: Added new biologics compliance program 7345.848 Inspection of Biological Drug Products, and removed four programs that the new program supersedes: 7341.001, 7342.006, 7345.001, and 7345.002.

04/25/2005 Revised CPG 100.700 GWQAP Pre-Award Evaluation—Inadequate Information to Evaluate Prospective Supplier

04/25/2005 Revised CPG 390.300 Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products

04/18/2005: Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990 Updated April 18, 2005

04/13/2005 Revised CPG Sec. 560.400 Imported Milk and Cream—Federal Import Milk Act CPG 7119.05

04/12/2005: Revised Debarment List, 04/12/2005—One person added.

04/11/2005: Revised list to add 3 new members, Restricted List for Clinical Investigators

03/23/2005 Revised list to add one new member; and remove one Application Integrity Policy List

03/15/2005 Revised CPG Sec. 100.050—Reprocessing of Single Use Devices (CPG 7124.16)

03/10/2005 Revised 8 CPGs to make corrections/minor changes: Sec. 390.100; Sec. 390.400; Sec. 393.100; Sec. 396.300; Sec. 398.100; Sec. 398.325; Sec. 398.425; Sec. 399.700;

03/10/2005 Revoked CPG: Sec. 355.100—Celloxtron Machine


03/08/2005: Revised list to add 2 new members, Restricted List for Clinical Investigators

03/04/2005: Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

02/18/2005: Draft revised CPG Sec. 310.210 “Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy (CPG 7124.23) FR Notice of Availability Draft Revision

02/01/2005: Revised list to add 1 new member, Restricted List for Clinical Investigators

01/14/2005: Revised list to add 1 new member, Disqualified/Totally Restricted List for Clinical Investigators

2004 Revisions and Updates:


11/18/2004 Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990 Updated November 18, 2004

11/16/2004 New CPG Sec. 400.210—Radiofrequency Identification Feasibility Studies and Pilot Programs

11/03/2004 Revised CPG Sec. 110.300—Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

11/02/2004 Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

10/29/2004 Draft CPG (Not for Implementation), Sec. 560.400 “Imported Milk and Cream—Federal Import Milk Act (CPG 7119.05).” When finalized it will replace the existing CPG at Sec. 560.400. Comments due 30 days after date of publication in the Federal Register dated October 29, 2004

10/03/2004 Revised list to add 1 new member, Disqualified/Totally Restricted List for Clinical Investigators

08/31/2004 Edited Debarment List—at Uddin, Mohammad, added “NMI” to indicate that FDA records show no middle initial for this person.

08/16/2004 Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

07/29/2004 Revised CPG Sec. 394.500—Importation of Television Products, Microwave Ovens, and Inherent Class I Laser Products for Investigation and Evaluation

07/29/2004 Replaced/Retitled CPG Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14)

07/23/2004 Updated links to FDA Regulations (2004) on the Bioresearch Monitoring Information Page; links to laws enforced by FDA and related regulation on the Welcome to Compliance References page

06/24/2004 Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

06/16/2004 AIP Procedures—procedures March 5, 1998

06/10/2004 Revised to update citations Sec. 690.300 Canned Pet Food (CPG 7126.18)

06/15/2004 Correction in classification (Class)—Charles River Laboratories, West Chester, OH

05/12/2004 John B. Najarian on Restricted List for Clinical Investigators


04/09/2004 Corrected entry for Arthur Riba on Restricted List for Clinical Investigators

04/05/2004 Revised Application Integrity Policy List to add Plus Orthopedics, San Diego, California.

3/12/2004 Revised to update content of August 2000 paper edition: Sec. 490.100 Process Validation Requirements for Drug Products and Active Pharmaceutical Ingredients Subject to Pre-Market Approval CPG 7132c.08

02/23/2004 Revised list to add 1 new member, 02/23/2004: Restricted List for Clinical Investigators; Revised list to add 1 new member, 02/23/2004: Disqualified/’Totally Restricted List for Clinical Investigators

02/13/2004 Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990 Updated February 9, 2004


Revoked 1/5/2004 Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse CPG 7124.06

2003 Revisions and Updates:

New CPG Sec. 110.310—“Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002” is available at: http://www.cfsan.fda.gov/~dms/cpgreg.html

Revised: Application Integrity Policy Committee Contact Persons list on 12/18/2003

Revised Application Integrity Policy List to add AGA Medical Corporation, Golden Valley, Minnesota


Revised Debarment List, 10/22/2003—One person added. Published 10/23/03.

Revised list to add 2 new members, 10/17/2003: Disqualified/Totaly Restricted List for Clinical Investigators. Published 10/21/03.

Revised Debarment List, 10/10/2003—debarment terminated for one person; three people added. Published 10/10/03.

Added pdf version of Guideline for the Monitoring of Clinical Investigations, Jan., 1988. Published 9/30/03.

Revised list to add 2 new members, 09/09/2003: Restricted List for Clinical Investigators. Published 09/10/03.

Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990, Updated 08/11/2003. Published 09/04/03.

Revised Debarment List, 8/8/2003—one person added. Published 8/15/03.

Revised Sec. 608.400—Compounding of Drugs for Use in Animals. Published 7/14/03.

Revised 3 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990. Updated 01/27/3. Published 7/2/03.

New CPGM link to Compliance Programs published by CBER: Inspection of Source Plasma Establishments and Inspections of Licensed Vaccines. Published 6/6/03.

Updated ORA page on Electronic Records/Signatures, 21 CFR Part 11. Published 6/6/03.

Revised Debarment List, 5/9/2003—one person added. Published 5/30/03.


Revised list to update Dr. J.L. Williams, 5/15/2003: Disqualified/Totaly Restricted List for Clinical Investigators. Published 5/23/03.

Replaced Reference: Good Laboratory Practice (GLP) Final Rule, 12/22/1978. Published 5/23/03.

Revised—Four Lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990, Updated 03/06/2003. Published 5/1/03.


Revised list to add new member, 04/10/2003: Disqualified/Totaly Restricted List for Clinical Investigators.

Revised Debarment List on 04/09/2003—One person removed (Hernandez, Delfina); One correction inserted (Lai, Elaine).

Revised: Application Integrity Policy Committee Contact Persons list. Updated 3/31/2003.

Revised 03/23/2003, HTML/online links changed for Biologics Compliance Programs 7342.006, 7342.008. and 7345.001 (CBER). No content was changed.


Revised list to add new member, 02/10/2003: Disqualified/Totaly Restricted List for Clinical Investigators.

Revised Debarment List on 01/13/2003—2 people added.

2002 Revisions and Updates

Revised list to add new member, 10/28/2002: Disqualified/Totaly Restricted List for Clinical Investigators.

Revised list to add new member, 10/22/2002: 1) Inactive Labs List and 2) Active Tox Labs List

Revised Debarment List on 12/03/2002—one person added

Typographical errors (1 per page) 11/27/2002: CPGuides Manual—Sec 555.425—Foods—Adulteration Involving Hard or Sharp Foreign Objects; and Sec. 515.350 Candy—Mixed with Trinkets and Sold in Vending Machines (CPG 7105.04)


Updated 11/14/2002: 4 Lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990

Revoked effective 11/12/2002: Sec. 398.475 Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17)

Revised 11/13/2002 Debarment List—3 people added

Revised 2 lists to add new or update member(s), 10/16/2002: Disqualified/Totaly Restricted List for Clinical Investigators and Restricted List for Clinical Investigators

Revised effective 10/07/2002, Sec. 300.700 Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30) per Federal Register, 09/05/2002 (67 FR 56850)


New—Four Lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990. Updated 08/2002

Revised list to add new member, 09/27/2002: Disqualified/Totaly Restricted List for Clinical Investigators

Revoked effective on 09/27/2002: Sec. 315.200 Status of Dental Supplies such as Denture Cleaners, Adhesives, Cushions, and Repair Materials as a Device or Cosmetic (CPG 7124.05) See 67 FR 45129, 07/08/2002

Revised list to add new member, 06/27/2002: Restricted List for Clinical Investigators

Revised list to add new member, 06/27/2002: Disqualified/Totaly Restricted List for Clinical Investigators

Reissued 05/28/2002, Sec. 460.200 Pharmacy Compounding

Revoked effective on 06/20/2002, Sec. 391.100 Advertisement Literature for High-Intensity Mercury Vapor Discharge Lamps (CPG 7133.13)

Revoked effective on 06/20/2002, Sec. 396.100 Applicability of the Sunlamp Performance Standard To UVA Tanning Products (CPG 7133.16)

Corrected 05/16/2002, Sec 575.100 Pesticide Residues...Heptachlor table

New CPG Sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor issued 05/07/2002

Revised BioResearch Monitoring Information references added or updated 05/16/2002

Revised Debarment List on 05/07/2002—person added

Revised Compliance Program Manual: three people removed. Published 03/06/2002

Revised Debarment List on 04/09/2002
ORA GUIDANCE DOCUMENTS (OBTAINED FROM THE FDA WEB SITE ON MARCH 14, 2006)—Continued

VALIDATION OF CLEANING PROCESSES (7/93)
DOSAGE FORM DRUG MANUFACTURERS—CGMP’S (10/93)
ORAL SOLID DOSAGE FORMS PRE/POST APPR. ISSUES (1/94)
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TOPICAL DRUG PRODUCTS (7/94)
ORAL SOLUTIONS AND SUSPENSIONS (8/94)

FOODS COSMETICS
ALLERGY INSPECTION GUIDE (April, 2001)
ASEPTIC PROCESSING AND PACKAGING FOR THE FOOD INDUSTRY
NUTRITIONAL LABELING AND EDUCATION ACT (NLEA) REQUIREMENTS (8/94–2/95)

COSMETIC PRODUCT MANUFACTURERS (2/95)

COMPUTERIZED SYSTEMS IN THE FOOD PROCESSING INDUSTRY

GUIDE TO INTERNATIONAL INSPECTIONS AND TRAVEL

INTERNATIONAL INSPECTIONS AND TRAVEL

GOURMET PRODUCT MANUFACTURERS

INTERSTATE CARRIERS AND SUPPORT FACILITIES (4/95)

DAIRY PRODUCT MANUFACTURERS (4/95)

MISCELLANEOUS FOOD PRODUCTS—VOL. 1 (5/95)
MISCELLANEOUS FOOD PRODUCTS—VOL. 2 (9/96)
LOW ACID CANNED FOOD MANUFACTURERS Part 1—ADMINISTRATIVE PROCEDURES/SCHEDULED PROCESSES
LOW ACID CANNED FOOD MANUFACTURERS Part 2—PROCESSES/PROCEDURES
LOW ACID CANNED FOOD MANUFACTURERS Part 3—CONTAINERS/CLOSURES (11/98)

ACIDIFIED FOOD MANUFACTURERS

TRACEBACK OF FRESH FRUITS AND VEGETABLES IMPLICATED IN EPIDEMIOLOGICAL INVESTIGATIONS

SALMONELLA ENTERITIDIS (SE) GUIDE TO TRACEBACK IN EGGS (07/03/2003)

MISCELLANEOUS

FOREIGN MEDICAL DEVICE MANUFACTURERS (9/95)
FOREIGN PHARMACEUTICAL MANUFACTURERS (5/96)


Guide to International Inspections and Travel—Procedure manual for FDA personnel performing inspections and other FDA-related activities abroad.

Inspection Technical Guides—Guidance documents that provide FDA personnel with technical background in a specific piece of equipment, or a specific manufacturing or laboratory procedure, or a specific inspectional technique, etc.

1. Introductory IssueAll Programs 1/20/72
2. Steam Generation in Canneries Food Canneries 2/11/72
3. Steam Distribution for Retort Venting in Food Canneries Food Canneries 3/03/72
5. Ethylene Oxide Sterilization 1. Calculation of Initial Gas Concentration Drugs, Sterile Devices 6/09/72
7. Sterilizing Symbols (D, Z, F) Low Acid Canned Foods 1/09/72
8. “Package Unit” Italian Flour Mills Cereal Flours & Related Products 12/14/72
9. Polariscoppe Sterile Packaging—Foods, Drugs, Devices, Hardened Lenses 5/21/73
10. Diathermy Medical Devices 5/21/73
11. Steam Pressure for Retorts and Autoclaves Sterile Drugs and Devices Low Acid Canned Foods, Biologics 6/29/73
12. Stroboscope Food, Drug, Device, Manufacture and Packaging 8/08/73
13. Field Submission of Articles All Programs 9/05/73 (8/03/84 Revised)
14. Thermocouple Surface Pyrometers Food Canneries 12/20/73
15. Common Valves Used in Process Fluid Systems Sterile Drugs, Devices, Low Acid Canned Foods and Biologics 1/15/74
16. A.T.I. Steam Activated Heat Sensitive Indicators Food, Drugs, Medical Devices 3/08/74
17. New Source of Lead and Other Contamination Various Foods and Drugs 6/18/74
18. Ultrasound in the Food, Drug, and Device Industries Food, Drugs, and Medical Devices 3/03/75
19. Screening Electronic Components Medical Devices 4/20/75
20. Hermetically Sealed Electronic Component Leak Detection Medical Devices 7/18/75
21. Noise Control Mufflers for Bleeders on Retorts and Sterilizers Food, Drugs 9/15/75
22. Ground Fault Circuit Interrupter All Programs, Personnel Safety 3/05/76
23. The Computer in FDA Regulated Industries Foods, Drugs, and Medical Devices 5/21/76
24. Air Velocity Meters Sterile Drugs and Devices, Foods and Cosmetics 7/30/76
25. Ethylene Oxide Sterilization 2. Graphical Aid to Determine Gas Concentration Sterile Devices, Drugs 9/01/76
26. Evaluation of Production Cleaning Processes for Electronic Medical Devices—Part I, Contaminants Medical Devices 1/07/77
27. Evaluation of Production Cleaning Processes for Electronic Medical Devices—Part II, Cleaning Solvents Medical Devices 1/07/77
28. Evaluation of Production Cleaning Processes for Electronic Medical Devices—Part III, Methods Medical Devices 1/07/77
29. The Computer in FDA Regulated Industries—Part II Computer Hardware All Programs 9/22/77
30. The Nation is Going Metric (rescinded) All Programs 12/02/77
31. Electronic Components—Resistors Medical Devices, Radiological Health 1/16/78
32. Pyrogens, Still a Danger Parenterals, Biologicals, Devices, Drugs 1/12/79
34. Heat Exchangers to Avoid Contamination Drugs, Diagnostic Products Biologics 7/31/79
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37. Temperature Sensors in the Regulated Industry Foods, Drugs, Biologics, Medical Devices and Diagnostic Products 1/7/83
38. Industrial Applications of New Biochemical Technology All Programs 8/1/83
39. Water Activity (a) in Foods Foods 4/16/84
40. Bacterial Endotoxins/Pyrogens Drugs and Devices 3/20/85
41. Expiration Dating and Stability Testing for Human Drug Products Drugs 10/18/85

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The primary sponsors of this meeting are the NIH Office of Dietary Supplements and the NIH Office of Medical Applications of Research. Advance information about the conference and conference registration materials may be obtained from American Institutes for Research of Silver Spring, Maryland, by calling 888-644-2667, or by sending e-mail to consensus@mail.nih.gov. American Institutes for Research’s mailing address is 10720 Columbia Pike, Silver Spring, MD 20901. Registration information is also available on the NIH Consensus Development Program Web site at http://consensus.nih.gov.

Please note: The NIH has recently instituted new security measures to ensure the safety of NIH employees and property. All visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the new security measures at NIH, please visit the Web site at http://www.nih.gov/about/visitorsecurity.htm.

Raynard S. Kington,
Deputy Director, National Institutes of Health.
[FR Doc. E6–4437 Filed 3–27–06; 8:45 am]