
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In the Federal Register of November 20, 2001 (66 FR 58151), FDA announced the availability of the draft guidance entitled “Guidance for Clinical Trial Sponsors on the Establishment and Operation of Clinical Trial Data Monitoring Committees” dated November 2001. FDA received a number of comments on the draft guidance and considered those comments carefully as the guidance was finalized.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(n)(2), FDA stated that it intended to publish an annual comprehensive list of guidance documents. The list in this document updates a comprehensive list that published 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 guidelines that have been withdrawn from January 5, 2005, to January 5, 2006. The list of current guidance documents is a printout 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 guidances or, where applicable, the last date we revised a document. Because each issuing Center or Office maintains its own database, there are slight variations in the way in which they provide 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: STB 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 Review 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
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 SB Immunotoxicity Studies for Human Pharmaceuticals—2/7/2005

2004

International Conference on Harmonisation (ICH); Guidance for Industry: M4: 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 MDUFMA—11/17/2004
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)s)—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


International Conference on Harmonisation (ICH); Guidance for Industry: E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs—11/1/1996


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

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
<table>
<thead>
<tr>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidance for Industry: Providing Submissions in Electronic Format—General Considerations—1/28/1999</td>
</tr>
<tr>
<td>Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion—9/22/2003</td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>Question and Answer on FDA Guidance Entitled &quot;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&quot;—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.</td>
</tr>
<tr>
<td>Draft Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices—7/24/2003</td>
</tr>
<tr>
<td>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</td>
</tr>
<tr>
<td>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)</td>
</tr>
<tr>
<td>Questions and Answers on FDA Guidance Entitled &quot;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&quot;—6/14/2002</td>
</tr>
</tbody>
</table>
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


REVISED Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA) / Establishment License Application (ELA) and New Drug Application (NDA)]—11/12/1999, REVISED 11/22/1999

CBER Computer Assisted License Application (CALA) Questionnaire


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) Quaranline and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV), (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV)—6/17/1999

FEDERAL REGISTER Notice of Availability—6/22/1999


Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls 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 Antitibiotic 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: Content and Format 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 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


Guidance For the Submission of Chemical, Manufacturing and Controls Information and Establishment Description for Autologous Somatic Cell Therapy Products—1/10/1997

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


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

FDA 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

III. Center for Drug Evaluation and Research (CDER)

For information on a specific guidance document or to obtain a hard copy, contact: Division of Drug Information, Office of Training and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573, http://www.fda.gov/cder/guidance/index.htm.

The following is a list of CDER 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>
<tbody>
<tr>
<td>Preclinical Development of Antiviral Drugs</td>
<td>11/1/1990</td>
<td>7/6/2005</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>Phenytoin/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>
</tr>
<tr>
<td>Organization of an Abbreviated New Drug Application</td>
<td>3/2/1999</td>
<td>11/18/2005</td>
</tr>
</tbody>
</table>

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: Guidelines 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 2/2001, 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)
Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice Posted 9/29/2004

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

Current Good Manufacturing Practice for Combination Products (Posted 9/29/2004)
INDs—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

Container Closure Systems for Packaging Human Drugs and Biologics (Issued 5/1999, Posted 7/6/1999)
Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products
Drug Master Files (9/1/1989)
Current DMF Information (e.g. lists, addresses, guidances, etc.)
Drug Master Files for Bulk Antibiotic Drug Substances (Issued 11/1999, Posted 11/26/1999)
Environmental Assessment of Human Drug and Biologics Applications (Issued 7/1998, Posted 7/24/98)
Format and Content for the CMC Section of an Annual Report (9/1/1994)
INDs for Phase 2 and Phase 3 Studies Chemistry, Manufacturing, and Controls Information (Posted 5/20/2003)
The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) (12/20/2000)
SUPAC-IR Questions and Answers about SUPAC-IR Guidance (2/18/1997)
SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes; Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation
SUPAC-SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation
Reviewer Guidance, Validation of Chromatographic Methods
Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products
Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substances
Submitting Samples and Analytical Data for Methods Validation
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances

Chemistry (Draft)

Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (Posted 9/11/2003)
Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations (7/24/1999)

Clinical/Antimicrobial

Clinical Evaluation of Anti-Infective Drugs (Systemic) (Issued 9/77, Posted 3/2/1998)

Clinical/Antimicrobial (Draft)

Acute or Chronic Bacterial Prostatitis—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Evaluating Clinical Studies Of Antimicrobials In The Division Of Anti-Infective Drug Products (2/18/1997)
Role of HIV Drug Resistance Testing In Developing Antimicrobial Drugs Development (Issued 11/26/04, Posted 11/26/04)

Clinical/Medical

Acceptance of Foreign Clinical Studies (Posted 3/12/2001)
Available Therapy (Posted 7/22/2004)
Calcium DTPA and Zinc DTPA Drug Products—Submitting a New Drug Application (Posted 8/13/2004)
Cancer Drug and Biological Products—Clinical Data in Marketing Applications (Posted 10/11/2001)
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (Issued 1/1999, Posted 2/16/1999)
Clinical Evaluation of Analgesic Drugs (Withdrawn per August 5, 2003, Federal Register Notice)
Clinical Evaluation of Antacid Drugs (Withdrawn per July 20, 2004, Federal Register notice.)
Clinical Evaluation of Anti-Inflammatory and Antirheumatic Drugs (adults and children)
Clinical Evaluation of Antidepressant Drugs (Issued 9/77, Posted 3/2/1998)
Clinical Evaluation of Antihypertensive Drugs (Withdrawn per July 20, 2004, Federal Register notice.)
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs (Withdrawn per July 20, 2004, Federal Register notice.)
Clinical Evaluation of Laxative Drugs (Withdrawn per July 20, 2004, Federal Register notice.)
Clinical Evaluation of Local Anesthetics (Posted 3/2/1998)
Clinical Evaluation of Radiopharmaceutical Drugs (Withdrawn per July 20, 2004, Federal Register notice.)
Collection of Race and Ethnicity Data in Clinical Trials (Issued 9/16/2005, Posted 9/16/2005)
Content and Format for Pediatric Use Supplements
Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products
Developing Medical Imaging Drug and Biological Products

FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer (Posted 3/2/1998)
FDA Requirements for Approval of Drugs to Treat Superficial Bladder Cancer (Withdrawn per July 20, 2004, Federal Register notice.)
General Considerations for the Clinical Evaluation of Drugs
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (Revised 1/15/2004, Posted 1/15/2004)
Levothyroxine Sodium Tablets—In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing (Issued 2/2001, Posted 3/8/2001)
Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer (Posted 3/2/1998)
Oncologic Drugs Advisory Committee Discussion on FDA Requirements or Approval of New Drugs for Treatment of Colon and Rectal Cancer (Posted 3/2/1998)
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)
Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)) (Posted 12/1/2000)

Clinical Pharmacology

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

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/electd.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 Bulk 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 under 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 12/1998, Posted 1/26/1999)
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 I (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

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 7/2001, 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 3/4/05)
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
E7 Studies in Support of Special Populations: Geriatrics
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 9/1999, Posted 12/14/2001)

International Conference on Harmonisation (Draft)

Efficacy
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 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 356h
Sample formats for chemistry, manufacturing, and controls sections
Sample formats for labeling
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 Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease Evaluation of Drug Toxicity Prior to Phase I Clinical Studies (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 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)
Levothyroxine 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)
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 controls 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 9/2001, Posted 9/5/2001)

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.
<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Date of Issuance</th>
<th>Date of Withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guidance for Industry; In Vitro Diagnostic C-Reactive Protein Immunological Test System</td>
<td>July 20, 1998</td>
<td>September 22, 2005</td>
</tr>
<tr>
<td>Guidance for Over-the-Counter (OTC) Ovulation Predictor 510(k)s</td>
<td>July 22, 2000</td>
<td>September 7, 2005</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>CDRH Interim Regulatory Policy for External Penile Rigidity Devices</td>
<td>September 10, 1997</td>
<td>January 2005</td>
</tr>
<tr>
<td>Guidance for Neurological Embolization Devices</td>
<td>November 1, 2000</td>
<td>January 2005</td>
</tr>
<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>
</tr>
<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>
</tr>
<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>
</tr>
</tbody>
</table>

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 1000) 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 1002.10 251 09/01/1985
(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 07/26/2001
(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
CDR Guidance Documents (Obtained from the FDA Web Site on March 14, 2006)—Continued

(31) Reporting Guide for Product Reports on High Intensity Mercury Vapor Discharge Lamps (21 CFR 1002) 348 09/01/1995
(32) Reporting of New Model Numbers to Existing Model Families 675 06/14/1983
(34) Suggested State Regulations for Control of Radiation—Volume II Nonionizing Radiation—Lasers (FDA Pub No. 83–8220) 70 01/01/1982
(36) Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products; Guidance for Industry and FDA CBER 1201 02/25/2003
(37) Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002—Identification of Manufacturer of Medical Devices—Draft Guidance for Industry and FDA Staff CBER 1217 06/23/2003
(38) Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals CBER 09/06/2002
(39) Guidance for Industry: FDA Export Certificates CBER 1417 07/12/2004
(40) “Help-Seeking” and Other Disease Awareness Communications by or on behalf of Drug and Device Firms - Draft Guidance for Industry CBER CDER CDRH 02/10/2004
(41) Bundling Multiple Devices or Multiple Indications in a Single Submission—Guidance for Industry and FDA Staff CBER CDRH 1215 11/26/2003
(45) Guidance for Industry and FDA Staff—Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use CBER CDRH 4444 11/30/2004
(47) Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA—Guidance for Industry and FDA Staff CBER CDRH 1303 11/17/2004
(48) User Fees and Refunds for Premarket Approval Applications—Guidance for Industry and FDA Staff CBER CDRH 1224 11/24/2003
(49) User Fees and Refunds for Premarket Notification Submissions (510(k)s)—Guidance for Industry and FDA Staff CBER CDRH 1511 05/28/2004
(50) Acceptance of Foreign Clinical Studies; Guidance for Industry CBER 03/13/2001
(51) Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis CDER 2199 07/07/1999
(53) Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds Developing Products for Treatment CDER 06/01/2000
(54) Guidance for Industry; Collection of Race and Ethnicity Data in Clinical Trials CDER 09/01/2005
(55) Part 11, Electronic Records; Electronic Signatures—Scope and Application CDER 09/05/2003
(57) Alternative to Certain Prescription Device Labeling Requirements OC 1150 01/21/2000
(58) Civil Money Penalty Policy OC 1124 06/08/1999
(59) Classification Names for Medical Devices and In Vitro Diagnostic Products (FDA Pub No. 95–4246) OC 10 03/01/1995
(60) Color Additive Petitions (p. II–19 of PMA Manual) OC 296 06/01/1987
(61) Color Additive Status List (Inspection Operations Manual) OC 268 02/01/1989
(62) Commercial Distribution/Exhibit Letter OC 246 04/10/1992
(63) Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturer on Single-Use Devices—Draft Guidance for Industry and FDA Staff OC 1217 10/11/2005
(64) Consumer-Directed Broadcast Advertising of Restricted Devices OC 1513 02/10/2004
(65) FDA Guide for Validation of Biological Indicator Incubation Time OC 283 01/01/1986
(66) General Principles of Software Validation; Final Guidance for Industry and FDA Staff OC 938 01/11/2002
(68) Guideline for the Monitoring of Clinical Investigations OC 428 01/01/1998
(70) Letter to Medical Device Manufacturer on Pentium processors OC 456 02/14/1995
(71) Medical Device Tracking—Guidance for Industry and FDA Staff OC 169 05/05/2003
(72) Preproduction Quality Assurance Planning: Recommendations for Medical Device Manufacturers (FDA 90–4236) OC 295 09/01/1989
(73) Sec. 300.600 Commercial Distribution with Regard to Premarket Notification [Section 510(k)] [CPG 7124.19] OC 181 09/24/1987
(74) Sterile Convenience Kits for Clinical and Surgical Use; Final Guidance for Industry OC 1390 01/07/2002
(75) User Labeling for Devices that Contain Natural Rubber (21 CFR 801.437); Small Entity Compliance Guide; Guidance for Industry OC 1212 04/01/2003
(76) Draft Guidance for Industry on Endoscopy and Laparoscopy Accessories (Galdi) OC/DE1 545 05/17/1993
(77) Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi) OC/DE1 545 05/17/1993
(78) Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi) OC/DE1 545 05/17/1993
(79) Letter to Medical Device Industry on Endoscopy and Laparoscopy Accessories (Galdi) OC/DE1 545 05/17/1993
(80) All U.S. Condom Manufacturers, Importers and Repackers OC/DE2 291 04/07/1987
(81) Condoms: Inspection and Sampling at Domestic Manufacturers and of all Repackers; Sampling from all Importers (Damska Memo to Field on 4/8/87) OC/DE2 293 04/08/1987
(82) Dental Handpiece Sterilization (Dear Doctor Letter) OC/DE2 589 09/28/1992
(83) Draft Guidance for Industry on Surveillance and Detention Without Physical Examination of Condoms OC/DE2 1139 08/14/2000
(84) Ethylene Oxide; Ethylene Chlorohydrin; and Ethylene Glycol; Proposed Maximum Residue Limits and Maximum Levels of Exposure OC/DE2 1019 06/23/1978
CDR Guidance documents (obtained from the FDA web site on March 14, 2006)—Continued

(250) Policy Development and Review Procedures #190–1 (blue book memo) ODE 368 02/15/1990

(251) Premendment Class III Devices ODE 584 03/11/1992

(252) Premamendments Class III Strategy ODE 611 04/19/1994


(254) Premarket Approval Application Modular Review—Guidance for Industry and FDA Staff ODE 855 11/03/2003


(256) Premarket Notification [510(k)] Status Request Form ODE 858 03/07/1994

(257) Procedures for Class II Device Exemptions from Premarket Notification Guidance for Industry and CDRH Staff; Final ODE 159 02/19/1998

(258) Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities ODE 1198 09/03/1996

(259) Real-Time Review Program for Premarket Approval Application (PMA) Supplements ODE 673 04/22/1997


(262) Shelf Life of Medical Devices ODE 415 04/01/1991

(263) SMDA Changes—Premarket Notification; Regulatory Requirements for Medical Devices (510k) Manual Insert ODE 655 04/17/1992

(264) Substantial Equivalence (SE) Decision Making Documentation ATTACHED: ‘SE’ Decision Making Process (Detailed) i.e. the decision making tree ODE 390 01/01/1990

(265) Suggested Content for Original IDE Application Cover Letter ODE 797 02/27/1996

(266) Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA ODE 1195 11/02/2000

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(313) Guidance for 510(k) Submissions for Implanted Infusion Ports ODE/DAGID/GHDB 392 10/01/1990
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(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
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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
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(366) Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Electromyograph Needle Electrodes ODE/DGRND/GSDB 325 07/26/1995


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

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(424) Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA ODE/DOED/ENTB 1414 11/07/2000


(426) Implantable Middle Ear Hearing Device; Guidance for Industry and FDA ODE/DOED/ENTB 1406 08/01/2003


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(433) Guidance for Premarket Submissions of Orthokeratology Rigid Gas Permeable Contact Lenses; Final ODE/DOED/VEDB 1134 04/10/2000

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(497) Guidance for Industry and FDA Staff; Replacement Reagent and Instrument Family Policy OIVD 950 12/11/2003

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V. Center for Food Safety and Applied Nutrition (CFSAN)


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

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

Recently Issued 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. PB95–920500 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
Guidance for Small Businesses: Submission of Comments for CFSAN Rulemaking
Regulatory Procedures Manual (August 1997) Contains directives for recalls, legal actions, and cooperative agreements with states, such as those under the Public Health Service. Order No. PB95–265534 Source: National Technical Information Service

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)
Channels of Trade Policy for Commodities with Vinclozolin Residues (June 12, 2002)
FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments for Cry9C Protein Residues (January 19, 2001)
Channels of Trade Policy for Commodities with Methyl Parathion Residues (December 2000)
Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed (2000) Booklet. Lists allowable action levels for contaminants in food and feed. Source: Industry Activities Staff
Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers (June 13, 1995)
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)
Source: Industry Activities Staff
Source: Office of Nutritional Products, Labeling & Dietary Supplements
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

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)
Describes requirements for chemistry data needed to support food additive and GRAS petitions for the preparation of enzymes used in processing food.
Source: Office of Premarket Approval
Submitting Requests under 21 CFR 170.39 Threshold of Regulation for Substances used in Food Contact Articles (April 2005)
Lists the information that should be submitted to FDA when requesting that the agency review a specific use of a food contact article to determine whether its components will require regulation as a food additive.
Source: Office of Premarket Approval
Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations (December 1992)
This document provides assistance to manufacturers of food packaging in evaluating processes for producing packaging from post-consumer recycled plastic.
Source: Office of Premarket Approval
Frequently Asked Questions about Generally Recognized as Safe (GRAS) (December 2004)
Source: Office of Food Additive Safety
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)
Describes the types of chemistry data necessary for supporting petitions for regulations of direct food additives such as synthetic sweeteners, and preservatives; or the affirmation of the use of food ingredients as generally recognized as safe (GRAS) such as sucrose, and many enzymes used in food processing.
Source: Office of Premarket Approval
Pre-Claim Guidance for Industry and Center for Food Safety and Applied Nutrition Staff (January 1997)
Source: Office of Premarket Approval
Guidelines for the Preparation of Petition Submissions (1996)
Source: Office of Premarket Approval
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)
Source: Office of Premarket Approval
Estimating Exposure to Direct Food Additive and Chemical Contaminants in the Diet (September 1995)
Source: Office of Premarket Approval
Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as Redbook I) (1982)
Source: National Technical Information Service (NTIS)
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.
Toxicological Testing of Food Additives (1983)
Source: Office of Premarket Approval
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)
Source: Office of Premarket Approval
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
Source: Office of Premarket Approval
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 WEBSITE ON MARCH 14, 2006)—Continued

### Food Labeling Publications

<table>
<thead>
<tr>
<th>Publication</th>
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<tbody>
<tr>
<td>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</td>
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<tr>
<td>Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006 (December 30, 2005)</td>
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<td>Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003)</td>
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<td>Small Business Food Labeling Exemption (June 1996) Information sheet and sample small business exemption application form. Source: Industry Activities Staff</td>
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<tr>
<td>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</td>
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<td>Structure/Function Claims: Small Entity Compliance Guide (January 9, 2002)</td>
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<td>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</td>
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<td>Food Labeling—Serving Sizes Reference Amount for Baking Powder, Baking Soda, Pectin; Small Entity Compliance Guide (July 2001)</td>
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<td>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)</td>
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### Food Processing Publications

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### Food and Cosmetic Security Publications

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<tr>
<td>Entry Types and Entry Identifiers—Prior Notice of Imported Food (April 7, 2005)</td>
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<tr>
<td>Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2) (November 10, 2005)</td>
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<tr>
<td>What You Need to Know About Establishment and Maintenance of Records (December 2004)</td>
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<td>What You Need to Know About Administrative Detention of Foods (November 2004)</td>
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<td>Questions and Answers Regarding Registration of Food Facilities (Edition 4) (August 6, 2004)</td>
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<td>Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance (December 17, 2003)</td>
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<td>Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance (December 17, 2003)</td>
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<td>What You Need to Know About Registration of Food Facilities (November 25, 2003)</td>
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<td>What You Need to Know About Prior Notice of Imported Food Shipments (November 25, 2003)</td>
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<tr>
<td>Necessity of the Use of Food Product Categories in Registration of Food Facilities (July 17, 2003)</td>
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<tr>
<td>Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance (July 11, 2003)</td>
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<tr>
<td>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</td>
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### Imports and Exports Publications

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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
Certification of Fish and Fishery Products for Export to the European Union and European Free Trade Association (November 2004)
Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association (November 2004)
Implementation of Section 403(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(t)) Regarding the Use of the Term “Catfish” (December 2002)
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)
Food Labeling—Serving Sizes Reference Amount for Baking Powder, Baking Soda, Pectin; Small Entity Compliance Guide (July 2001)
Source: Industry Activities Staff

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.
<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Date of Issuance</th>
<th>Date of Withdrawal</th>
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<tbody>
<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>
<td>12/1999</td>
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The following is a copy of a list obtained from the FDA Web site as of March 14, 2006.

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

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. Animal Drug Applications replaced by Guideline number 3
8. Guidelines for Toxicological Investigations replaced by Guideline number 3
9. Preclearance Guidelines for Production Drugs Withdrawn pending revisions
10. Amendment of Section II(G)(1)(b)(4) of the Preclearance Guidelines 10/75
11. Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Free-Choice Foods revision of Medicated Block 01/85
14. FOI Summary Guideline 05/85
15. Working Guidelines for Assigning Residue Tolerances replaced by Guideline #3
20. Nutritional Ingredients in Animal Drugs and Feeds Nutritional Ingredients in Animal Drugs and Feeds (see Policy and Procedures Guide 1240.3420) rev. 03/93
21. Nutritional Ingredients in Animal Drugs and Feeds Nutritional Ingredients in Animal Drugs and Feeds (see Policy and Procedures Guide 1240.3420) rev. 03/93
22. 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 (superceded by Guidance #61) 04/86; see also Guidance 61, below.
27. 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 (superceded by Guidance #61) 04/86; see also Guidance 61, below.
32. Guidelines for the Efficacy Evaluation of Equine Anthelmintics Replaced by Guidance 109
33. Guidelines for the Efficacy Evaluation of Equine Anthelmintics Replaced by Guidance 109
34. Biomass Guideline—Guideline for New Animal Drugs and Food Additives Derived From a Fermentation; Human Food Safety Evaluation replaced by Guideline number 3
35. Bioequivalence Guideline revised 10/09/02
36. Guidelines for Efficacy Evaluation of Canine/Feline Anthelmintics 07/85
37. Guidelines for Efficacy Evaluation of New Animal Drugs for Use in Poultry Feed for Pigmentation 03/84
38. Guidelines for Efficacy Evaluation of Topical/Otic Animal Drugs 03/84
40. Draft Guideline for the Evaluation of the Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry 04/92
42. Series of four guidelines entitled “Animal Drug Manufacturing Guidelines” 1994
43. Draft Guideline for Generic Animal Drug Products Containing Fermentation-Derived Drug Substances 10/95
44. Draft Guideline for Generic Animal Drug Products Containing Fermentation-Derived Drug Substances 10/95
45. Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle 08/93
46. Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle 08/93
49. Draft Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products 02/93
50. Points to Consider Guideline—Development of a Pharmacokinetic Guideline Enabling Flexible Labeling of Therapeutic Antimicrobials
   “Please see Guidance 66 for updated information.”
51. Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora, February 18, 2004
52. Draft Guideline for the Evaluation of the Utility of Food Additives in Diets Fed to Aquatic Animals 05/94
53. Draft Guideline for the Evaluation of the Utility of Food Additives in Diets Fed to Aquatic Animals 05/94
54. Draft Guideline for the Evaluation of the Utility of Food Additives in Diets Fed to Aquatic Animals 05/94
55. Supportive Data for Cat Food Labels Bearing “Reduces Urinary pH Claims: Guideline in Protocol Development 06/94
56. Protocol Development Guidance for Clinical Effectiveness and Target Animal Safety Trials 07/10/01
57. Master Files: Guidance for Industry for the Preparation and Submission of Veterinary Master Files 1995
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
68. Guidance for Industry: Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors 02/98
69. Guía de la FDA para la Industria Número 68: Para Mezcladores de Proteínas, Fabricantes de Alimentos para Animales y Distribuidores 02/08
70. Guía de la FDA para la Industria Número 69: Para Alimentadores de Animales Rumiantes con Operaciones de Mezclado de Alimentos en la Granja 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
83. Guidance for Industry: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling: DRAFT GUIDANCE 03/00
84. Guidance for Industry: Good Clinical Practices: VICH GL9, Final Guidance 05/09/01
85. Guidance for Industry—How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Form by E-Mail 1/17/06
86. Guidance for Industry—How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Form by E-Mail 01/17/06
87. Guidance for Industry—How to Submit a Request for a Meeting or Teleconference in Electronic Form by E-Mail 01/17/06
88. Guidance for Industry—How to Submit Information in Electronic Format by E-Mail 01/17/06
89. Guidance for Industry—How to Submit Information in Electronic Format by E-Mail 1/17/06
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: Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients: VICH GL18, Final Guidance 05/15/01
102. Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products 08/99
103. Guidance for Industry: Contention 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
104. Draft Guidance for Industry: Computerized Systems Used in Clinical Trials, Revision 1, Erratum, September 2004 09/04
105. The Use of Published Literature in Support of New Animal Drug Approval 08/31/00
106. Guidance for Industry: How to Submit a Protocol in Electronic Format by E-Mail 01/17/06
107. Guidance for Industry: How to Submit Information in Electronic Format by E-Mail 01/17/06
108. Guidance for Industry: How to Submit Information in Electronic Format by E-Mail 1/17/06
110. Guidance for Industry #110: Effectiveness of Anthelmintics: Specific Recommendations for Porcine—VICH GL16—Final Guidance 06/27/02
111. Guidance for Industry #111: Effectiveness of Anthelmintics: Specific Recommendations for Canine—VICH GL19—Final Guidance 06/27/02
113. Guidance for Industry: Effectiveness of Anthelmintics: Specific Recommendations for Feline—VICH GL20—Final Guidance 06/19/02
114. Guidance for Industry: Effectiveness 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 GL24—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 Bioengineering—Draft 01/17/01


127. Guidance for Industry: Validation of Analytical Procedures for Type C Medicated Feeds, Final 11/07/05


129. CVM Guidance for Industry #143: Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms—VICH GL30—Draft Guidance 02/01/02

130. 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

131. Bioanalytical Method Validation 05/01

132. 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

133. 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

134. 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

135. Guidance for Industry: Status of Clove Oil and Eugenol for Anesthesia of Fish 06/11/02

136. Guidance for Industry: FDA Export Certificates 07/04


138. Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals 09/02

139. Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records Withdrawn 02/25/03


141. Draft Guidance for Industry: Comparability Protocols—Chemistry, Manufacturing, and Controls Information; Availability 02/03

142. Guidance for Industry: Part 11, Electronic Records, Electronic Signatures—Scope and Application 08/03

143. Guidance for Industry—Use of Material from Deer and Elk in Animal Feed 09/15/03

144. 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

145. 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

146. Draft Guidance for Industry—Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information 09/03


149. Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations 10/03

150. Guidance for Industry—Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMPs), Phase II, Final Guidance, VICH GL38, 01/09/06

151. Guidance for Industry: Prior Notice of Imported Food Questions and Answers 12/12/03

152. Guidance for Industry: Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators 11/20/03


155. 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

156. Guidance for Industry #172—Use of unapproved hormone implants in veal calves, April 2, 2004 Withdrawn 07/15/04


158. Guidance for Industry—Use of Material from BSE Positive Cattle in Animal Feed 09/30/04


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 Premarket 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.

<table>
<thead>
<tr>
<th>Title of Document</th>
<th>Date of Issuance</th>
<th>Date of Withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPG—Sec. 160.800 Year 2000 (Y2K) Computer Compliance (CPG 7153.15)</td>
<td>April 26, 1999</td>
<td>March 8, 2005</td>
</tr>
<tr>
<td>CPG—Sec. 355.100 Cellutron Machine (CPG 7124.03)</td>
<td>May 31, 1990</td>
<td>March 10, 2005</td>
</tr>
<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>
</tr>
</tbody>
</table>
The following is a copy of a list of current ORA guidance documents obtained from the FDA Web site as of March 14, 2006.

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

FDA contact sources for industry assistance and inquiries.

| Medical Devices—Division of Small Manufacturers, International and Consumer Assistance (DSMICA) |
| Quality Systems/Good Manufacturing Practices Survey/Report |
| FDA Small Business Program Office |
| Regional Small Business Representatives |
| A Small Business Guide to FDA |
| FDA Industry focus page |
| Code of Federal Regulations |
| FDA Public Workshops |

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.

ORA Compliance Reference

Revisions and Update List
Recent:
03/08/2006: Revised list to add 1 new member, Restricted List for Clinical Investigators
02/09/2006: Updated the program contact person (s) information on the following pages: http://www.fda.gov/ora/compliance_ref/bimo/default.htm http://www.fda.gov/ora/compliance_ref/bimo/background.html http://www.fda.gov/ora/compliance_ref/bimo/comparison_chart/preface.html
01/19/2006: Change in classification (Class)—Pine Acres Research Facility, Norton, MA
01/11/2006: Updated list to remove restriction for 1 member. Restricted List for Clinical Investigators
12/29/2005: Revised Restricted List for Clinical Investigators to add 1 new member
12/21/2005: 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
12/12/2005: 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)
12/06/2005: Updated list to remove restriction for 1 member, 11/23/2005: Restricted List for Clinical Investigators
12/01/2005: Updated “FDA AIP Contacts List” (August 2005) on the Application Integrity Policy Information page
11/29/2005: Edited Compliance Policy Guides Sec. 160.100 and 118 pages in Chapter 5 to reflect FDA organization and contact changes.
11/18/2005: 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
11/14/2005: Revised list to add 1 new member, Disqualified/Totally Restricted List for Clinical Investigators
11/03/2005: Revised list to remove one member from the Application Integrity Policy List
10/31/2005: Revised http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm to add one person and update the list contact person. Also, the contact person was updated on: http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm http://www.fda.gov/ora/compliance_ref/bimo/restlist.htm
09/15/2005: Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990 Updated September 15, 2005
09/13/2005: Revised list to remove one member on the Application Integrity Policy List
08/08/2005: 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)
08/02/2005: Table for Veterinary Medicine compliance programs is updated to reflect on-line documents and/or information now supplied by the Center for Veterinary Medicine.
07/18/2005: 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).”
5/31/2005 Draft revised CPG Sec. 480-200—Expiration Dating of Unit-Dose Repackaged Drugs (CPG 7132b.11) Notice of Availability Draft Guidance
05/20/2005: Revised list to add 1 new member, Restricted List for Clinical Investigators
05/19/2005: Revised CPG Sec. 315.100 Illegal Interstate Commercial Shipment of Dentures (CPG 7124.07)
05/17/2005: Revised list to add 1 new member, Restricted List for Clinical Investigators
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
03/18/2005 Revised CPG Sec. 300.500—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. 398.700;
03/10/2005 Revoked CPG: Sec. 355.100—Cellutron 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, Debarment List
01/14/2005: Draft CPG 1/14/2004 Draft CPG (Not for Implementation), Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14)
01/06/2005: Revised list to add 1 new member, Disqualified/Partially 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. 310.310—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/Partially 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
05/06/2004 Revised Application Integrity Policy Committee Contact Persons list on 12/18/2003
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/Partially 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:

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/Totally 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/Totally Restricted List for Clinical Investigators. 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/Totally 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/Totally 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/Totally Restricted List for Clinical Investigators.

Edited lists 12/16/2002: 1) Inactive Labs List and 2) Active Tow 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)


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 7313.17)

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

Revised 2 lists to add new or update new member(s), 10/15/2002: Disqualified/Totally 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, 09/7/2002: Disqualified/Totally Restricted List for Clinical Investigators

Revoked effective on 08/07/2002: 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/Totally Restricted List for Clinical Investigators

Reissued 05/29/2002, 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 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...Hexachloro 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 04/26/2002 page—page text and links were updated

Edited Debarment List on 04/09/2002...
ORÁ Guidance Documents (obtained from the FDA Web site on March 14, 2006)—Continued

Revised as Draft 05/29/2002—Sec. 345.100 Male Condom Defects (CPG 7124.21) for comment
Edited page to remove dates that may become obsolete, 04/2/2002: Application Integrity Policy Information
Revised list to add new member, 04/02/2002: Disqualified/Totally Restricted List for Clinical Investigators
Revised list to add new member, 02/20/2002: Application Integrity Policy List
Revised lists to align members to groups, 01/15/2002: a) Restricted List for Clinical Investigators b) Disqualified/Totally Restricted List for Clinical Investigators

2001 Revisions and Updates
Revised as Draft Dec 18, 2001—Sec. 555.600 Filth "from Insects, Rodents, and Other Pests” in Foods (CPG 7120.18)
New CPG Oct., 2001—Sec. 510.150 Apple Juice, Apple Juice Concentrates, and Apple Juice Products—Adulteration with Patulin
Reformat CPG Oct., 2001—Sec. 570.425 Tree Nuts—Adulteration Involving Rejects (Insect Infestation, Moldy, Rancid, Otherwise Decomposed, Blanks, and Shriveled) (CPG 7112.05)
Final CPG April 2001—Sec. 615.115 Extra-Label Use of Medicated Feeds for Minor Species
New CPG April 2001, Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens
New RPM Chapter 5, March, 2001, Subchapter Civil Money Penalties, Reduction of Civil Money Penalties for Small Entities
New RPM Chapter 9, January 2001, Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food
New RPM Chapter 9, January 2001, Secured Storage

2000 Revisions and Updates
Draft CPG—December 2000, Sec. 230.150 Blood Donor Incentives
Revised 8/10/2000, Sec. 540.650 Unviscerated Fish Products that are Salt-cured, Dried, or Smoked (CPG 7108.17)
New 06/29/2000, Sec. 100.950 International Partnership Agreements for Compliance Activities—Agreements among the USFDA, Foreign Government Agencies, and Domestic and Foreign Trade Associations and/or Other Organizations
Deleted 07/03/2000, Sec. 405.100 Prescriptions Prepared from Certified Antibiotics (CPG 7122.01)
Deleted 07/03/2000, Sec. 405.200 Export of Uncertified Antibiotics (CPG 7122.02)
Deleted 07/03/2000, Sec. 405.210 Returned Antibiotics Exported Under 801(d) of the Act (CPG 7122.03)
Revised 05/01/2000, Sec. 651.100 Ethylenediamine Dihydroiodide (EDDI) (CPG 7125.18)
Revised 04/14/2000, Section 110.100, Certification for Exports (CPG7150.01)
Deleted 03/28/2000, Section 215.100, IND Filings: Completion of Applicable...
Reissued 03/22/2000, Section 257.100, Deferral of Source Plasma Donors Due to Red Cell Loss During Collection of Source Plasma by Automated Plasmapheresis
New 03/06/2000, Section 252.110, Volume Limits for Automated Collection of Source Plasma
Deleted (Revoked) 01/24/2000, Sec. 305.100 Acupuncture Devices and Accessories (CPG 7124.11)

1999 Revisions and Updates
Draft CPG—8/04/1999, Section 615.115 Use of Medicated Feed for Minor Species

Welcome to Inspection Reference
This page includes information provided to FDA investigators and inspectors to assist them in their daily activities.

Field Management Directives—The primary vehicle for distributing procedural information/policy on the management of Office of Regulatory Affairs (ORA) field activities.

Guides to Inspections of...—Guidance documents written to assist FDA personnel in applying FDA’s regulations, policies and procedures during specific types of inspection or for specific manufacturing processes. Note: These documents are reference material for investigators and other FDA personnel. The documents do not bind FDA and do not confer any rights, privileges, benefits or immunities for or on any person(s). An alternative approach may be used if such an approach satisfies the applicable statutes, regulations or both. Updated: June 2005

BIOENGINEERING
BIOENGINEERING INSPECTION GUIDELINES (11/91)

BIOLOGICS
BLOOD BANKS (9/93)
SOURCE PLASMA ESTABLISHMENTS (Rev 4/01)
INFECTIOUS DISEASE MARKER TESTING FACILITIES (6/96)
VIRAL CLEARANCE PROCESSES FOR PLASMA DERIVATIVES

COMPUTER ISSUES
COMPUTERIZED SYSTEMS IN DRUG ESTABLISHMENTS (2/93)
COMPUTERIZED SYSTEM IN THE FOOD PROCESSING INDUSTRY
GLOSSARY COMP. SYSTEMS. SOFTWARE DEVELOPMENT TERMINOLOGY (8/95)

DEVICES
QUALITY SYSTEMS
ELECTROMAGNETIC COMPATIBILITY ASPECTS OF MEDICAL DEVICE QUALITY SYSTEMS
BIORESEARCH MONITORING INSPECTIONS OF IN VITRO DIAGNOSTIC DEVICES
INSTRUMENTATIONAL QUALITY STANDARDS ACT AUDITOR'S GUIDE
MEDICAL DEVICE MANUFACTURERS

DRUGS
BULK PHARMACEUTICAL CHEMICALS (9/91)
HIGH PURITY WATER SYSTEMS (7/93)
LYOPHILIZATION OF PARENTERALS (7/93)
MEDICAL DEVICES. PHARMACEUTICAL QUALITY CONTROL LABS (7/93)
PHARMACEUTICAL QUALITY CONTROL LABORATORIES (7/93)
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)

STERILE DRUG SUBSTANCE MANUFACTURERS (7/94)

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

GROSS 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


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 Sources 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 9/07/76

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 Biologicals 7/31/79

35. Reliability of Manufactured Products Medical Device, Radiological Health Products 9/26/80

36. Reverse Osmosis Drugs, Medical Devices and Diagnostic Products 10/21/80

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) 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
National Institutes of Health

State-of-the-Science Conference: Multivitamin/Mineral Supplements and Chronic Disease Prevention; Notice

Notice is hereby given of the National Institutes of Health (NIH) “State-of-the-Science Conference: Multivitamin/Mineral Supplements and Chronic Disease Prevention” to be held May 15–17, 2006, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on May 15 and 16, and at 9 a.m. on May 17, and will be open to the public.

It is estimated that more than one-third of American adults take multivitamin/mineral (MVM) supplements regularly. Recommendations regarding supplement use from expert groups vary widely, as does the strength of the evidence supporting such guidelines. As more and more Americans seek strategies for maintaining good health and preventing disease, and as the marketplace offers an increasing number of products to fill that desire, it is important that consumers have the best possible information to inform their choices.

The Office of Dietary Supplements and the Office of Medical Applications of Research of the NIH will convene a State-of-the-Science Conference on Multivitamin/Mineral Supplements and Chronic Disease Prevention, May 15 to 17, 2006, in Bethesda, Maryland. The goal of the conference is to assess the evidence available on MVM use and outcomes for chronic disease prevention in adults and to make recommendations for future research. Specifically, the conference will explore the following key questions:

- What are the current patterns and prevalence of the public’s use of MVM supplements?
- What is known about the dietary nutrient intake of MVM users versus non-users?
- What is the efficacy of single vitamin/mineral supplement use in chronic disease prevention?
- What is the efficacy of MVM in chronic disease prevention in the general population of adults?
- What is known about the safety of MVM for the generally healthy population?
- What are the major knowledge gaps and research opportunities regarding MVM use?

An impartial, independent panel will be charged with reviewing the available published literature in advance of the conference, including a systematic literature review commissioned through the Agency for Healthcare Research and Quality. The first day and a half of the conference will consist of presentations by expert researchers and practitioners and open public discussions. On Wednesday, May 17, the panel will present a statement of its collective assessment of the evidence to answer each of the questions above. The panel will also hold a press conference to address questions from the media. The draft statement will be published online later that day, and the final version will be released approximately six weeks later.

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.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

State-of-the-Science Conference: Tobacco Use: Prevention, Cessation and Control; Notice

Notice is hereby given of the National Institutes of Health (NIH) “State-of-the-Science Conference on Tobacco Use: Prevention, Cessation, and Control” to be held June 12–14, 2006, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on June 12 and 13, and at 9 a.m. on June 14, and will be open to the public.

Tobacco use remains the Nation’s leading preventable cause of premature death. Each year, more than 440,000 Americans die from disease caused by tobacco use, accounting for one in every five deaths. Cigarette smoking alone is responsible for more than 30 percent of cancer deaths annually in the U.S., and...