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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 It also provides information on guidance documents that have been added or withdrawn in the past year.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 guidances 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.

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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 The list of guidance documents that have been withdrawn is for those guidances that have been withdrawn from January 5, 2005, to January 5, 2006.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)

For information on a specific guidance document or to obtain a hard copy, contact: Office of Communication, Training, and Manufacturers Assistance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 1–800–835–4709 or 301–827–1800, *http://www.fda.gov/cber/guidelines.htm*.

The following is a list of CBER guidance documents that have been withdrawn from January 5, 2005, to January 5, 2006.

Title of Document	Date of Issuance	Date of Withdrawal
Draft Guideline for the Validation of Blood Establishment Computer Systems	9/28/1993	3/9/2005
Draft Guidance for Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments	8/3/2001	6/28/2005
Guidance for Industry: Discontinuation of Donor Referral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection	5/6/2005	6/30/2005

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

Draft Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines—3/2/2006
Draft Guidance for Industry: Clinical Data Needed to Support the Licensure of Trivalent Inactivated Influenza Vaccines—3/2/2006
FDA Initiative Helps Expedite Development of Seasonal and Pandemic Flu Vaccines—3/2/2006
Guidance for Industry: Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997—2/15/2006
Guidance for Industry: Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications—2/13/2006
Draft Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims—2/2/2006
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: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format—1/18/2006
Draft Guidance for Industry: Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements—1/18/2006
Draft Guidance for Industry: INDs—Approaches to Complying with CGMP During Phase 1—1/12/2006
Guidance for Industry: Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP—1/11/2006
Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review—1/11/2006
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—12/30/3005
Draft Guidance for Industry: Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency—11/30/2005
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

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

International Conference on Harmonisation (ICH); Guidance for Industry: S7B Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals—10/19/2005
Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications—10/18/2005
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
Draft Guidance for Industry: Using Electronic Means to Distribute Certain Product Information—9/29/2005
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
Draft Guidance for Industry: Gene Therapy Clinical Trials—Observing Participants for Delayed Adverse Events—8/23/2005
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
Draft Guidance: Emergency Use Authorization of Medical Products—7/5/2005
FEDERAL REGISTER: Guidance for Industry: Discontinuation of Donor Deferral Related to Recent Fever with Headache as a Symptom of West Nile Virus Infection; Withdrawal of Guidance—6/30/2005
International Conference on Harmonisation (ICH); Guidance for Industry: Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process—6/29/2005
FEDERAL REGISTER: Draft Guidance for Food and Drug Administration Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments; Withdrawal of Guidance—6/28/2005
Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection—6/23/2005
Draft Guidance for Industry: Bar Code Label Requirements—Questions and Answers—6/7/2005
Guidance for Industry: Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients—5/18/2005
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
Reviewer Guidance: Evaluating the Risks of Drug Exposure in Human Pregnancies—4/27/2005
Guidance for Industry and FDA Staff: Application User Fees for Combination Products—4/20/2005
Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Content of Labeling—4/20/2005
Guidance for Industry and FDA Staff: Submission and Resolution of Formal Disputes Regarding the Timeliness of Premarket Review of a Combination Product—4/11/2005
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 Review Staff and Industry: Good Review Management Principles for PDUFA Products—3/30/2005
Guidance for Industry: Premarketing Risk Assessment—3/25/2005
Guidance for Industry: Development and Use of Risk Minimization Action Plans—3/25/2005
Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment—3/25/2005
Draft Guidance for Industry: Using a Centralized IRB Review Process in Multicenter Clinical Trials—3/25/2005
Guidance for Industry: Pharmacogenomic Data Submissions—3/22/2005
Attachment to Guidance on Pharmacogenomic Data Submissions—3/22/2005
International Conference on Harmonisation (ICH) Guidance for Industry: M2: eCTD Specification; Questions & Answers and Change Requests—3/11/2005
Companion Document: Current Q&As and Change Requests—3/11/2005—Updated—7/18/2005—Updated—1/6/2006
International Conference on Harmonisation (ICH) Guidance for Industry: M2 eCTD: Electronic Common Technical Document Specification—4/1/2003
International Conference on Harmonisation (ICH) Guidance for Industry: E2B(M): Data Elements for Transmission of Individual Case Safety Reports: Questions and Answers (Revision 2)—3/9/2005
FEDERAL REGISTER: Draft Guideline for the Validation of Blood Establishment Computer Systems; Withdrawal of Guidance—3/9/2005
Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle—3/9/2005
Draft Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms—2/23/2005
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
Draft Guidance for Industry: Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling—2/7/2005
International Conference on Harmonisation (ICH); Draft Guidance on S8 Immunotoxicity Studies for Human Pharmaceuticals—2/7/2005
Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees—1/3/2005

2004

International Conference on Harmonisation (ICH); Guidance for Industry: M-4: CTD—Efficacy: Questions and Answers (Revision 3)—12/22/2004
International Conference on Harmonisation (ICH); Guidance for Industry: M4: The CTD—General: Questions and Answers (Revision 3)—12/22/2004
Guidance for Industry and FDA Staff: Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use—11/30/2004
Guidance for Industry: Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act of 1992; Notice of extension of application deadline—11/19/2004
Guidance for Industry: Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA—10/6/2003
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: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)—11/12/2004
Draft Guidance for FDA Review Staff and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs)—11/8/2004
Draft Guidance for Industry: Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Blood Cell Substitutes—10/28/2004
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

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

Guidance for Industry, FDA Staff, and Third Parties: Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria—10/1/2004
Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information—10/1/2004
Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice—9/29/2004
Draft Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations—9/29/2004
Draft Guidance for Industry and FDA: Current Good Manufacturing Practice for Combination Products—9/29/2004
Draft Guidance for Industry: Computerized Systems Used in Clinical Trials 9/29/2004
Guidance for Industry: Computerized Systems Used in Clinical Trials—5/10/1999
FEDERAL REGISTER—Annual Guidance Agenda—9/23/2004
Guidance for Industry and Clinical Investigators: The Use of Clinical Holds Following Clinical Investigator Misconduct—9/2/2004
Guidance on Research Involving Coded Private Information or Biological Specimens—8/30/2004
Guidance for Industry and FDA: FY 2005 MDUFMA Small Business Qualification Worksheet and Certification—8/20/2004
Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols—8/18/2004
Guidance for Industry: Available Therapy—7/21/2004
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
Guidance for Industry: Developing Medical Imaging Drug and Biological Products—6/17/2004
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: M4: The CTD—Quality: Questions and Answers/Location Issues—6/8/2004
International Conference on Harmonisation (ICH); Guidance for Industry: Q1E Evaluation of Stability Data—6/7/2004
International Conference on Harmonisation (ICH); Guidance for Industry: E5—Ethnic Factors in the Acceptability of Foreign Clinical Data—Questions and Answers—6/3/2004
Guidance for Industry and FDA Staff: User Fees and Refunds for Premarket Notification Submissions (510(k)s)—5/28/2004
Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment—5/20/2004
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
Draft Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components—4/23/2004
Draft Guidance for Industry: Vaccinia Virus—Developing Drugs to Mitigate Complications from Smallpox Vaccination—3/8/2004
International Conference on Harmonisation (ICH); Guidance for Industry: Addendum to E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs—2/4/2004
International Conference on Harmonisation (ICH); Guidance for Industry: E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs—11/1996
Draft Guidance for Industry and FDA: Consumer-Directed Broadcast Advertising of Restricted Devices—2/4/2004
Draft Guidance for Industry: Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements—2/4/2004
Example of Fictional Highlights of Prescribing Information (Based on Proposed Physician Labeling Rule)—2/4/2004
Example of Fictional Highlights of Prescribing Information (Based on Proposed Physician Labeling Rule) Translated in Consumer-Friendly Language and Formatted for Use in Consumer-Directed Advertisement—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
Draft Guidance for Industry: Drug Substance—Chemistry, Manufacturing, and Controls Information—1/6/2004

2003

Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Human Dura Mater—12/17/2003
Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components—12/09/2003
Guidance for Industry and FDA Staff: Expedited Review of Premarket Submissions for Devices—11/21/2003
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
Guidance for Industry and FDA: 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—3/12/2003
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: Q3C Impurities: Residual Solvents—12/24/1997
Guidance for Industry: Product Recalls, Including Removals and Corrections—10/31/2003
Guidance for Industry and FDA Staff: Premarket Approval Application Modular Review—10/31/2003
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
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations—10/22/2003
Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations—1/28/1999
Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Performance Assessment—10/8/2003
Guidance for Industry: Continuous Marketing Applications: Pilot 1—Reviewable Units for Fast Track Products Under PDUFA—10/6/2003
Guidance for Industry: Notifying FDA of Fatalities Related to Blood Collection or Transfusion—9/22/2003
Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS—9/16/2003
Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS—4/17/2003
Question and Answer on FDA Guidance Entitled "Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Suspected and Probable Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS"—Since Publication of this guidance, CDC issued a health alert for travelers arriving from Toronto Canada, and updated their case definition. As discussed in the guidance under section II.B.3., Updated Information on Case Definitions in Areas Affected by SARS, the FDA indicated that you should consult with the CDC website and phone number for updates. Phone (888) 246-2675.
Updated Interim U.S. Case Definition of Severe Acute Respiratory Syndrome (SARS). http://www.cdc.gov/ncidod/sars/casedefinition.htm.
ICH Draft Guidance: E2D Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting—9/12/2003
Draft Guidance for Industry: Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information—9/3/2003

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

Guidance for Industry: Part 11, Electronic Records; Electronic Signatures—Scope and Application—9/3/2003
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Annual Reports for New Drug Applications and Abbreviated New Drug Applications—8/27/2003
Draft Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Control (CMC) Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications (INDs)—8/15/2003
Guidance for Industry and FDA: FY 2004 MDUFMA Small Business Qualification Worksheet and Certification—8/1/2003
Draft Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices—7/24/2003
Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires—7/3/2003
Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices—7/3/2003
Draft Guidance for Industry: Revised Recommendations for Donor and Product Management Based on Screening Tests for Syphilis—6/25/2003
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports—6/23/2003
Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations—6/19/2003
Guidance for Industry: Pharmacokinetics in Patients With Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling—5/30/2003
Guidance for Industry: Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications—5/5/2003
Guidance for Industry and FDA Staff: Premarket Approval Application Filing Review—5/1/2003
FEDERAL REGISTER—Annual Guidance Agenda—4/4/2003
Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans—4/3/2003
International Conference on Harmonisation (ICH) Guidance for Industry: M2 eCTD: Electronic Common Technical Document Specification—4/1/2003
International Conference on Harmonisation (ICH) Guidance for Industry: M2: eCTD Specification; Questions & Answers and Change Requests—3/11/2005
Companion Document: Current Q&As and Change Requests—3/11/2005—Updated—7/18/2005—Updated—1/6/2006
Guidance for Industry and FDA: FY 2003 MDUFMA Small Business Qualification Worksheet and Certification—3/12/2003
Draft Guidance for Industry; Comparability Protocols—Chemistry, Manufacturing, and Controls Information—2/20/2003
International Conference on Harmonisation (ICH); Guidance for Industry: Q3A Impurities in New Drug Substances—2/11/2003
Guidance for Industry and FDA Staff: Quality System Information for Certain Premarket Application Reviews—2/3/2003
International Conference on Harmonisation (ICH); Guidance for Industry: M4: The CTD—Safety: Questions and Answers—2/3/2003
Draft Guidance for Industry: Drug Product: Chemistry, Manufacturing, and Controls Information—1/28/2003
International Conference on Harmonisation (ICH); Guidance for Industry; Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products—1/15/2003
Draft Guidance for Industry and Reviewers on Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers—1/15/2003
Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox VaccineRecipients—12/30/2002—(Corrected 2/4/2003)
Questions and Answers on FDA Guidance Entitled "Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients"

2002

The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry—10/3/2002
Guidance for Industry: Establishing Pregnancy Exposure Registries—9/20/2002—
Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals—9/6/2002
Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)—6/14/2002
Guidance for Industry: Special Protocol Assessment—5/16/2002
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Questions and Answers—5/13/2002
Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Documentation—7/7/1999
Draft Guidelines for Ensuring the Quality of Information Disseminated to the Public—5/2/2002—HHS Guideline
Draft Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBsAg) Assays Used to Test Blood, Blood Components and Source Plasma Donations—4/10/2002
Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs)—3/26/2002
Electronic IND Demo
Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation—3/8/2002
Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts—2/1/2002
Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts—12/23/1999
Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff—1/11/2002
Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products—1/9/2002
Questions and Answers on "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products"

2001

Guidance for Industry Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act—11/21/2001
Draft Guidance for Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees—11/15/2001
Guidance for Industry—Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax—10/17/2001
International Conference on Harmonisation (ICH); Guidance on M4 Common Technical Document—10/16/2001—
M4: Organization of the CTD
M4E: The CTD—Efficacy
M4Q: The CTD—Quality
M4S: The CTD—Safety
M4S: The CTD—Safety Appendices
Guidance for Industry: Content and Format of Geriatric Labeling—10/5/2001
Guidance for Industry: Cancer Drug and Biological Products—Clinical Data in Marketing Applications—10/5/2001
International Conference on Harmonisation (ICH) Guidance; Q7A Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients—9/25/2001
Draft Guidance for Industry: Submitting Marketing Applications According to the ICH–CTD Format—General Considerations—9/5/2001
Draft Guidance for Industry: Premarket Notifications [510(k)s] for In Vitro HIV Drug Resistance Genotype Assays: Special Controls—8/28/2001
Draft Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research—8/22/2001
Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis—8/22/2001
Draft Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments—8/10/2001
Draft Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components—8/10/2001

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

Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture—8/7/2001
Guidance for FDA Reviewers: Premarket Notification Submissions for Blood and Plasma Warmers—7/19/2001
Guidance for FDA Reviewers: Premarket Notification Submissions for Transfer Sets (Excluding Sterile Connecting Devices)—7/19/2001
Guidance for FDA Reviewers: Premarket Notification Submissions for Empty Containers for the Collection and Processing of Blood and Blood Components—7/19/2001
ICH Guidance for Industry: S7A Safety Pharmacology Studies for Human Pharmaceuticals—7/12/2001
Guidance for Industry: Revised Recommendations Regarding Invalidation of Test Results of Licensed and 510(k) Cleared Bloodborne Pathogen Assays Used to Test Donors—7/11/2001
Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained From An Outside Supplier—7/11/2001
Guidance for Industry: IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing and Controls Information—5/25/2001
Draft Guidance for Industry: Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—5/14/2001
ICH Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials—5/11/2001
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports—5/3/2001
Guidance for Industry: Monoclonal Antibodies Used as Reagents in Drug Manufacturing—3/29/2001
Guidance for Industry: Financial Disclosure by Clinical Investigators—3/28/2001
Guidance for Industry: Acceptance of Foreign Clinical Studies—3/13/2001
Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines—3/12/2001
Draft Guidance for Industry: Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research—2/15/2001
Guidance for Industry: Recommendations for Collecting Red Blood Cells by Automated Apheresis Methods—Technical Correction February 2001—2/13/2001
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling—1/31/2001
Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion—1/23/2001
PHS Guideline on Infectious Disease Issues in Xenotransplantation—1/19/2001

2000

International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances—12/29/2000
International Conference on Harmonisation (ICH) Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population—12/15/2000
Draft Guidance for Industry: Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27(a))—12/4/2000
Guidance for Industry: Use of Sterile Connecting Devices in Blood Bank Practices—11/22/2000
Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol—11/20/2000
Guidance for Industry: Testing Limits in Stability Protocols for Standardized Grass Pollen Extracts—11/20/2000
Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds—10/26/2000
Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors—10/18/2000
Guidance for Industry: Q & A Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products—10/3/2000
Guidance for Industry: Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products—11/1995
Draft Guidance for Industry: Analytical Procedures and Methods Validation—Chemistry, Manufacturing, and Controls Documentation—8/30/2000
Guidance for Industry and FDA Staff: Guidance on Amended Procedures for Advisory Panel Meetings—7/22/2000
Draft Guidance for Industry: Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment—6/28/2000
Guidance for Industry: Availability of Licensed Donor Screening Tests Labeled for Use with Cadaveric Blood Specimens—6/23/2000
Draft Guidance for Industry: Pediatric Oncology Studies In Response to a Written Request—6/21/2000
Draft Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria—6/8/2000
Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components—6/6/2000
Guidance for Industry: United States Industry Consensus Standard for the Uniform labeling of Blood and Blood Components Using ISBT 128—11/1999
Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing—3/15/2000
Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products—3/7/2000
Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level—3/7/2000
International Conference on Harmonsation of Technical Requirements for Registration of Pharmaceuticals for Human Use—2/10/2000

1999

Guidance for Industry: In the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Nucleic Acid Sequences of Human Immunodeficiency Viruses Types 1 and 2—12/14/1999
Guidance for Industry: In Vivo Drug Metabolism / Drug Interaction Studies—Study Design, Data Analysis and Recommendations for Dosing and Labeling—11/24/1999
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
Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug and Cosmetic Act—10/8/1999
Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications—9/13/1999
Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products—8/27/1999
ICH Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products—8/18/1999
Guidance for Industry: Consumer-Directed Broadcast Advertisements—8/6/1999
Draft Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics—8/3/1999
Draft Guidance for Industry: Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations—7/24/1999
Draft Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)—7/15/1999
ICH Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing); Availability—6/25/1999
Draft Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with 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: 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 Antidoby 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
Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use—5/20/1999
Draft Guidance for Industry For Platelet Testing and Evaluation of Platelet Substitute Products—5/20/1999

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

Guidance for Industry For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h "Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use"—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
Draft Guidance for Industry: Accelerated Approval Products—Submission of Promotional Materials—3/26/1999
Draft Guidance for Industry: Product Name Placement, Size and Prominence in Advertising and Promotional Labeling—3/12/1999
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 and Establishment Description Information for Human Plasma-Derived Biological Products, Animal Plasma or Serum-Derived Products—2/17/1999
Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products for the Treatment of Rheumatoid Arthritis (RA)—2/17/1999
Guidance for Industry: Population Pharmacokinetics—2/10/1999
Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products—2/3/1999
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; Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997—10/30/1998
Draft Guidance for Industry: Submitting Debarment Certification Statements—10/2/1998
ICH Guidance on Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin—9/24/1998
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 Antidoby 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
Withdrawal of "Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)"—Information Sheet—9/8/1998
Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)—3/20/1998
Guidance for Industry: How to Complete the Vaccine Adverse Reporting System Form (VAERS-1)—9/8/1998
Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications—7/27/1998
Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements—7/21/1998
Draft Guidance for Industry: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996—6/12/1998
Guidance for Industry: Errors and Accidents Regarding Saline Dilution of Samples Used for Viral Marker Testing—6/11/1998
ICH Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data—6/10/1998
Draft Guidance for Industry: Stability Testing of Drug Substances and Drug Products—6/8/1998
Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products—5/15/1998
Guidance for Industry: Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements—5/15/1998
Guidance for Industry: Pharmacokinetics in Patients with Impaired Renal Function—Study Design, Data Analysis and Impact on Dosing and Labeling—5/15/1998
Guidance for Industry: Classifying Resubmissions in Response to Action Letters—5/14/1998
Draft Guidance for Industry: Instructions for Submitting Electronic Lot Release Protocols to the Center for Biologics Evaluation and Research—5/13/1998
Draft Guidance for Industry: Manufacturing, Processing or Holding Active Pharmaceutical Ingredients—4/17/1998
Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy—3/30/1998
Draft Guidance for Industry: Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products—1/28/1998
Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products—1/8/1998

1997

Draft Guidance for Industry: Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMS)—12/1997
Final Guidance on Industry-Supported Scientific and Educational Activities; Notice—12/3/1997
Guidance for FDA and Industry: Direct Final Rule Procedures—11/21/1997
Guidance for Industry: Industry-Supported Scientific and Educational Activities—11/1997
Guidance for Industry—The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA-Regulated Products for Human Use—10/07/1997
Guidance for Industry—Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report—8/27/1997
Guidance for Industry—Donor Screening for Antibodies to HTLV-II—8/15/1997
Guidance for Industry—Screening and Testing of Donors of Human Tissue Intended for Transplantation—7/29/1997
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
International Conference on Harmonisation (ICH) Guidance for Industry: Q2B Validation of Analytical Procedures: Methodology—5/19/1997
International Conference on Harmonisation (ICH) Guidelines for the Photostability Testing of New Drug Substances and Products—5/16/1997
Guidance for Industry for the Evaluation of Combination Vaccines for Preventable Diseases: Production, Testing and Clinical Studies—4/10/1997
Proposed Approach to Regulation of Cellular and Tissue-Based Products—2/28/1997
Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use—2/28/1997
Guidance For the Submission of Chemistry, 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
International Conference on Harmonisation: Final Guidance on Stability Testing of Biotechnological / Biological Products—7/10/1996
Guidance for Industry—The Content and Format for Pediatric Use Supplements—5/1996
Guidance on Applications for Products Comprised of Living Autologous Cells Manipulated ex vivo and Intended for Structural Repair or Reconstruction—5/1996
FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-Derived Products—4/1996
International Conference on Harmonisation: Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals—3/1996

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

International Conference on Harmonisation: Final Guideline on Quality of Biotechnical Products: Analysis of the Expression Construct in Cells Used for the Production of r-DNA Derived Protein Products—2/1996

1995 and earlier

Draft Reviewers' Guide: Disease Associated Antibody Collection Program—10/1/1995
Draft Reviewers' Guide: Informed Consent for Plasmapheresis / Immunization—10/1/1995
Guideline for Quality Assurance in Blood Establishments—7/11/1995 (NOTE: The text version does not contain Tables 1–8)
FDA Guidance Document Concerning Use of Pilot Manufacturing Facilities for the Development and Manufacturing of Biological Products—7/11/1995
Points to Consider in the Manufacture and Testing of Therapeutic Products for Human Use Derived from Transgenic Animals—1995
Guidance for Industry for the Submission of Chemistry, Manufacturing, and Controls Information for Synthetic Peptide Substance—11/1/1994
Guidance for Industry for the Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products—11/1994
Guidance on Alternatives to Lot Release for Licensed Biological Products—7/14/1993
Draft Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (1993)—7/12/1993
FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics—11/25/1992
Supplement to the Points to Consider in the Production and Testing of New Drugs and Biologics Produced by Recombinant DNA Technology: Nucleic Acid Characterization and Genetic Stability—4/6/1992
Guideline for the Determination of Residual Moisture in Dried Biological Products—1/1/1990
Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers ("High Risk" Donors)—10/26/1989
Points to Consider in the Collection, Processing, and Testing of Ex-Vivo Activated Mononeuclear Leukocytes for Administering to Humans—8/22/1989
Draft Points to Consider in the Manufacture and Clinical Evaluation of In Vitro Tests to Detect Antibodies to the Human Immunodeficiency Virus Type 1—8/8/1989
Revised Guideline for the Collection of Platelets, Pheresis—10/7/1988
Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test For Human and Animal Parenteral Drugs, Biological Products and Medical Devices—12/1987
Guideline on General Principles of Process Validation—5/1987
Guideline for the Uniform Labeling of Blood and Blood Components—8/1985
Points to Consider in the Production and Testing of New Drugs and Biologicals Produced by Recombinant DNA Technology—4/10/1985
Interferon Test Procedures: Points to Consider in the Production and Testing of Interferon Intended for Investigational Use in Humans—7/28/1983
Guidelines for Immunization of Source Plasma (Human) Donors with Blood Substances—6/1980

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.

Title of Document	Date of Issuance	Date of Withdrawal
Preclinical Development of Antiviral Drugs	11/1/1990	7/6/2005
Conjugated Estrogens, USP: LC–MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence	3/9/2000	8/12/2005
Phenytoin/Phenytoin Sodium Capsules, Tablets and Suspension In Vivo Bioequivalence and In Vitro Dissolution Testing	3/4/1994	9/6/2005
Organization of an Abbreviated New Drug Application	3/2/1999	11/18/2005
Preclinical Development of Immunomodulatory Drugs for Treatment of HIV Infection and Associated Disorders	9/4/1992	12/29/2005

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)

FDA's Good Guidance Practices regulation of September 19, 2000.
Comprehensive List of Guidance Documents (updated 2/28/2006)
Guidance Agenda: Guidances CDER is Planning to Develop During Calendar Year 2006 (03/01/2006)
New/Revised/Withdrawn List for 2006 (updated 2/28/2006)

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

New/Revised/Withdrawn List for 2005 (updated 1/4/2006)

Advertising

Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling (Issued 12/1997, Posted 1/12/1998)
Consumer-Directed Broadcast Advertisements (Issued 8/1999, Posted 8/6/1999)
Questions and Answers (Posted 8/6/1999)
Industry-Supported Scientific and Educational Activities (Issued 12/3/1997, Posted 12/4/1997)

Advertising Draft

Accelerated Approval Products: Submission of Promotional Materials (Posted 3/26/1999)
Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements (Posted 2/4/2004)
Labeling Example
Labeling Example; Consumer-Friendly Version
Consumer-Directed Broadcast Advertising of Restricted Devices (Issued 1/26/2004, Posted 2/4/2004)
"Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms (Issued 1/26/2004, Posted 2/4/2004)
Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling (Issued 1/1999, Posted 3/12/1999)
Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Management Companies (PBMs) (Issued 12/1997. Posted 1/5/1998)

Biopharmaceutics

Bioanalytical Method Validation (Issued 5/2001, Posted 5/22/2001)
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations (Issued 3/2003, Posted 3/19/2003)
Cholestyramine Powder in Vitro Bioequivalence (Intermin Guidance)
Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing (Issued 6/17/2005, Posted 6/17/2005)
Corticosteroids, Dermatologic (topical) In Vivo (Issued 6/2/1995, Posted 3/6/1998)
Dissolution Testing of Immediate Release Solid Oral Dosage Forms (Issued 8/1997, Posted 8/25/1997)
Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations (Issued 9/1997, Posted 9/26/1997)
Food-Effect Bioavailability and Fed Bioequivalence Studies (Issued 12/2002, Posted 1/30/2003)
Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro (Issued 6/27/1989, Posted 3/2/1998)
Potassium Chloride (slow-release tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing (Revised 6/6/1994, Posted 6/22/1998)
Statistical Approaches to Establishing Bioequivalence (Issued 2/2001, Posted 2/1/2001)
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. (Issued 8/2000, Posted 8/31/2000)

Biopharmaceutics (Draft)

Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (Posted 4/2/2003)
Statistical Information from the June 1999 Draft Guidance and Statistical Information for In Vitro Bioequivalence Data (Posted 4/11/2003)
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)

Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP (Issued 1/11/2006; Posted 1/11/2006)
Questions and Answers on Current Good Manufacturing Practices (cGMP) for Drugs (Posted 8/4/2004)
Part 11, Electronic Records; Electronic Signatures—Scope and Application (Posted 9/3/2003)
PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance (posted 9/29/2004)
Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice Posted 9/29/2004

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

Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information (Posted 9/3/2003)
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)
Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment (Issued 11/2003, Posted 11/6/2003)
Revised Attachments (Issued 11/2003, Posted 11/21/2003)
Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations (Posted 9/29/2004)

Chemistry

BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation (Issued 2/2001, Posted 2/16/2001)
Botanical Drug Products (Issued 6/2004, Posted 6/9/2004)
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)
Container Closure Systems for Packaging Human Drugs and Biologics (Issued 5/1999, Posted 7/6/1999)
Container Closure Systems for Packaging Human Drugs and Biologics—Questions and Answers (Issued 5/2002, Posted 5/10/2002)
Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products
Development of New Stereoisomeric Drugs (5/1/1992) (Post Date: 1/3/1996)
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 of the Chemistry, Manufacturing and Controls Section of an Application* (Issued 2/1987, Posted 3/2/1998)
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)
IND Meetings for Human Drugs and Biologics Chemistry, Manufacturing, and Controls Information (Issued 5/2001, Posted 6/4/2001)
Monoclonal Antibodies Used as Reagents in Drug Manufacturing (Issued 3/2001, Posted 3/28/2001)
Nasal Spray and Inhalation Solution, Suspension, and Drug Products (Issued 7/2002, Posted 7/3/2002)

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

NDAs: Impurities in Drug Substances (Issued 2/2000, Posted 2/24/2000)
PAC-ATLS: Postapproval Changes—Analytical Testing Laboratory Sites (Issued 4/28/1998, Posted 4/28/1998)
The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) (12/20/2000)
SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation
SUPAC-IR Questions and Answers about SUPAC-IR Guidance (2/18/1997)
SUPAC-IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum (Issued 1/1999, Posted 2/25/1999)
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 (Issued 10/6/1997, Posted 10/6/1997)
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 (Issued 5/1997; Posted 6/16/1997)
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 Documentation for the Manufacturing of and Controls for Drug Products* (Issued 2/1987, Posted 3/2/1998)
Submitting Documentation for the Stability of Human Drugs and Biologics* (Issued 2/1987, Posted 3/2/1998)
Submitting Samples and Analytical Data for Methods Validation
Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances

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Chemistry (Draft)

Analytical Procedures and Methods Validation. (Issued 8/2000, Posted 8/30/2000)
Comparability Protocols—Chemistry, Manufacturing, and Controls Information (Issued 2/2003, Posted 2/20/2003)
Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (Posted 9/11/2003)
Drug Product: Chemistry, Manufacturing, and Controls Information (Issued 1/2003, Posted 1/28/2003)
Drug Substance: Chemistry, Manufacturing, and Controls Information (Issued 1/2004, Posted 1/6/2004)
Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations (7/24/1999)
Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products (Issued 11/13/1998, Posted 11/19/1998, Posted 9/27/1999)
Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation. (Issued 7/2002, Posted 8/20/2002)
Stability Testing of Drug Substances and Drug Products (Issued 6/5/1998, Posted 6/8/1998)
SUPAC-SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum (Issued 12/1998, Posted 1/5/1999)

Clinical/Antimicrobial

Antiretroviral Drugs Using Plasma HIV RNA Measurements—Clinical Considerations for Accelerated and Traditional Approval (Issued 10/2002, Posted 10/31/2002)
Clinical Development and Labeling of Anti-Infective Drug Products (Issued 10/1992, Posted 3/2/1998, Revised 2/12/2001)
Clinical Evaluation of Anti-Infective Drugs (Systemic) (Issued 9/77, Posted 3/2/1998)

Clinical/Antimicrobial (Draft)

Acute Bacterial Exacerbation of Chronic Bronchitis—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Acute Bacterial Meningitis—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Acute Bacterial Sinusitis—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Acute or Chronic Bacterial Prostatitis—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Acute Otitis Media—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Antiviral Drug Development—Conducting Virology Studies and Submitting the Data to the Agency (Issued 5/24/2005, Posted 5/24/2005)
Bacterial Vaginosis—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Catheter-Related Bloodstream Infections—Developing Antimicrobial Drugs for Treatment (Issued 10/1999, Posted 10/18/1999)
Community-Acquired Pneumonia—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Complicated Urinary Tract Infections and Pyelonephritis—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Developing Antimicrobial Drugs—General Considerations for Clinical Trials (Issued 7/22/1998, Posted 7/22/1998)
Empiric Therapy of Febrile Neutropenia—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)
Inhalational Anthrax (Post Exposure)—Developing Antimicrobial Drugs (Issued 3/15/2002, Posted 3/15/2002)
Lyme Disease—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
Nosocomial Pneumonia—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
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Streptococcal Pharyngitis and Tonsillitis—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
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Uncomplicated Gonorrhea—Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998)
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Clinical/Medical

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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 Development Programs for MDI and DPI Drug Products (Issued 9/19/1994, Posted 3/2/1998)
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 Antianxiety Drugs (Issued 9/77, Posted 3/2/1998)
Clinical Evaluation of Antidepressant Drugs (Issued 9/77, Posted 3/2/1998)
Clinical Evaluation of Antidiarrheal Drugs (Withdrawn per July 20, 2004, Federal Register notice.)
Clinical Evaluation of Antiepileptic Drugs (adults and children) (Issued 1/1981, Posted 3/2/1998)
Clinical Evaluation of Gastric Secretory Depressant (GSD) Drugs (Withdrawn per July 20, 2004, Federal Register notice.)
Clinical Evaluation of General Anesthetics (Issued 5/1982, Posted 3/2/1998)
Clinical Evaluation of Hypnotic Drugs (Issued 9/77, Posted 3/2/1998)

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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 Psychoactive Drugs in Infants and Children (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
Part 1: Conducting Safety Assessments (Issued 6/17/2004, Posted 6/17/2004)
Part 2: Clinical Indications (Issued 6/17/2004, Posted 6/17/2004)
Part 3: Design, Analysis, and Interpretation of Clinical Studies (Issued 6/17/2004, Posted 6/17/2004)
Development and Use of Risk Minimization Action Plans (Issued 3/24/2005, Posted 3/24/2005)
Establishing Pregnancy Exposure Registries (Issued 8/2002, Posted 9/20/2002)
Evaluating the Risks of Drug Exposure in Human Pregnancies (Issued 4/27/2005, Posted 4/27/2005)
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products (Issued 12/1998, Posted 2/2/1999, posted 9/14/1999)
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.)
Format and Content of the Clinical and Statistical Sections of an Application (Issued 7/1988, Posted 5/21/1997)
Format and Content of the Summary for New Drug and Antibiotic Applications* (Issued 2/1987, Posted 3/2/1998)
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General Considerations for the Clinical Evaluation of Drugs
General Considerations for the Clinical Evaluation of Drugs in Infants and Children (Issued 9/77, Posted 3/2/1998)
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (Issued 3/24/2005, Posted 3/24/2005)
Guidance for the Development of Vaginal Contraceptive Drugs (NDA) (Posted 3/2/1998)
Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Waiver of IRB Requirements for Drug and Biological Product Studies (Issued 1/2006)
IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer (Revised 1/15/2004, Posted 1/15/2004)
Internal Radioactive Contamination—Development of Decorporation Agents (Issued 3/1/2006, Posted 3/1/2006)
Integration of Dose-Counting Mechanisms into MDI Drug Products (Issued 3/2003, Posted 3/12/2003)
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)
Premarketing Risk Assessment (Issued 3/24/2005; Posted 3/24/2005)
Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report (Issued 8/27/1997, Posted 8/27/1997)
Postmarketing Reporting of Adverse Drug Experiences (Issued 3/1992, Posted 3/2/1998)
Preparation of Investigational New Drug Products (Human and Animal) (Issued 11/1992, Posted 3/2/1998)
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (Issued 5/14/1998, Posted 5/14/1998)
Prussian Blue Drug Products—Submitting a New Drug Application (Issued 1/2003, Posted 2/4/2003)
Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (Issued 7/22/1993, Posted 3/2/1998)
Study of Drugs Likely to be used in the Elderly (Issued 11/1989, Posted 3/2/1998)
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (Issued 8/1999, Posted 9/13/1999)
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)
Allergic Rhinitis: Clinical Development Programs for Drug Products (Issued 6/2000, Posted 6/20/2000)
Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment (Issued 6/2000, Posted 6/27/2000)
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (Issued 7/07/1999, Posted 7/14/1999)
Clinical Evaluation of Lipid-Altering Agents (Issued 10/1990, Posted 2/18/1998)
Clinical Evaluation of Weight-Control Drugs (9/24/1996, Posted 2/18/1998)
Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics (Issued 4/1/2005, Posted 4/1/2005)
Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis (Issued 5/2000, Posted 6/13/2000)
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)
Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs (Posted 4/27/2004)
Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment (Issued 5/2000, Posted 5/18/2000)
Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention (Issued June 24, 2005, Posted June 27, 2005)
Guidance for Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees (Issued 12/01/2005, Posted 2/07/2006)
Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (3/31/2000)
Inhalation Drug Products Packaged in Semipermeable Container Closure Systems (Issued 7/2002, Posted 7/25/2002)
OTC Treatment of Herpes Labialis with Antiviral Agents (Issued 3/8/2000, Posted 3/8/2000)
Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims (Issued 2/2/2006), Posted 2/2/2006)
Pediatric Oncology Studies In Response to a Written Request (Issued 6/2000, Posted 6/19/2000)
Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis (Issued 4/1994, Posted 2/18/1998)
Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)) (Posted 12/1/2000)
Systemic Lupus Erythematosus—Developing Drugs for Treatment (Issued 3/28/2005, Posted 3/28/2005)

Clinical Pharmacology

Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro (Issued 4/1997, Posted 4/8/1997)
Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications (Posted 5/5/2003)
Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application* (Issued 2/1987, Posted 3/2/1998)
In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling (Issued 11/24/1999, Posted 11/24/1999)
Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling (Posted 5/30/2003)
Pharmacokinetics in Patients with Impaired Renal Function (Issued 5/14/1998, Posted 5/14/1998)
Population Pharmacokinetics (Issued 2/1999, Posted 2/10/1999)

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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)
Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling (Issued 10/29/2004, Posted 10/29/2004)

Combination Products (Drug/Device/Biologic)

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

Compliance

A Review of FDA's Implementation of the Drug Export Amendments of 1986 (Issued 11/1989, Posted 3/2/1998)
Compressed Medical Gases (Issued 2/1989, Posted 3/10/1997)
Computerized Systems Used in Clinical Trials (Issued 4/1999, Posted 5/11/1999)
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)
Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron (Issued 6/27/1997, Posted 6/27/1997)
Monitoring of Clinical Investigations (Posted 3/2/1998)
Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment (Posted 3/2/1998)
Pharmacy Compounding—Compliance Policy Guide (Issued 5/2002, Posted 3/12/2004)
Possible Dioxin/PCB Contamination of Drug and Biological Products (Issued 8/23/1999, Posted 8/23/1999)
Prescription Drug Marketing Act—Donation of Prescription Drug Samples to Free Clinics (Issued 3/2006, Posted 3/13/2006)
Street Drug Alternatives (Issued 3/2000, Posted 3/31/2000)

Compliance (Draft)

Bar Code Label Requirements—Questions and Answers. (Issued 6/7/2005, Posted 6/7/2005)
Computerized Systems Used in Clinical Trials (Posted 9/29/2004)
Current Good Manufacturing Practice for Medical Gases (Posted 5/6/2003)
Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide (5/27/2005)
Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (21 CFR 50.24) Draft released for comment 3/30/2000 (5/12/2000)
Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production (Issued 9/30/1998, Posted 9/30/1998)
Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients (Issued 4/17/1998, Posted 4/17/1998)
Marketed Unapproved Drugs—Compliance Policy Guide (Issued 10/15/2003, Posted 10/17/2003)
PET Drug Products—Current Good Manufacturing Practice (CGMP) (Issued 9/15/2005, Posted 9/15/2005)

Drug Safety

Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review (Issued 2/2005, Posted 2/2005)

Drug Safety Draft

FDA's "Drug Watch" for Emerging Drug Safety Information (Issued 5/5/2005; Posted 5/5/2005)
Questions and Answers (Qs & As)

Electronic Submissions

Part 11, Electronic Records; Electronic Signatures—Scope and Application (Posted 9/3/2003)
Providing Regulatory Submissions in Electronic Format—ANDAs (Issued 6/2002, Posted 6/27/2002)
Providing Regulatory Submissions in Electronic Format—Content of Labeling (Issued 4/20/2005, Posted 4/20/2005)
Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications. To ensure you have the most recent versions of the specifications referenced in this document, check the appropriate center's guidance Web page. For CBER, this Web site is *http://www.fda.gov/cber/esub/esub.htm*. For CDER, this Web site is *http://www.fda.gov/cder/regulatory/ersr/ectd.htm*. (Issued 10/18/2005, Posted 10/18/2005)
Regulatory Submissions in Electronic Format; General Considerations (Issued 1/1999, Posted 1/27/1999)
Regulatory Submissions in Electronic Format; New Drug Applications (Issued 1/1999, Posted 1/27/1999)
SPL Standard for Content of Labeling Technical Qs & As (Issued 12/2005, Posted 12/8/2005)
Example of an Electronic New Drug Application Submission (Posted 2/17/1999).

Electronic Submissions Draft

Providing Regulatory Submissions in Electronic Format—Annual Reports for NDAs and ANDAs (Posted 8/27/2003)
Providing Regulatory Submissions in Electronic Format—General Considerations (Issued 10/2003, Posted 10/22/2003)
Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports (Issued 5/2001, Posted 5/3/2001)
Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports (Posted 6/23/3003)
Providing Regulatory Submissions in Electronic Format—Prescription Drug Advertising and Promotional Labeling (Issued 1/2001, Posted 1/30/2001)

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)
ANDA's: Impurities in Drug Substances (Issued 11/1999, Posted 12/2/1999)
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (Posted 3/27/2000)
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)

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Letter on the Provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters (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 on the response to 12/20/1984 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act (Posted 3/2/1998)
Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law (Posted 3/2/1998)
Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria and bioequivalence requirements (Posted 3/2/1998)
Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications (Issued 12/2001, Posted 12/20/2001)
Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing (Issued 10/25/2005; Posted 10/25/2005)
Revising ANDA Labeling Following Revision of the RLD Labeling (Issued 4/26/2000, 4/26/2000)
Variations in Drug Products that May Be Included in a Single ANDA (Issued 12/1998, Posted 1/26/1999)

Generics (Draft)

ANDAs: Impurities in Drug Products (Issued 8/26/2005, Posted 8/26/2005)
ANDAs: Impurities in Drug Substances (Issued 1/28/2005, Posted 1/28/2005)
ANDAs: Pharmaceutical Solid Polymorphism (Issued 12/17/2004, Posted 12/17/2004)
Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Questions and Answers (Issued 10/2004, Posted 11/3/2004)

Good Review Practices (GRPs)

Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review (Posted 2/18/2005)
Pharmacology/Toxicology Review Format (Posted 5/9/2001)

Good Review Practices (GRPs) (Draft)

Industry Letters

Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program (Posted 3/2/1998)
Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required (Posted 3/2/1998)
Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I (Posted 3/2/1998)
Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance (Posted 3/2/1998)
Implementation Plan USP injection nomenclature (Posted 3/2/1998)
Seventh of a series of letters about the Act providing guidance on the "130-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C (Posted 3/2/1998)
Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity provisions of sections 505(c)(3)(D) and 505(j)(4)(D) of the FD&C Act (Posted 3/2/1998)
Supplement to 10/11/1984 letter about policies, procedures and implementation of the Act (Q&A format) (Posted 3/2/1998)
Third of a series of letters regarding the implementation of the Act (Posted 3/2/1998)
Year 2000 Letter from Dr. Janet Woodcock (10/19/98)

International Conference on Harmonisation

Safety
- S1A The Need for Long-term Rodent Carcinogenicity Studies of Pharmaceuticals
- S1B Testing for Carcinogenicity of Pharmaceuticals (Issued 2/28/1998, Posted 3/24/1998)
- S1C Dose Selection for Carcinogenicity Studies of Pharmaceuticals
- S1C(R) Guidance on Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes (Issued 12/4/1997, Posted 12/11/1997)
- S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals
- S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals (Issued 11/21/1997, Posted 5/4/1998)
- S3A Toxicokinetics: 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
- S5A Detection of Toxicity to Reproduction for Medicinal Products (Issued 9/1994, Posted 4/23/1997)
- S5B Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility
- S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals (Issued 11/1997, Posted 11/18/1997)
- 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: Electronic Common Technical Document Specification (Posted 4/1/2003)
  - M2: eCTD Specification Questions and Answers and Change Requests (Posted 3/14/05)
    - Companion Document: Current Q & As and Change Requests (Issued 1/6/2006; Posted 1/6/2006)
- M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals (Issued 11/1997, Posted 11/25/1997)
- M4: Common Technical Document for the Registration of Pharmaceuticals for Human Use (Posted 10/15/2001)
  - M4: Organization of the CTD
    - M4 Granularity Annex (Issued 10/18/2005, Posted 10/18/2005)
    - M4: The CTD—General Questions and Answers (Issued 12/04, Posted 12/22/2004)
  - M4: The CTD—Quality
    - M4: The CTD—Quality Questions and Answers /Location Issues (Issued 6/2004, Posted 6/8/2004)
  - M4: The CTD—Efficacy
    - M4: The CTD—Efficacy Questions and Answers (Issued 12/2004, Posted 12/22/2004)
  - M4: The CTD—Safety
  - M4: The CTD—Safety Appendices
    - M4: The CTD—Safety Questions and Answers (Issued 2/2003, Posted 2/4/2003)

Efficacy
- E1A The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions

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E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
E2B International Conference on Harmonisation; Guidance on Data Elements for Transmission of Individual Case Safety Reports (Issued 1/15/1998, Posted 1/15/1998)
E2BM Data Elements for Transmission Of Individual Case Safety Reports (Issued 4/2002, Posted 4/4/2002)
E2B(M) Questions and Answers (Revised 3/09/2005, Posted, 3/16/2005)
E2C Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs (Issued 5/19/1997, Posted 3/19/1998)
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
E5 Questions and Answers (Issue 6/2004, Posted 6/4/2004)
E6 Good Clinical Practice: Consolidated Guideline Spanish Version (Issued 5/9/1997, Posted 3/19/1998)
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)
E10 Choice of Control Group and Related Issues in Clinical Trials (Issued 5/2001, Posted 5/11/2001)
E11 Clinical Investigation of Medicinal Products in the Pediatric Population (Issued 12/2000, Posted 12/14/2000)
E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (Issued 10/19/2005, Posted 10/19/2005)

Quality

Q1A(R2) Stability Testing of New Drug Substances and Products (Issued 11/2003, Posted 11/20/2003)
Q1B Photostability Testing of New Drug Substances and Products (Issued 11/1996, Reposted 7/7/1998)
Q1C Stability Testing for New Dosage Forms (Issued 5/9/1997, Posted 3/19/1998)
Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products (Issued 1/2003, Posted 1/15/2003)
Q1E Evaluation of Stability Data (Issued 6/2004, Posted 6/7/2004)
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
Q2B Validation of Analytical Procedures: Methodology (Issued 5/19/1997, Posted 3/19/1997)
Q3A Impurities in New Drug Substances (Issued 2/10/2003, Posted 2/10/2003)
Q3B(R) Impurities in New Drug Products (Issued 11/2003, Posted 11/13/2003)
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)
Maintenance Procedures for Updating (Posted 2/11/2002)
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)
Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process (Issued 6/2005, Posted 6/29/2005)
Q6A International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances. (12/29/2000)
Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products (Issued 8/1999, Posted 12/14/2001)
Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (Issued 8/2001, Posted 9/24/2001]

International Conference on Harmonisation (Draft)

Efficacy
E2B(R) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (Issued 9/30/2005, Posted 9/30/2005)
E2D Postapproval Safety Data Management: Definitions and Standards for Expedited Reporting (Posted 9/12/2003)
Principles for Clinical Evaluation of New Antihypertensive Drugs. (Issued 8/2000, Posted 8/8/2000)
Joint Safety/Efficacy (Multidisciplinary) (Draft)
International Conference on Harmonisation; Draft Guidance on M5 Data Elements and Standards for Drug Dictionaries (Issued 9/2005, Posted 9/2/2005)
Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (Issued 9/2001, Posted 9/5/2001)
Quality
Q8 Pharmaceutical Development (Issued 2/7/2005, Posted 2/8/2005)
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)

Labeling (Draft)

Labeling for Combined Oral Contraceptives (Issued 3/2/2004, Posted 3/4/2004)
Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements (Issued 1/18/2006; Posted 1/18/2006)
Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis) (Issued 6/1998, Posted 7/20/1998)
Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Recommended Prescribing Informtion for Health Care Providers and Patient Labeling (Issued 11/15/2005, Posted 11/15/2005)
Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications (Issued 10/2000, Posted 10/25/2000)
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

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

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)
Classifying Resubmissions in Response to Action Letters (Issued 5/14/1998, Posted 5/14/1998)
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act (Issued 11/1998, Posted 11/20/1998)
Fast Track Drug Development Programs—Designation, Development, and Application Review (Posted 7/22/2004)
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)
Formal Dispute Resolution: Appeals Above the Division Level (Issued 2/2000, Posted 3/6/2000)
Formal Meetings With Sponsors and Applicants for PDUFA Products (Issued 2/2000, Posted 3/6/2000)
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997—Advisory Committees (Issued 10/1998, Posted 11/02/98)
Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements (Issued 7/1998, Posted 7/20/98)
Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (Issued 3/2002, Posted 3/18/2002)
National Uniformity for Nonpresciption Drugs—Ingredient Listing for OTC Drugs (Issued 4/1998, Posted 5/5/1998)
Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products (Issued 5/14/1998, Posted 5/14/1998)
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act (Issued 9/1999, Posted 10/4/1999)
  Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric "Rule," and Their Interaction (Posted 7/27/1999)
Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act (Revised 5/1998, Posted 6/12/1998)
Standards for Prompt Review of Efficacy Supplements (Issued 5/15/1998, Posted 5/15/1998)
Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (Issued 8/1998, Posted 9/15/98)
Submitting and Reviewing Complete Responses to Clinical Holds (Revised) (Issued 10/2000, Posted 10/25/2000
Women and Minorities Guidance Requirements (Issued 7/20/1998, Posted 11/25/1998)

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
Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (Posted 4/4/2001)

Over-the-Counter (OTC) Guidances

Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16) (Posted 3/2/1998)
General Guidelines for OTC Combination Products (Posted 3/2/1998)
Labeling OTC Human Drug Products Using a Column Format (Issued 12/2000, Posted 12/18/2000)
Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs
  Example Drug Facts Labels
    Acetaminophen 120 mg in a Suppository Dosage Form
    Acetaminophen 325 mg in a Suppository Dosage Form
    Acetaminophen 650 mg in a Suppository Dosage Form
    Cimetidine 200 mg in a Tablet Dosage Form
    Clemastine Fumerate 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
Upgrading Category III Antiperspirants to Category I (43 FR 46728–46731) (Posted 3/2/1998)

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—Submitting Requests for Exemptions and Deferrals (Issued 12/2000, Posted 12/18/2000)
Labeling OTC Human Drug Products (Small Entity Compliance Guide) (Issued 12/2004, Posted 6/8/2005)
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)
Time and Extent Applications (Issued 2/2004, Posted 2/11/2004)

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
  Part 1: Conducting Safety Assessments (Issued 6/17/2004, Posted 6/17/2004)
Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers (Issued 7/21/2005, Posted 7/21/2005.
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)
Immunotoxicology Evaluation of Investigational New Drugs (Issued 10/2002, Posted 10/31/2002)
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)

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

Photosafety Testing (Posted 5/7/2003)
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 Antivial Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease Evaluation of Drug Toxicity Prior to Phase I Clinical Studies (Posted 3/2/1998)
Single Dose Acute Toxicity Testing for Pharmaceuticals

Pharmacology/Toxicology Draft

Integration of Study Results to Assess Concerns about Human Reproductive and Developmental Toxicities (Issued 11/2001, Posted 11/9/2001)
Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals (Issued 6/17/2005; Posted 6/17/2005)
Nonclinical Safety Evaluation of Drug Combinations (Issued 1/26/05, Posted 1/26/05)
Safety Testing of Drug Metabolites (Issued 6/2005, Posted 6/3/2005)
Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals (Issued 5/2001, Posted 5/7/2001)

Procedural

180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (Issued 6/1998, Posted 6/22/1998)
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)
Paperwork Reduction Act Burden Statement (Posted 7/27/2004)
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (Posted 3/27/2000)
Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000 (Issued 11/1999, Posted 11/29/1999)
Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate—Labeling Enforcement Policy (Posted 6/3/2003)
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act (Issued 11/1998, Posted 11/20/1998)
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)
FDA Export Certicates (Issued 7/2004, Posted 7/13/2004)
Financial Disclosure by Clinical Investigators (3/27/2001)
Formal Dispute Resolution: Appeals Above the Division Level (Issued 2/2000, Posted 3/6/2000)
Formal Meetings With Sponsors and Applicants for PDUFA Products (Issued 2/2000, Posted 3/6/2000)
Good Review Management Principles and Practices for PDUFA Products (Issued 3/2005; Posted 3/30/2005)
Guidance for FDA Staff: The Leveraging Handbook; An Agency Resource for Effective Collaborations (Revised 6/2003)
Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997—Advisory Committees (Issued 10/1998, Posted 11/02/98)
Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997—Elimination of Certain Labeling Requirements (Issued 7/1998, Posted 7/20/98)
Independent Consultants for Biotechnology Clinical Trial Protocols (Issued 8/18/2004, Posted 8/192/2004)
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)
National Uniformity for Nonpresciption Drugs—Ingredient Listing for OTC Drugs (Issued 4/1998, Posted 5/5/1998)
Pharmacogenomic Data Submissions (Issued 3/2005, Posted 3/22/2005)
Examples of Voluntary Submissions or Submissions Required Under 21 CFR 312, 314, or 601 (Issued 3/2005, Posted 3/22/2005)
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies (Issued 12/2001, Posted 12/10/2001)
KI in Radiation Emergencies—Questions and Answers (Issued 12/20/2002, Posted 12/23/2002)
Potassium Iodide Tablets—Shelf Life Extension (Posted 3/8/2004)
Reduction of Civil Money Penalties for Small Entities (Issued 3/20/2001)
Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act (Issued 9/1999, Posted 10/4/1999)
Refusal to File (Issued 7/12/1993, Posted 11/26/99)
Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act (Revised 5/1998, Posted 6/12/1998)
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)
Special Protocol Assessment (Issued 5/2002, Posted 5/16/2002)
Standards for Prompt Review of Efficacy Supplements (Issued 5/15/1998, Posted 5/15/1998)
Submitting and Reviewing Complete Responses to Clinical Holds (Revised) (Issued 10/2000, Posted 10/25/2000)

Procedural Draft

Applications Covered by Section 505(b)(2) (Issued 10/1999, Posted 12/7/1999)
Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000 (Issued 12/1999, Posted 12/22/1999)
Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees (2/14/2002)
Emergency Use Authorization of Medical Products; Availability (Issued 7/5/2005; Posted 7/5/2005.
Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV (5/17/2004)
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
Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (Issued 3/2001, Posted 3/9/2001)
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)
The Use of Clinical Holds Following Clinical Investigator Misconduct (Issued 4/2002, Posted 8/26/2002)
Useful Written Consumer Medication Information (CMI) (Issued 5/25/2005, Posted 5/25/2005)
Using a Centralized IRB Review Process in Multicenter Clinical Trials (Issued 3/25/2005, Posted 3/25/2005)

Small Entity Compliance Guides

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

Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation—Small Entity Compliance Guide (Posted 11/7/2001)
Small Entity Compliance Guides (Draft)
Labeling OTC Human Drug Products (Small Entity Compliance Guide) (Issued 12/2004, Posted 6/8/2005)
User Fees
Classifying Resubmissions in Response to Action Letters (Issued 5/14/1998, Posted 5/14/1998) Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act (Issued 6/1999, Posted 6/25/99) Guidance for Industry and FDA Staff: Application User Fees for Combination Products. (Issued 4/2005, Posted 5/3/2005) Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act (Issued 11/2001) Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Issued 12/30/2004, Posted 12/30/2004)
User Fees (Draft)
Attachment G—Draft Interim Guidance Document for Waivers of and Reductions in User Fees (7/16/1993) User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR (Issued 4/15/2005, Posted 4/15/2005)
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)

For information on a specific guidance document or to obtain a hard copy, contact: Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 1–800–638–2041 or 301–443–6597, *http://www.fda.gov/cdrh/guidance.html.*

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

Title of Document	Date of Issuance	Date of Withdrawal
Methods for Conducting Recall Effectiveness Checks	June 16, 1978	January 2006
Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver; Draft Guidance for Industry and FDA	March 1, 2001	September 7, 2005
Guidance for Industry; In Vitro Diagnostic C-Reactive Protein Immunological Test System	July 20, 1998	September 22, 2005
Guidance for Over-the-Counter (OTC) Ovulation Predictor 510(k)s	July 22, 2000	September 7, 2005
Draft Review Criteria for Nucleic Acid Amplification Based In Vitro Diagnostic Devices for Direct Detection of Infectious Microorganisms	June 14, 1993	December 8, 2005
CDRH Interim Regulatory Policy for External Penile Rigidity Devices	September 10, 1997	January 2005
Guidance for Neurological Embolization Devices	November 1, 2000	January 2005
Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices	Draft of this document was issued on June 30, 2004	Final issued on: April 28, 2005
Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices	Draft of this document was issued on February 25, 2004	Final issued on: December 29, 2004
Class II Special Controls Guidance Document: External Penile Rigidity Devices	Draft of this document was issued March 17, 2004	Final issued on: December 28, 2004

The following is a copy of a list of current CDRH guidance documents obtained from the FDA Web site as of March14, 2006.

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

(1) A Guide for the Submission of Abbreviated Radiation Safety Reports on Image Receptor Support Devices for Mammographic X-Ray Systems 979 03/01/1996
(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
(4) Compliance Program Guidance Manual: Field Implementation of the Sunlamp and Sunlamp Product Performance Standard, as amended; Final Guidance for Industry and FDA 75 10/06/2001
(5) Frequently Asked Questions (FAQs) on the Status of Reprocessed Single Use Devices (SUDs) that receive a Not Substantially Equivalent (NSE) Letter—Guidance for Industry and FDA Staff 1544 11/08/2004
(6) Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21-CFR 1020.40 241 02/01/1975
(7) Guidance on the Department of Defense Exemption from the FDA Performance Standard for Laser Products; Guidance for Industry and FDA 1412 07/12/2002
(8) Guide for Preparing Abbreviated Reports of Microwave and RF Emitting Electronic Products Intended for Medical Use 399 09/01/1996
(9) Guide for Preparing Annual Reports for Ultrasonic Therapy Products 261 09/01/1996
(10) Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General) 243 10/01/1987
(11) Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps 263 09/01/1995
(12) Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products 262 09/01/1995
(13) Guide for Preparing Product Reports for Medical Ultrasound Products 960 09/01/1996
(14) Guide for Preparing Product Reports for Ultrasonic Therapy Products (physical therapy only) 249 08/01/1996
(15) Guide for Preparing Product Reports on Sunlamps and Sunlamp Products (21-CFR 1002) 279 09/01/1995
(16) Guide for Preparing Reports on Radiation Safety of Microwave Ovens 239 03/01/1985
(17) Guide for Submission of Information on Accelerators Intended to Emit X-Radiation Required Pursuant to 21-CFR 1002.10 235 04/01/1971
(18) Guide for Submission of Information on Analytical X-Ray Equipment Required Pursuant to 21-CFR 1002.10 240 04/30/1974
(19) Guide for Submission of Information on Industrial Radiofrequency Dielectric Heater and Sealer Equipment Pursuant to 21 CFR 1002.10 and 1002.12 (FDA 81–8137) 254 09/01/1980
(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) 1346 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
(29) Reporting and Compliance Guide for Television Products including Product Report, Supplemental Report, Radiation Safety Abbreviated Report, Annual Report, Information and Guidance 260 10/01/1995
(30) Reporting Guide for Laser Light Shows and Displays (21-CFR1002) (FDA 88–8140) 251 09/01/1995
(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
(33) Revised Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products (replaces FDA 82–8127) 264 09/01/1995
(34) Suggested State Regulations for Control of Radiation—Volume II Nonionizing Radiation—Lasers (FDA Pub No. 83–8220) 70 01/01/1982
(35) Wireless Medical Telemetry Risks and Recommendations 1173 09/27/2000
(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
(42) Expedited Review of Premarket Submissions for Devices—Guidance for Industry and FDA Staff CBER CDRH 108 11/26/2003
(43) FY 2005 MDUFMA Small Business Qualification Worksheet and Certification—Guidance for Industry and FDA CBER CDRH 2005 08/02/2004
(44) FY 2006 MDUFMA Small Business Qualification Worksheet and Certification—Guidance for Industry and FDA CBER CDRH 2006 08/17/2005
(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
(46) 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—Gudiance for Industry, FDA Staff, and FDA-Accredited Third-Parties CBER CDRH 1532 09/15/2005
(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 CDER 03/13/2001
(51) Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis CDER 2199 07/07/1999
(52) Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—General Considerations CDER 10/22/2003
(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
(56) Implementation of the Inspection by Accredited Persons Program Under The Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties CDRH 1200 10/04/2004
(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 Manufacturers 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
(67) Guidance on Performance Standard for Lead Wires and Patient Cables OC 1197 03/09/1998
(68) Guideline for the Monitoring of Clinical Investigations OC 428 01/01/1988
(69) Implementation of the Biomaterials Access Assurance Act of 1998; Draft Guidance for Industry and FDA OC 1324 04/02/2001
(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

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

(73) Sec. 300.600 Commercial Distribution with Regard to Premarket Notification [Section 510(k)] [CPG 7124.19] OC 181 09/24/1987
(74) Sterilized 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) Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects OC/DBM 2229 03/19/1999
(77) Regulating In Vitro Diagnostic Device (IVD) Studies OC/DBM 1132 12/17/1999
(78) Guidance on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables OC/DE1 1129 11/15/1999
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(486) Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters ODE/DRARD/ULDB 97 09/12/1994
(487) Guidance for the Content of Premarket Notifications for Intracorporeal Lithotripters; Final ODE/DRARD/ULDB 2235 11/30/1998
(488) Guidance for the Content of Premarket Notifications for Penile Rigidity Implants; Final ODE/DRARD/ULDB 177 01/16/2000
(489) Guidance for the Content of Premarket Notifications for Ureteral Stents ODE/DRARD/ULDB 431 02/10/1993
(490) Guidance for the Content of Premarket Notifications for Urine Drainage Bags ODE/DRARD/ULDB 96 06/07/1994
(491) Guidance for the Content of Premarket Notifications for Urodynamic/Uroflowmetry Systems ODE/DRARD/ULDB 490 07/29/1994
(492) Analyte Specific Reagents; Small Entity Compliance Guidance; Guidance for Industry OIVD 1205 02/26/2003
(493) Assessing the Safety/Effectiveness of Home-use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions OIVD 272 10/01/1988
(494) Determination of Intended Use for 510(k) Devices; Guidance for CDRH Staff OIVD 857 12/03/2002
(495) Guidance for Administrative Procedures for CLIA Categorization OIVD 1143 08/14/2000
(496) Guidance for Industry—Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final OIVD 1247 02/22/1999
(497) Guidance for Industry and FDA Staff; Replacement Reagent and Instrument Family Policy OIVD 950 12/11/2003
(498) Guidance on Labeling for Laboratory Tests; Draft OIVD 1352 06/24/1999
(499) Guideline for the Manufacture of In Vitro Diagnostic Products OIVD 918 01/10/1994
(500) Letter to IVD Manufacturers on Streamlined PMA; Final OIVD 1395 12/22/1997
(501) Points to Consider for Collection of Data in Support of In-Vitro Device Submissions for 510(k) Clearance OIVD 95 09/26/1994
(502) Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices/Cover Letter dated 3/14/1996 OIVD 553 02/01/1996
(503) Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft OIVD 2231 02/03/1999
(504) Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications—Draft Guidance for Industry and FDA Staff OIVD 1171 09/07/2005
(505) Draft Guidance for Industry and FDA Staff—Pharmacogenetic Tests and Genetic Tests for Heritable Markers CBER CDER OIVD 1549 02/09/2006
(506) Format for Traditional and Abbreviated 510(k)s—Guidance for Industry and FDA Staff OIVD ODE 1567 08/12/2005
(507) Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications OIVD ODE 2237 09/28/2004
(508) Premarket Approval Application Filing Review—Guidance for Industry and FDA Staff OIVD ODE 297 05/01/2003
(509) Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices—Guidance for Industry and FDA Staff CBER OIVD ODE 337 05/11/2005
(510) Breath Nitric Oxide Test System—Class II Special Controls Guidance Document OIVD/DCTD 1211 07/07/2003
(511) Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers OIVD/DCTD 1072 11/30/2000
(512) Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA OIVD/DCTD 1380 09/16/2002
(513) Draft Guidance on the Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing OIVD/DCTD 1359 12/21/1999
(514) Drug Metabolizing Enzyme Genotyping System—Class II Special Controls Guidance Document—Guidance for Industry and FDA Staff OIVD/DCTD 1551 03/10/2005
(515) Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use OIVD/DCTD 605 07/14/1995
(516) Guidance for Industry—Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays OIVD/DCTD 1246 09/22/2005
(517) Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Sirolimus Test Systems OIVD/DCTD 1300 09/30/2004
(518) Guidance for Industry In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Final OIVD/DCTD 1102 07/06/1998
(519) Guidance for Industry In Vitro Diagnostic Chloride Test System; Final OIVD/DCTD 1103 07/06/1998
(520) Guidance for Industry In Vitro Diagnostic Creatinine Test System; Final OIVD/DCTD 1104 07/02/1998
(521) Guidance for Industry In Vitro Diagnostic Glucose Test System; Final OIVD/DCTD 1105 07/06/1998
(522) Guidance for Industry In Vitro Diagnostic Potassium Test System; Final OIVD/DCTD 1107 07/06/1998
(523) Guidance for Industry In Vitro Diagnostic Sodium Test System; Final OIVD/DCTD 1109 07/06/1998
(524) Guidance for Industry In Vitro Diagnostic Urea Nitrogen Test System; Final OIVD/DCTD 1110 07/06/1998
(525) Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s OIVD/DCTD 1172 07/22/2000
(526) Instrumentation for Clinical Multiplex Test Systems—Class II Special Controls Guidance Document—Guidance for Industry and FDA Staff OIVD/DCTD 1546 03/10/2005
(527) Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry—Class II Special Controls Guidance Document OIVD/DCTD 1301 12/24/2004
(528) Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery OIVD/DCTD 122 02/20/1996
(529) Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests—Draft Guidance for Industry and FDA Staff OIVD/DCTD 152 12/02/2003
(530) Review Criteria for Assessment of Portable Blood Glucose In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase, or Hexokinase Methodology OIVD/DCTD 604 02/14/1996
(531) Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs) OIVD/DCTD 1345 11/06/1996
(532) 510(k) Submissions for Coagulation Instruments—Guidance for Industry and FDA Staff OIVD/DIHD 1223 06/19/2003
(533) CFTR Gene Mutation Detection Systems—Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document OIVD/DIHD 1564 10/26/2005
(534) Class II Special Control Guidance Document for Anti-Saccharomyces cerevisia (S. cerevisiae) Antibody (ASCA) Premarket Notifications OIVD/DIHD 1183 08/23/2000
(535) Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems OIVD/DIHD 1570 10/03/2005
(536) Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems—Guidance for Industry and FDA Staff OIVD/DIHD 1236 03/16/2004
(537) Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA OIVD/DIHD 1184 12/04/2001
(538) Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing) OIVD/DIHD 1563 08/25/2005
(539) Document for Special Controls for Erythropoietin Assay Premarket Notifications [510(k)s]; Final OIVD/DIHD 2241 04/28/1999
(540) Draft Guidance Document for 510(k) Submission of Fecal Occult Blood Tests OIVD/DIHD 772 07/29/1992
(541) Draft Guidance Document for 510(k) Submission of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin for IVDs OIVD/DIHD 658 09/30/1991
(542) Draft Guidance Document for 510(k) Submission of Immunoglobulins A,G,M,D and E Immunoglobulin System In Vitro Devices OIVD/DIHD 785 09/01/1992
(543) Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs using Monoclonal Antibodies OIVD/DIHD 475 09/26/1991

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

(544) Guidance Document for the Submission of Tumor Associated Antigen Premarket Notification [510(k)] to FDA OIVD/DIHD 957 09/19/1996
(545) Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems OIVD/DIHD 1550 03/23/2005
(546) Guidance for Submission of Immunohistochemistry Applications to the FDA; Final OIVD/DIHD 364 06/03/1998
(547) Immunomagnetic Circulating Cancer Cell Selection and Enumeration System—Class II Special Controls Guidance Document—Guidance for Industry and FDA Staff OIVD/DIHD 1531 05/11/2004
(548) In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Final OIVD/DIHD 2242 04/27/1999
(549) Points to Consider for Cervical Cytology Devices OIVD/DIHD 968 07/25/1994
(550) Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k)s; Final Guidance for Industry and FDA OIVD/DIHD 08/22/2001
(551) Review Criteria for Assessment of Alpha-Fetoprotein (AFP) in vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies OIVD/DIHD 459 07/15/1994
(552) Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers OIVD/DIHD 417 07/15/1991
(553) Review Criteria for Assessment of Rheumatoid Factor(RF) In Vitro Diagnostic Devices Using Engzyme-Linked Immunoassay (EIA), Enzyme Linked Immunosorbent Assay (ELISA), Particle Agglutination Tests, and Laser and Rate Nephelometry OIVD/DIHD 165 02/21/1997
(554) Review Criteria for Blood Culture Systems OIVD/DIHD 82 08/12/1991
(555) Review Criteria for In Vitro Diagnostic Devices for Detection of IGM Antibodies to Viral Agents OIVD/DIHD 527 08/01/1992
(556) Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoasay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA) OIVD/DIHD 51 02/01/1994
(557) Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic) OIVD/DIHD 980 02/15/1996
(558) Review Criteria for the Assessment of Anti-nuclear Antibodies (ANA) In-Vitro Diagnostic Devices Using Indirect Immunofluorescence Assay (IFA), Immunodiffusion (IMD) and Enzyme Linked Immunosorbant Assay (ELISA) OIVD/DIHD 848 09/01/1992
(559) Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDa OIVD/DMD 631 02/05/2003
(560) Class II Special Controls Guidance Document: Endotoxin Assay OIVD/DMD 1222 10/31/2003
(561) Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays OIVD/DMD 1305 01/09/2006
(562) Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays OIVD/DMD 1536 02/09/2006
(563) Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus OIVD/DMD 1206 10/30/2003
(564) Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan OIVD/DMD 1825 09/23/2004
(565) Nucleic Acid Based In Vitro Diagnostic Devices for Detection of Microbial Pathogens—Draft Guidance for Industry and FDA Staff OIVD/DMD 1560 12/08/2005
(566) Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs OIVD/DMD 1631 10/30/1996
(567) Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Chlamydiae in Clinical Specimens OIVD/DMD 778 01/01/1992
(568) Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. [Tuberculosis (TB)] OIVD/DMD 862 07/06/1993
(569) Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter pylori OIVD/DMD 588 09/17/1992
(570) Review Criteria for Devices Assisting in the Diagnosis of C. Difficile Associated Diseases OIVD/DMD 629 05/31/1990
(571) Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe OIVD/DMD 554 12/30/1991
(572) Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19 OIVD/DMD 770 05/15/1992
(573) Addendum to the Instructions for Completing FDA form 3500A with Coding Manual (MEDWATCH)(MDR) OSB 06/09/1999
(574) Perspectives on Clinical Studies for Medical Device Submissions (Statistical) OSB 78
(575) PMA Review Statistical Checklist OSB 84
(576) Statistical Guidance for Clinical Trials of Non Diagnostic Medical Devices OSB 476 01/01/1996
(577) Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests; Draft Guidance for Industry and FDA Reviewers OSB/DB 1428 03/12/2003
(578) Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements OSB/DPS 946 02/02/2000
(579) Guidance on Criteria and Approaches for Postmarket Surveillance OSB/DPS 9 11/02/1998
(580) Guidance on Procedures for Review of Postmarket Surveillance Submissions OSB/DPS 317 02/19/1998
(581) Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies OSB/DPS 316 02/19/1998
(582) Procedures for Handling Post-Approval Studies Imposed by PMA Order—Draft Guidance for Industry and FDA Staff OSB/DPS 09/15/2005
(583) SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance OSB/DPS 318 11/02/1998
(584) Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment—Guidance for Industry and FDA Staff OSB/DPS OCER/DDUPSA 1537 03/10/2006
(585) Common Problems: Baseline Reports and MedWatch Form 3500A (letter to manufacturers updated) OSB/DSS 379
(586) Instructions for Completing FDA Form 3500A with Coding Manual for Form 3500A (MEDWATCH) OSB/DSS 853 04/04/2001
(587) Instructions for Completing Form 3417: Medical Device Reporting Baseline Report [MDR] OSB/DSS 1061 03/31/1997
(588) MDR Guidance Document No. 1 - IOL - E1996004 OSB/DSS 216 08/07/1996
(589) Medical Device Reporting: An Overview OSB/DSS 509 04/01/1996
(590) MEDWATCH FDA Form 3500A For Use By User Facilities, Distributors and Manufacturers for Mandatory Reporting OSB/DSS 854 06/01/1993
(591) Variance from Manufacturer Report Number Format OSB/DSS 08/12/1996
(592) Variance from Manufacturer Report Number Format [MDR letter] OSB/DSS 1059 07/16/1996
(593) Guidance for Industry: Medical Device Reporting—Alternative Summary Reporting (ASR) Program OSB/DSS/RSMB 315 10/19/2000
(594) Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use OSB/DSS/RSMB 1334 04/24/2001
(595) Medical Device Reporting - Remedial Action Exemption; Guidance for Industry and FDA OSB/DSS/RSMB 188 09/26/2001
(596) Needlesticks—Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers OSB/DSS/RSMB 250 11/12/2002
(597) CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition; Final Guidance for Industry OSEL 616 06/20/2001
(598) Draft Document—A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems OSEL 952 02/07/1997
(599) Frequently Asked Questions on the Recognition of Consensus Standards; Guidance for Industry and for FDA Staff OSEL 109 07/22/2002
(600) Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA OSEL 321 06/20/2001
(601) Guidance for Industry Guidance on FDA's Expectations of Medical Device Manufacturers Concerning the Year 2000 Date Problem OSEL/DECS 2000 05/15/1998
(602) Immunotoxicity Testing Guidance OSEL/DLS 635 05/06/1999
(603) 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms; Draft Guidance for Industry OUT 09/24/2001
(604) 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation; Draft Guidance for Industry OUT 09/24/2001
(605) Combination Products—Timeliness of Premarket Reviews—Dispute Resolution Guidance—Draft Guidance for Industry OUT 05/04/2004
(606) Computerized Systems Used in Clinical Trials OUT 04/01/1999
(607) Draft Guidance for Industry on Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records OUT 11/12/2002
(608) Guidance for Industry and FDA Staff: Application User Fees for Combination Products OUT 04/21/2005
(609) Information Sheet Guidance for IRB's—Frequently Asked Questions about IRB Review of Medical Devices OUT 01/01/2006
(610) Information Sheet Guidance for IRB's—Significant Risk and Nonsignificant Risk Medical Device Studies OUT 01/01/2006
(611) Small Business Guide to FDA (FDA 96–1092) OUT 16 01/01/1996

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

For information on a specific guidance document or to obtain a hard copy, contact: Industry Activities Staff, Center for Food Safety and Applied Nutrition/FDA, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2600, *http://www.cfsan.fda.gov/~dms/guidance.html.*

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

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

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. PB96–920500 Drugs and Biologics Order No. PB96–920500 Veterinary Medicine Order No. PB96–920800 Medical and Radiological Devices Order No. PB96–920900 Source: National Technical Information Service
Compliance Programs Guidance Manual (March 1995) Manual. Contains inspectional and analytical directives implemented by FDA Field Units. Provides direction for general enforcement of laws and regulations. Order No. PB95–915499 (manual only) Source: National Technical Information Service
FDA Recall Policy (2002) Explains the three classes of recalls and discusses FDA's role in the recall process. Source: Industry Activities Staff
Guidance for FDA Staff: The Leveraging Handbook; An Agency Resource for Effective Collaborations
Guidance for Small Businesses: Submission of Comments for CFSAN Rulemaking
Investigations Operations Manual (May 1996) Manual. Provides standard operation procedures for FDA Investigators. The inspectional methods cover sanitation, micro problems, labeling, standards, and GMP's. Order No. PB–95–913399 Source: National Technical Information Service
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
Pesticides Analytical Manual (1999) Contains the procedures and methods used in FDA labs for regulatory examination of food and feed samples to determine compliance with the FD&C Act. Volume 1—Order No.PB94–911899 Source: National Technical Information Service
Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers (June 13, 1995)
FDA Advisory for Deoxynivanol (DON) in Finished Wheat Products Intended for Human Consumption and in Grain and Grain By-Products for Animal Feed (September 16, 1993) 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

FDA's Cosmetic Labeling Manual (October 1991) Booklet. A summary of regulatory requirements for labeling of cosmetics marketed in the United States. Available from: Food and Drug Administration Office of Cosmetics and Colors (HFS–100) 5100 Paint Branch Parkway College Park, MD 20740–3235
Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance (December 17, 2003)
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)

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

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)
Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide (January 1999) Source: Industry Activities Staff
Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (December 1999) 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
Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide (October 17, 2003)

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
Statement of Policy: Foods Derived from New Plant Varieties: Notice (May 1992) FEDERAL REGISTER notice dated May 29, 1992; 57 FR 22984. 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)
Toxicological Principles for the Safety of Food Ingredients (Redbook 2000) (July 7, 2000; Updated October 2001, November 2003, January 2006) The Agency is in the process of updating the Redbook and is now making Redbook 2000 chapters available electronically. The Redbook 2000 chapters now substitute for, or supplement, guidance available in the 1982 Redbook I (see above) and in the 1993 Draft Redbook II, which can be obtained from the Office of Food Additive Safety. As additional chapters of Redbook 2000 are completed they will become available electronically.
Toxicological Testing of Food Additives (1983) Source: Office of Premarket Approval
Templates for Reporting Toxicology Data (March 2004)
Draft Guidance: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition (September 17, 2003)
Environmental Assessment Technical Handbook (March, 1987) Order No. PB87175345-AS, A-01 Source: National Technical Information Service (NTIS)
Guidance on Consultation Procedures Foods Derived From New Plant Varieties (October 1997) Source: Office of Premarket Approval
Recommendations for the Early Food 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
Food Additive Petition Expedited Review—Guidance for Industry and Center for Food Safety and Applied Nutrition Staff (January 1999) 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
Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations (April 2002) Source: Office of Food Additive Safety

Food Labeling Publications

A Food Labeling Guide (May 1997) Booklet. This booklet is a summary of the required statements that must appear on food labels. Source: Industry Activities Staff
Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Small Entity Compliance Guide (August 20, 2003)
Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006 (December 30, 2005)
Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003)
Interim Evidence-based Ranking System for Scientific Data (July 10, 2003)
Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements (December 18, 2002)
Draft Guidance: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (January 2001)
Small Business Food Labeling Exemption (June 1996) Information sheet and sample small business exemption application form. Source: Industry Activities Staff
Food Labeling: Questions and Answers Volume I, (August 1994) Booklet. Provided to facilitate the advice to retail businesses process of developing or revising labels for foods other than dietary supplements. Source: Industry Activities Staff
Food Labeling: Questions and Answers Volume II, (February 1996) Booklet. Contains FDA's advice to retail businesses and restaurants making health and nutrient claims on their food products. Source: Government Printing Office
Fair Packaging and Labeling Act Manual (June, 1978) Book. Presents FDA's interpretations of the requirements of the Fair Packaging and Labeling Act as it applies to foods, drugs, cosmetics, and medical devices. Order No. PB-83-222117 Source: National Technical Information Service
Implementation of Section 10809 of the Farm Security and Investment Act of 2002, Pub. L. No. 107-171, § 10809 (2002) regarding the Petition Process to Request Approval of Labeling for Foods that Have Been Treated by Irradiation. (available in PDF)
Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (December 1999) Source: Office of Nutritional Products, Labeling & Dietary Supplements

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

Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide (October 17, 2003)
Structure/Function Claims: Small Entity Compliance Guide (January 9, 2002)
Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (July 1998) Source: Office of Food Labeling
FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases (March 1998) Source: Office of Food Labeling
Guidelines for Determining Metric Equivalents of Household Measures (October 1, 1993) Source: Office of Food Labeling
Food Labeling—Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution Small Entity Compliance Guide (July 2001)
Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction (October 7, 2002)
Food Labeling—Serving Sizes Reference Amount for Baking Powder, Baking Soda, Pectin; Small Entity Compliance Guide (July 2001)
Whole Grain Label Statements (February 2006)
Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 2) (December 14, 2005)

Food Processing Publications

Bacteriological Analytical Manual 7th Edition (1992) Manual. Provides quantitative and qualitative bacteriological testing procedures for detecting microbiological contamination. Contains screening procedures for Salmonella, Shigella, Clostridium botulinum, etc. Source: AOAC International
Bacteriological Analytical Manual Online (2001)

Food and Cosmetic Security Publications

Entry Types and Entry Identifiers—Prior Notice of Imported Food (April 7, 2005)
Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (November 16, 2005)
Questions and Answers Regarding Establishment and Maintenance of Records (Edition 2) (November 10, 2005)
What You Need to Know About Establishment and Maintenance of Records (December 2004)
What You Need to Know About Administrative Detention of Foods (November 2004)
Prior Notice of Imported Food Contingency Plan for System Outages (August 12, 2004)
Questions and Answers Regarding Registration of Food Facilities (Edition 4) (August 6, 2004)
Prior Notice of Imported Food Questions and Answers (Edition 2) (May 3, 2004)
Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance (December 17, 2003)
Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance (December 17, 2003)
What You Need to Know About Registration of Food Facilities (November 25, 2003)
What You Need to Know About Prior Notice of Imported Food Shipments (November 25, 2003)
Necessity of the Use of Food Product Categories in Registration of Food Facilities (July 17, 2003)
Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors Food Security Preventive Measures Guidance (July 11, 2003)
Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance (March 21, 2003)
Importers and Filers: Food Security Preventive Measures Guidance (March 21, 2003)
See also: Compliance Policy Guides—Guidance for FDA Staff on enforcement of Registration of Food Facilities December 2003, Last Revised November 2004 and Prior Notice of Imported Foods December 2003, Last Revised November 2005

Imports and Exports Publications

Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators (August 26, 2004) HTS Codes Revision History
Prior Notice of Imported Food Contingency Plan for System Outages (August 12, 2004)
Prior Notice of Imported Food Questions and Answers (Edition 2) (May 3, 2004)
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)
Importers and Filers: Food Security Preventive Measures Guidance (March 21, 2003)
Guidance for Industry: FDA Export Certificates (2002) (also available in PDF)
Draft Guidance: Regulatory Procedures Manual Chapter 9, Subchapter: Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned (November 5, 2002)
Guidance for Industry: Letter to Manufacturers, Importers, and Distributors of Imported Candy and Candy Wrappers (June 13, 1995)
FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods (1985) Booklet. Question-and-Answer guide for importers, low-acid and acidified import requirements. Source: Industry Activities Staff
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)
Guidelines Concerning Notification and Testing of Infant Formula (1985)Source: Office of Nutritional Products, Labeling & Dietary Supplements
Guidelines for Evaluation of the Safety and Suitability of New Infant Formulas for Feeding Preterm Infants (1988) Source: Office of Nutritional Products, Labeling & Dietary Supplements
Clinical Testing of Infant Formulas with Respect to Nutritional Suitability for Term Infants (1988) Source: Office of Nutritional Products, Labeling & Dietary Supplements
Guidelines for Evaluation of the Safety and Suitability of Infant Formulas for Feeding Infants with Allergic Diseases (1990) Source: Office of Nutritional Products, Labeling & Dietary Supplements
Guidelines for the Clinical Evaluation of New Products Used in the Dietary Management of Infants, Children and Pregnant Women with Metabolic Disorders (1987) Source: Office of Nutritional Products, Labeling & Dietary Supplements

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)
Juice HACCP Hazards and Control Guidance—First Edition (March 3, 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)

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

Low-Acid and Acidified Foods Publications

FDA Food Importer's Guide for Low-Acid Canned and Acidified Foods (1985) Booklet. Question-and-Answer guide for importers, low-acid and acidified import requirements. Source: Industry Activities Staff

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)
Evaluation of Milk Laboratories (1995 Edition) Provides the procedures for the evaluation of milk laboratories. Source: Milk Safety Branch
Methods of Making Sanitation Ratings of Milk Supplies (1999) Rating method for evaluating sanitary quality of milk. Source: Milk Safety Branch
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
Frozen Dessert Processing Guidelines (1989) Sanitation Standards. 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
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 Somatropin (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
Seafood HACCP Transition Policy (December 1999) Source: Office of Seafood Seafood List (1993) Booklet. FDA's guide to acceptable market names for seafood sold in the interstate commerce.
Fish and Fisheries Products Hazards and Control Guide 3rd Edition (2001) Source: Office of Seafood
HACCP Regulation for Fish and Fishery Products: Questions and Answers (1998) 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)
Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Small Entity Compliance Guide (August 20, 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)

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

Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide (January 1999) Source: Industry Activities Staff
Iron-Containing Supplements and Drugs: Label Warning Statements: Small Entity Compliance Guide (October 17, 2003)

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.

Title of Document	Date of Issuance	Date of Withdrawal
#78 Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals	12/1999	1/2006

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

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

1. Anticoccidial Guidelines replaced by Guideline #40
2. Anthelmintics Withdrawn 12/22/2004
3. General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals 06/21/05
4. Guidelines for Efficacy Studies for Systemic Sustained Release Sulfonamide Boluses for Cattle Withdrawn 12/22/2004
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
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
13. Guidelines for Evaluation of Effectiveness of New Animal Drugs for Use in Free-Choice Feeds revision of Medicated Block 01/85
14. Guideline and Format for Reporting the Details of Clinical Trials Using An Investigational New Animal Drug in Food Producing Animals Withdrawn 12/22/2004
15. Guideline and Format for Reporting the Details of Clinical Trials Using An Investigational New Animal Drug in Non-Food Producing Animals (2277) Withdrawn 12/22/2004
16. FOI Summary Guideline 05/85
17. Working Guidelines for Assigning Residue Tolerances replaced by Guideline # 3
18. Antibacterial Drugs in Animal Feeds: Human Health Safety Criteria Withdrawn 12/22/2004
19. Antibacterial Drugs in Animal Feeds: Animal Health Safety Criteria Withdrawn 12/22/2004
20. Antibacterial Drugs in Animal Feeds: Antibacterial Effectiveness Criteria Withdrawn 12/22/2004
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 Labeling of Arecoline Base Drugs Intended for Animal Use
23. Medicated Free Choice Feeds—Manufacturing Control 07/85
24. Guidelines for Drug Combinations for Use in Animals 10/83
25. Guidelines for the Efficacy Evaluation of Equine Anthelmintics Replaced by Guidance 109
26. Guidelines for the Preparation of Data to Satisfy the Requirements of Section 512 of the Act Regarding Animal Safety, Effectiveness, Human Food Safety and Environmental Considerations for Minor Use of New Animal Drugs (superceded by Guidance #61) 04/86; see also Guideline 61, below.
27. New Animal Drug Determinations (see Policy and Procedures Guide 1240.3500) 07/89
28. Animal Drug Applications Expedited Review Guideline (see Policy and Procedures Guide 1240.3135) 06/90
29. Guidelines for the Effectiveness Evaluation of Swine Anthelmintics 09/80
30. Guidelines for Anti-infective Bovine Mastitis Product Development replaced by guideline #49
31. Guidelines for the Evaluation of Bovine Anthelmintics 07/81
32. Guideline for Threshold Assessment replaced by Guideline number 3
33. Target Animal Safety Guidelines for New Animal Drugs 06/89
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 Evaluation of Effectiveness of New Animal Drugs for Use in Poultry Feed for Pigmentation 03/84
38. Guideline for Effectiveness Evaluation of Topical/Otic Animal Drugs 03/84
39. Guideline on the Conduct of Clinical Investigations: Responsibilities of Clinical Investigators and Monitors for Investigational New Animal Drug Studies replaced by Guidance # 85
40. Draft Guideline for the Evaluation of the Efficacy of Anticoccidial Drugs and Anticoccidial Drug Combinations in Poultry 04/92
41. Draft Guideline: Formatting, Assembling, and Submitting New Animal Drug Applications 06/92

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

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
45. Guideline for Uniform Labeling of Drugs for Dairy and Beef Cattle 08/93
48. Guidance for Industry: Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products 11/94
49. Guidance Document For Target Animal Safety And Drug Effectiveness Studies For Anti-Microbial Bovine Mastitis Products (Lactating and Non-Lactating Cow Products) 04/96
50. Draft Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products 02/93
51. Points to Consider Guideline—Development of a Pharmacokinetic Guideline Enabling Flexible Labeling of Therapeutic Antimicrobials "Please see Guidance 66 for updated information."
52. Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora, February 18, 2004 Replaced by Guidance 159
53. Guideline for the Evaluation of the Utility of Food Additives in Diets Fed to Aquatic Animals 05/94
54. Draft Guideline for Utility Studies for Anti-Salmonella Chemical Food Additives in Animal Feeds—See Final Guidance #80 06/94
55. Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH Claims: Guideline in Protocol Development 06/94
56. Protocol Development Guideline 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
58. Guidance for Industry for Good Target Animal Study Practices: Clinical Investigators and Monitors Withdrawn 12/22/2004; superceded by guidance #85
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
62. Guidance for Industry: Consumer-Directed Broadcast Advertisements: Final Guidance 08/99
63. Guidance for Industry: Validation of Analytical Procedures: Definition and Terminology 07/99
64. Guidance for Industry: Validation of Analytical Procedures: Methodology: Final Guidance 07/99
65. Guidance for Industry: Industry-Supported Scientific and Educational Activities 11/97
66. Withdrawal of Guidance Document on Professional Flexible Labeling of Antimicrobial Drugs 01/02
67. Guidance for Industry: Small Entities Compliance Guide for Renderers 02/98
68. Guidance for Industry: Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors 02/98
68. Guía de la FDA para la Industria Número 68: Para Mezcladores de Proteínas, Fabricantes de Alimentos para Animales y Distribuidores 02/09
69. 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
69. Guidance for Industry: Small Entities Compliance Guide for for Feeders of Ruminant Animals with On-Farm Feed Mixing Operations 02/98
70. Guidance for Industry: Small Entities Compliance Guide for Feeders of Ruminant Animals without On-Farm Feed Mixing Operations 02/98
70. Guía de la FDA para la Industria Número70: Para Alimentadores de Animales Rumiantes sin 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
73. Guidance For industry: Stability Testing Of New Veterinary Drug Substances And Medicinal Products VICH GL3: FINAL GUIDANCE 09/99
74. Guidance for Industry: Stability Testing of New Veterinary Dosage Forms VICH GL4: FINAL GUIDANCE 09/99
75. Guidance For Industry: Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products: Final GUIDANCE 09/99
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
82. Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs—Final Guidance 10/28/02
83. Guidance for Industry: Chemistry, Manufacturing and Controls Changes to an Approved NADA or ANADA: DRAFT GUIDANCE 06/99
84. Guidance for Industry:Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling: DRAFT GUIDANCE 03/99
85. Guidance for Industry: Good Clinical Practices: VICH GL9, Final Guidance 05/09/01
86. Guidance for Industry—How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format by E-Mail 1/17/06
87. Guidance for Industry—How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format by E-mail 01/17/06
88. Guidance for Industry—How to Submit a Request for a Meeting or Teleconference in Electronic Format by E-mail 01/17/06
89. Guidance for Industry—Environmental Impact Assessments (EIA's) For Veterinary Medicinal Products (VMP's)—Phase I, VICH GL6: Final Guidance 03/07/01
90. Guidance for Industry—Effectiveness of Anthelmintics: General Recommendations, Final Guidance—VICH GL7 (replaces 3/26/2001) 10/11/01
91. Guidance for Industry: International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal products (VICH); Final Guidance on Stability Testing for Medicated Premixes (VICH GL8); Availability 03/00
92. Guidance for Industry #92: Impurities In New Veterinary Drug Substances (Revision), VICH GL10 (R) , Draft Revised Guidance, January 5, 2006 01/05/06
93. Guidance for Industry #93—Impurities in New Veterinary Medicinal Products (Revised), Draft Revised Guidance—VICH GL11 (R), January 10, 2006 01/10/05
95. Guidance for Industry: Efficacy Of Anthelmintics: Specific Recommendations for Bovines: VICH GL12, Final Guidance 03/26/01
96. Guidance for Industry: Efficacy Of Anthelmintics: Specific Recommendations for Ovines: VICH GL13, Final Guidance 03/26/01
97. Guidance for Industry: Efficacy Of Anthelmintics: Specific Recommendations for Caprines: VICH GL14, Final Guidance 03/26/01
98. Dioxin In Anti-Caking Agents Used In Animal Feed And Feed Ingredients Revised 04/14/00
99. 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: "Manufacture and Distribution of Unapproved Piperazine Products"—Revised 08/99
103. Guidance for Industry: Possible Dioxin/PCB Contamination of Drug and Biological Products 08/99
104. Guidance for Industry: Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports For Submission to the Division of Therapeutic Drugs for Non-Food Animals 07/10/01
105. Draft Guidance for Industry: Computerized Systems Used in Clinical Trials, Revision 1, Erratum, September 2004 09/04
106. The Use of Published Literature in Support of New Animal Drug Approval 08/31/00
107. Guidance for Industry: How to Submit a Protocol in Electronic Format by E-Mail 01/17/06
108. Guidance for Industry: How to Submit Information in Electronic Format by E-Mail 01/17/06
109. Guidance for Industry #109: Effectiveness of Anthelmintics: Specific Recommendations for Equine—VICH GL15—Final Guidance 06/27/02
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
112. Guidance For Industry 112 : Fumonisin Levels in Human Foods and Animal Feeds—Final Guidance 11/09/01
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
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

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

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
122. Guidance for Industry: Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores, May 18, 2004 Revised 11/09/04
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
126. Guidance for Industry #126—BACPAC I: Intermediates in Drug Substance Synthesis Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation, February 2001 02/01
132. Guidance for Industry: The Administrative New Animal Drug Application Process—Draft 11/06/02
135. Guidance for Industry: Validation of Analytical Procedures for Type C Medicated Feeds, Final 11/07/05
141. Guidance for Industry: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing, VICH GL28, Final Guidance 05/24/04
142. CVM Guidance for Industry #142: Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)—VICH GL29—Draft Guidance 12/12/01
143. CVM Guidance for Industry #143: Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms—VICH GL30—Draft Guidance 02/01/02
144. 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
145. Bioanalytical Method Validation 05/01
147. 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
148. 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
149. 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
150. Guidance for Industry: Status of Clove Oil and Eugenol for Anesthesia of Fish 06/11/02
151. Guidance for Industry: FDA Export Certificates 07/04
152. Guidance for Industry: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern 10/23/03
153. Draft Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals 09/02
154. Draft Guidance for Industry: 21 CFR Part 11; Electronic Records; Electronic Signatures, Maintenance of Electronic Records Withdrawn 02/25/03
155. Draft Guidance for Industry: 21 CFR Part 11: Electronic Records; Electronic Signatures; Electronic Copies of Electronic Records Withdrawn 02/04/03
156. Draft Guidance for Industry: Comparability Protocols—Chemistry, Manufacturing, and Controls Information; Availability 02/03
157. Guidance for Industry: Part 11, Electronic Records, Electronic Signatures—Scope and Application 08/03
158. Guidance for Industry—Use of Material from Deer and Elk in Animal Feed 09/15/03
159. 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
160. 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
162. Draft Guidance for Industry—Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information 09/03
163. Draft Guidance for Industry : Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP 08/03
164. Guidance for Industry—PAT—A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance, September 2004 09/04
165. Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format—General Considerations 10/03
166. Guidance for Industry—Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMPs), Phase II, Final Guidance, VICH GL38, 01/09/06
167. Guidance for Industry: Prior Notice of Imported Food Questions and Answers 12/12/03
168. Guidance to Industry: Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators 11/20/03
169. Guidance for Industry: Drug Substance: Chemistry, Manufacturing, and Controls Information, Draft Guidance 01/04
170. Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions, Final Guidance, March 15, 2004 03/15/04
171. 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
172. Guidance for Industry #172—Use of unapproved hormone implants in veal calves, April 2, 2004 Withdrawn 07/15/04
173. Guidance for Industry—Animal Drug Sponsor Fees Under the Animal Drug User Fee Act (ADUFA) Appendix 02/07/05
174. Guidance for Industry—Use of Material from BSE Positive Cattle in Animal Feed 09/30/04
176. Guidance for Industry #176—Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances—VICH GL–39, Draft Guidance—May 24, 2005 05/24/05
177. Guidance for Industry #177—Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products—VICH GL–40, Draft Guidance—May 24, 2005 05/24/05

VII. Office of the Commissioner/Office of Policy (OC/OP)

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

For guidance documents pertaining to Good Clinical Practices: Good Clinical Practices Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340, *http:///www.fda.gov/oc/gcp/guidance.html.*

For other guidance documents listed under OC/OP: Office of Policy, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, *http://www.fda.gov/opacom/morechoices/industry/guidedc.html.*

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
FDA Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996 (Federal Register June 12, 1998)
Guidance for FDA and Industry: Direct Final Rule Procedures (Federal Register Nov. 21, 1997)
Final Guidance on Industry-Supported Scientific and Educational Activities (Federal Register Dec. 3, 1997)

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

Guidances
- FDA Information Sheet Guidances 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 Biologicial Products for the Treatment of Cancer
- Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions
- Guidance for Industry: IRB Review of Stand-Alone HIPAA Authorizations Under FDA Regulations
- Guidance for Industry on Part 11, Electronic Records; Electronic Signatures—Scope and Application
- Guidance on Pharmacogenomic Data Submissions
- Guidance for Premarketing Risk Assessment
- Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
- Guidance for Industry and Clinical Investigators on the Use of Clinical Holds Following Clinical Investigator Misconduct

ICH Guidances

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

VIII. Office of Regulatory Affairs (ORA)

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

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

Title of Document	Date of Issuance	Date of Withdrawal
CPG—Sec. 160.800 Year 2000 (Y2K) Computer Compliance (CPG 7153.15)	April 26, 1999	March 8, 2005
CPG—Sec. 355.100 Cellutron Machine (CPG 7124.03)	May 31, 1990	March 10, 2005
CPG—Sec. 460.700 Controlled Release Dosage Form Drugs—Rate of Release of Active Ingredients (CPG 7132a.02)	January 1, 1973	August 19, 2005

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)

Industry Assistance Reference

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
11/10/2005: Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
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)
08/04/2005: 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 http://www.fda.gov/ora/compliance_ref/bimo/comparison_chart/preface.html http://www.fda.gov/ora/compliance_ref/bimo/glp/wh_list_intro.htm (and related GLP lists)
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.
07/28/2005: Revised Debarment List, 07/28/2005—One person added.

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

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
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 Revoked 03/08/2005, Compliance Policy Guide, Sec. 160.800 Y2K Computer Compliance
03/08/2005: Revised list to add 2 new members, Restricted List for Clinical Investigators
03/04/2005: Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
02/18/2005: Draft revised CPG Sec. 310.210 "Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy (CPG 7124.23) FR Notice of Availability Draft Revision
02/01/2005: Revised list to add 1 new member, Restricted List for Clinical Investigators
01/14/2005: Revised list to add 1 new member, Disqualified/Totally Restricted List for Clinical Investigators

2004 Revisions and Updates:
12/07/2004 Revised Debarment List, 12/07/2004—One person added. Published 12/02/2004.
11/18/2004 Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990 Updated November 18, 2004
11/16/2004 New CPG Sec. 400.210—Radiofrequency Identification Feasibility Studies and Pilot Programs
11/03/2004 Revised CPG Sec. 110.300—Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
11/02/2004 Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
10/29/2004 Draft CPG (Not for Implementation), Sec. 560.400 "Imported Milk and Cream—Federal Import Milk Act (CPG 7119.05)." When finalized it will replace the existing CPG at Sec. 560.400. Comments due 30 days after date of publication in the Federal Register dated October 29, 2004
10/03/2004 Revised list to add 1 new member, Disqualified/Totally Restricted List for Clinical Investigators
08/31/2004 Edited Debarment List—at Uddin, Mohammad, added "NMI" to indicate that FDA records show no middle initial for this person.
08/16/2004 Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
07/29/2004 Revised CPG Sec. 394.500—Importation of Television Products, Microwave Ovens, and Inherent Class I Laser Products for Investigation and Evaluation
07/29/2004 Replaced/Retitled CPG Sec. 560.750 Guidance Levels for Radionuclides in Domestic and Imported Foods (CPG 7119.14)
07/23/2004 Updated links to FDA Regulations (2004) on the Bioresearch Monitoring Information Page; links to laws enforced by FDA and related regulation on the Welcome to Compliance References page
06/24/2004 Revised CPG Sec. 110.310—Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
06/16/2004 AIP Procedures—procedures March 5, 1998
06/10/2004 Revised to update citations Sec. 690.300 Canned Pet Food (CPG 7126.18)
06/15/2004 Correction in classification (Class)—Charles River Laboratories, West Chester, OH
05/12/2004 John B. Najarian on Restricted List for Clinical Investigators
05/06/2004 March 2004 edition of the Regulatory Procedures Manual (RPM) published. New edition of FDA RPM is effective May 6th, 2004. All chapters have been changed except Chapter 9 "Import Operations/Actions."
04/09/2004 Corrected entry for Arthur Riba on Restricted List for Clinical Investigators
04/05/2004 Revised Application Integrity Policy List to add Plus Orthopedics, San Diego, California.
3/12/2004 Revised to update content of August 2000 paper edition: Sec. 490.100 Process Validation Requirements for Drug Products and Active Pharmaceutical Ingredients Subject to Pre-Market Approval CPG 7132c.08
02/23/2004 Revised list to add 1 new member, 02/23/2004: Restricted List for Clinical Investigators; Revised list to add 1 new member, 02/23/2004: Disqualified/Totally Restricted List for Clinical Investigators
02/13/2004 Revised 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990 Updated February 9, 2004
2/9/2004 Edited two pages to conform text (reference) on Internet pages to August 2000 paper edition: CPG Sec. 515.700 Chocolate & Chocolate Liquor—Adulteration with Insect and Rodent Filth CPG 7105.11 CPG Sec. 515.775 Cocoa Powder, Press Cake—Adulteration with Insect and Rodent Filth CPG 7105.13
Draft CPG 1/14/2004 Draft CPG (Not for Implementation), Sec. 560.750 "Guidance Levels for Radionuclides in Domestic and Imported Foods, Availability; and Draft Supporting Document, Supporting Document for Guidance Levels for Radionuclides in Domestic and Imported Foods." When finalized it will replace the existing CPG. Comments due March 15, 2004—The Draft Guidance—The Draft Guidance—Supporting Statement for Guidance Levels—Supporting Statement for Guidance Levels
Revoked 1/5/2004 Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse CPG 7124.06

2003 Revisions and Updates:
New CPG Sec. 110.300—"Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" is available at: http://www.cfsan.fda.gov/~furls/cpgreg.html.
Revised: Application Integrity Policy Committee Contact Persons list on 12/18/2003
Revised Application Integrity Policy List to add AGA Medical Corporation, Golden Valley, Minnesota
Revised CPGM list on 12/18/2003 by • added new Drugs program 7356.002M, "Inspections of Licensed Biological Therapeutic Drug Products" • added new Veterinary Medicine program 7371.009, "BSE/Ruminant Feed Ban Inspections" • added on-line links for Drug programs: 7346.832 "Pre-Approval Inspections/Investigations"; 7346.843, "Post-Approval Audit Inspections"; 7356.002A, "Sterile Drug Process Inspections"; 7356.002B, "Repackers and Relabelers", 7356.002C, "Radioactive drugs" and 7356.002E, "Compressed medical gases" • Corrected title of drug program 7356.002 "Drug Manufacturing Inspections" • corrected CPGM list by removing previously withdrawn Device programs 7385.002 "Ionizing Radiation Use Control Laboratory Support", 7385.003 "Federal Facility Use Control and Equipment Performance Survey Program", and 7386.006G "WEAC Testing of Medical Devices for Conformance to Voluntary Standards" • corrected Device program numbers 7382.014 to 7385.014 and 7385.004 to 7386.009.
New CPG Sec. 110.310—"Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" is available at: http://www.cfsan.fda.gov/~pn/cpgpn.html.
Revised Debarment List, 10/22/2003—One person added. Published 10/23/03.

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

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.
Revoked effective 02/19/2003: Compliance Policy Guide, Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17). See: 68 FR 8775 02/25/2003. 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.
Replaced Reference: Good Laboratory Practice (GLP) Final Rule, 12/22/1978. Published 5/23/03.
Revised—Four Lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990, Updated 03/06/2003. Published 5/1/03.
Revised Application Integrity Policy List to remove Gliatech, Inc., Beachwood, OH; and Solvay Pharmaceuticals, Inc., Beaudette, MN, and Marietta, GA, April 2003.
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.
New CPGM, 03/19/2003: Biologics Compliance Program March 2003, 7341.002, Inspection of Tissue Establishments (CBER).
Revoked effective 02/19/2003—Compliance Policy Guide, Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17) See: 68 FR 8775 02/25/2003.
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 Tox Labs List
Revised Debarment List on 12/03/2002—one person added
Typographical errors (1 per page) 11/27/2002: CPGuides Manual—Sec 555.425—Foods—Adulteration Involving Hard or Sharp Foreign Objects; and Sec. 515.350 Candy—Mixed with Trinkets and Sold in Vending Machines (CPG 7105.04)
Edited links 11/27/2002: 21 CFR Part 11 Guidance Documents Dockets Established—Topics for Guidance Development Revised 11/14/2002: Sec. 555.600 Filth *from Insects, Rodents, and Other Pests* in Foods (CPG 7120.18)
Updated 11/14/2002: 4 lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990
Revoked effective 11/12/2002: Sec. 398.475 Minimum X-Ray Field Size for Spot-Film Operation of Fluoroscopic Systems with Fixed SID and Without Stepless Adjustment of the Field Size (CPG 7133.17)
Revised 11/13/2002 Debarment List—3 people added
Revised 2 lists to add new or update member(s), 10/16/2002: Disqualified/Totally Restricted List for Clinical Investigators and Restricted List for Clinical Investigators
Revoked 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)
Revised Subchapter Import for Export in Chapter 9 of Regulatory Procedures Manual. 09/13/2002.
New—CryoLife, Inc., Kennesaw, GA, 08/13/2002. Order for Retention, Recall, and/or Destruction
New—Four Lists of Nonclinical Laboratories Inspected Since Fiscal Year 1990. Updated 08/2002
Revised list to add new member, 08/7/2002: 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 effective on 06/20/2002, Sec. 396.100 Applicability of the Sunlamp Performance Standard To UVA Tanning Products (CPG 7133.16)
Corrected 05/16/2002, Sec 575.100 Pesticide Residues...Heptachlor table
New CPG Sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor issued 05/07/2002
Revised BioResearch Monitoring Information references added or updated 05/16/2002
Revised Debarment List on 05/07/2002—person added
Revised Compliance Program Manual 04/26/2002 page—page text and links were updated
Edited Debarment List on 04/09/2002
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 Uneviscerated Fish Products that are Salt-cured, Dried, or Smoked (CPG 7108.17)
New 06/29/2000, Sec. 100.950 International Parnership Agreements for Compliance Activities—Agreements among the USFDA, Foreign Government Agencies, and Foreign or Domestic Trade Associations and/or Other Organizations
Deleted 07/03/2000, Sec. 405.100 Prescriptions Prepared from Certified Antibiotics (CPG 7122.01)

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

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—08/04/1999, Section 615.115 Use of Medicated Feeds for Minor Species
July 9, 1999, Compliance Policy Guide 230.140, Biologics, Evaluation and Processing Post Donation Information Reports
The "Draft Civil Money Penalty Reduction Policy for Small Entities" published in the Federal Register (FR) on May 18, 1999. See final copy of the RPM Subchapter March 20, 2001
New 5/13/1999, Compliance Policy Guide, Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17)
New, 4/26/1999, Compliance Policy Guide, Y2K Computer Compliance
Draft Revised CPG, 4/9/1999, Regulatory Policy on the Disposition of Publications that Constitute Labeling (CPG 7153.13) (Level I guidance document (see 62FR8961 2/27/97)) Not for Implementation

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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

BIOTECHNOLOGY
- BIOTECHNOLOGY INSPECTION GUIDE (11/91)

BIOLOGICS
- BLOOD BANKS (9/94)
- 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 (2/83)
- COMPUTERIZED SYSTEM IN THE FOOD PROCESSING INDUSTRY
- GLOSSARY COMP. SYSTEMS. SOFTWARE DEVELOPMENT TERMINOLOGY (8/95)

DEVICES
- QUALITY SYSTEMS
- ELECTROMAGNECTIC COMPATIBILITY ASPECTS OF MEDICAL DEVICE QUALITY SYSTEMS
- BIORESEARCH MONITORING INSPECTIONS OF IN VITRO DIAGNOSTIC DEVICES
- MAMMOGRAPHY 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)
- MICROBIOLOGICAL. PHARMACEUTICAL QUALITY CONTROL LABS (7/93)
- PHARMACEUTICAL QUALITY CONTROL LABORATORIES (7/93)
- 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
- GRAIN 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)

IOM: Investigations Operations Manual 2006 Centennial Edition—Primary procedure manual for FDA personnel performing inspections and special investigations.

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

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

3. Steam Distribution for Retort Venting in Food Canneries Food Canneries 3/03/72
4. New Equipment Kenics Static Mixers Food, Drug and Cosmetic 3/20/72
5.Ethylene Oxide Sterilization 1. Calculation of Initial Gas Concentration Drugs, Sterile Devices 6/09/72
6. Leak Testing Sealed Ampuls of Parenteral Solutions Drugs, Human and Veterinary Injectable Vitamins 4/28/72
7. Sterilizing Symbols (D, Z, F) Low Acid Canned Foods 1/09/72
8. "Package Unit" Italian Flour Mills Cereal Flours & Related Products 12/14/72
9. Polariscope Sterile Packaging—Foods, Drugs, Devices, Hardened Lenses 5/21/73
10. Diathermy Medical Devices 5/21/73
11. Steam Pressure for Retorts and Autoclaves Sterile Drugs and Devices Low Acid Canned Foods, Biologics 6/29/73
12. Stroboscope Food, Drug, Device, Manufacture and Packaging 8/08/73
13. Field Submission of Articles All Programs 9/05/73 (8/03/84 Revised)
14. Thermocouple Surface Pyrometers Food Canneries12/20/73
15. Common Valves Used in Process Fluid Systems Sterile Drugs, Devices, Low Acid Canned Foods and Biologics 1/15/74
16. A.T.I. Steam Activated Heat Sensitive Indicators Food, Drugs, Medical Devices 3/08/74
17. New Source of Lead and Other Contamination Various Foods and Drugs 6/18/74
18. Ultrasound in the Food, Drug, and Device Industries Food, Drugs, and Medical Devices 3/03/75
19. Screening Electronic Components Medical Devices 4/20/75
20. Hermetically Sealed Electronic Component Leak Detection Medical Devices 7/18/75
21. Noise Control Mufflers for Bleeders on Retorts and Sterilizers Food, Drugs 9/15/75
22. Ground Fault Circuit Interrupter All Programs, Personnel Safety 3/05/76
23. The Computer in FDA Regulated Industries Foods, Drugs, and Medical Devices 5/21/76
24. Air Velocity Meters Sterile Drugs and Devices, Foods and Cosmetics 7/30/76
25. Ethylene Oxide Sterilization 2. Graphical Aid to Determine Gas Concentration Sterile Devices, Drugs 9/01/76
26. Evaluation of Production Cleaning Processes for Electronic Medical Devices—Part 1, 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
33. Use of the Texas Instruments Model 59 Programmable Calculator in the Enforcement of the Diagnostic X-ray Performance Standard X-Ray Field Testing 7/12/79
34. Heat Exchangers to Avoid Contamination Drugs, Diagnostic Products Biologics 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 Technolgy All Programs 8/1/83
39. Water Activity (a{{w}}) in Foods Foods 4/16/84
40. Bacterial Endotoxins/Pyrogens Drugs and Devices 3/20/85
41. Expiration Dating and Stability Testing for Human Drug Products Drugs 10/18/85
42. Tin Whiskers—Problems, Causes, and Solutions Medical Devices 3/14/86
43. Lyophilization of Parenterals Drugs, Biologics, Diagnostics 4/18/86
44. Radiation Protection Terminology Foods 5/15/86
45. Circular Temperature Recording Chart Measurements All Programs 2/20/87
46. Water for Pharmaceutical Use Drugs, Biologics, Medical Devices 12/31/86
47. Measurement of Relative Humidity in the ETO Process Drugs and Medical Devices 4/30/87
48. Microbiological Contamination of Equipment Gaskets with Product Contact All Programs 12/31/86
49. Stock Rotomat Foods 5/30/87
50. Capacitor Medical Devices/Radiological Health 10/23/87
51. Electronic Relays Medical Devices/Radiological Health 11/10/87
52. Voice Recognition Systems GLP and Devices 11/10/87

Medical Device GMP Reference Information—(link to page maintained by CDRH)

QS Regulation/Design Controls

Dated: March 7, 2006.

Jeffrey Shuren

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