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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0046]

Quarterly 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SUMMARY: The Food and Drug Administration (FDA) is publishing a quarterly update of all guidance documents issued and withdrawn since we compiled the last quarterly list of guidance documents that published on March 14, 2000. FDA committed to publishing quarterly updates in our February 1997 "Good Guidance Practices" (GGP's) document, which set forth the agency's policies and procedures for developing, issuing, and using guidance documents. This list is intended to inform the public of the existence and availability of guidance documents issued since the annual comprehensive list was compiled.

DATES: General comments on this list and on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For information on where to obtain single copies of guidance documents listed here, see the specific center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its “Good Guidance Practices” (GGP’s), which set forth our policies and procedures for developing, issuing, and using guidance documents. We adopted the GGP’s to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of our guidance documents.

As part of FDA’s effort to ensure meaningful interaction with the public regarding guidance documents, we committed to publishing an annual comprehensive list of guidance documents and quarterly **Federal Register** notices that list all guidance documents that were issued and withdrawn during that quarter, including “Level 2” guidance documents. The following list of guidance documents represents all guidances that we issued or withdrew since we published the last quarterly list on March 14, 2000 (65 FR 13771). The guidance documents are organized by the issuing center or office within FDA, and are further grouped by the intended users or relevant regulatory activities. Dates provided in the following list refer to the date the guidance was issued or, where applicable, the last date the document was revised. We provided document numbers where available.

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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft guidance entitled "International Conference on Harmonisation i Technical Requirements for Registration of Pharmaceuticals for Human Use M4: Common Technical Document"	February 11, 2000	FDA Regulated Industry	Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 1-800-835-4709 or 301-827-1800, FAX Information System: 1-888-CBER-FAX (within U.S.) or 301-827-3844 (outside U.S. and local to Rockville, MD). Internet access: http://www.fda.gov/cber
Draft Guidance for Industry: Special Protocol Assessment	December 1999	Do	Do
Draft Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Protocol	February 2000	FDA Personnel	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft Guidance for Industry: IND Meetings for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information	February 2000	FDA Regulated Industry	Do
Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products	February 2000	Do	Do
Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level	February 2000	Do	Do
Guidance for Industry: Gamma Irradiation of Blood and Blood Components: A Pilot Program for Licensing	February 2000	Do	Do
Draft Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank	March 2000	Do	Do

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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals, Draft Guidance-Not for Implementation	February 8, 2000	Office of Compliance (OC)	Division of Small Manufacturers Assistance; 1-800-638-2041 or 301-827-0111 or FAX Facts-on-Demand 1-800-899-0381 Internet access: http://www.fda.gov/cdrh
Guidance for FDA Staff; Compliance Program Guidance Manual; Field Compliance Testing of Diagnostic (Medical) X-ray Equipment	March 15, 2000	OC/Division of Enforcement I (DOE1)	Do
Guidance for Industry and FDA; Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions	February 21, 2000	Office of Device Evaluation (ODE)	Do
Guidance on the Use of Standards in Substantial Equivalence Determination	March 12, 2000	Do	Do
Guidance Document for Premarket Notification Submission for Nitric Oxide Delivery Apparatus, Nitric Oxide Analyzer and Nitrogen Dioxide Analyzer	January 24, 2000	ODE/Division of Cardiovascular, Respiratory & Neurological Devices (DCRND)	Do
Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions	February 16, 2000	ODE/DCRND	Do
Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions	February 21, 2000	Do	Do
Guidance Document for the Preparation of IDEs for Spinal Systems (Replaces: Guidance Document for the Preparation of IDEs for Spinal Systems 8/26/98)	January 13, 2000	ODE/Division of General & Restorative Devices (DGRD)	Do
Guidance for the Arrangement and Content of a Premarket Approval (PMA) Application for an Endosseous Implant	May 16, 1989	ODE/Division of Dental, Infection Control and General Hospital Devices (DDIGD)	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
Guidance for Industry and FDA Reviewers: Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme (Replaces: Reprocessing and Reuse of Single-Use-Devices: Risk Categorization Scheme; Draft Guidance 12/9/99)	February 8, 2000	Do	Do
Guidance for Industry and for FDA Reviewers/ Staff; Guidance for the Content of Premarket Notifications for Penile Rigidity Implants (Replaced: Draft Guidance for the Content of Premarket Notifications for Penile Rigidity Implants 5/30/95)	January 16, 2000	ODE/Division of Reproductive Abdominal, ENT and Radiological Devices (DRAERD)	Do
Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers (Replaces: Guidance for the Content of Premarket Notification for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims 10/21/96)	March 12, 2000	ODE/Division of Ophthalmic and Ear, Nose, Throat Devices (DOED)	Do
Draft Guidance for Industry; Guidance on Medical Device Patient Labeling	March 3, 2000	Office of Health and Industry Programs (OHIP)/Division of Device User Programs and Systems Analysis (DDUPSA)	Do
The FDA Export Reform and Enhancement Act of 1996/Export Certification Package including "Instructions for Requests for Certificate to Foreign Governments" (Replaces: The FDA Export Reform and Enhancement Act of 1996/Export Certification Package including "Instructions for Requests for Certificate to Foreign Governments" 6/22/99)	February 7, 2000	OHIP/Division of Small Manufacturers Assistance (DSMA)	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2	February 25, 2000	OHIP/Division of Mammography Quality and Radiation Programs (DMQRP)	Do
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket (Replaces: Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements 2/22/99)	February 2, 2000	Office of Surveillance and Biometrics (OSB)/Division of Postmarket Surveillance (DPS)	Do

WITHDRAWALS

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
Guidance on Medical Device Tracking [FDAMA] Replaced by Guidance for Industry and FDA Staff-Guidance on Medical Device Tracking [FDAMA]	February 19, 1998	OC	January 24, 2000
Guideline for Preparing Notices of Availability of Investigational Medical Devices (Replaced by: Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects 3/19/99)	November 1, 1985	OC/BIMO	February 14, 2000

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
Review Proposal for Reagents and Analyzer Systems	March 14, 1995	ODE	February 17, 2000
Implantable Pacemaker Lead Testing Guidance for the Submission of a Section 510(k) Notification (Replaced by: Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions 1/14/00)	September 1, 1989	ODE/DCRND	January 21, 2000
Determining Equivalence of Intraortic Balloon Catheters Under the 510(k) Regulations	December 12, 1989	Do	April 7, 2000
510(k) Guidance for Screw Type Endosseous Implants for Prosthetic Attachment	August 11, 1992	ODE/DDIGD	April 5, 2000
Addendum to Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for General Purpose Disinfectants	March 9, 1994	Do	February 15, 2000
Reprocessing and Reuse of Single-Use-Devices: Risk Categorization Scheme; Draft Guidance (Replaced by: Guidance for Industry and FDA Reviewers: Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme Draft 2/8/00)	December 9, 1999	Do	February 9, 2000
Draft Guidance on the Content and Format of Premarket Approval Application (PMA) for Sharps Needle Destruction Devices	February 11, 1997	Do	April 10, 2000
Sunglass Package; including Certification Statement for the Impact-Resistance Test of Lenses in Eyeglasses and Sunglasses	March 19, 1998	ODE/DOD	February 8, 2000
Guidance for Submission of a 510(k) Premarket Notification for an Air Conduction Hearing Aid	April 1, 1991	ODE/DRAERD	April 7, 2000
Draft Guidance for the Content of Premarket Notifications for Penile Rigidity Implants (Replaced by: Guidance for Industry and for FDA Reviewer/Staff; Guidance for the Content of Premarket Notifications for Penile Rigidity Implants 1/16/00)	May 30, 1995	Do	March 20, 2000
Guidance for the Content of Premarket Notification for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims (Replaced by: Guidance for the Content of Premarket Notification for Disposable, Sterile, Ear, Nose and Throat Endoscope Sheaths with Protective Barrier Claims 3/12/00)	November 21, 1996	Do	March 22, 2000
Draft Guidance to Hearing Aid Manufacturers for Substantiation of Claims	August 5, 1994	Do	April 14, 2000
Medical Device Reporting for Distributors	April 1, 1996	OHIP/DSMA	February 16, 2000
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2 (Replaced by Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2 2/25/00)	March 5, 1999	OHIP/DMQRP	January 21, 2000

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
The FDA Export Reform and Enhancement Act of 1996/Export Certification Package including "Instructions for Requests for Certificate to Foreign Governments"	June 22, 1999	Do	February 14, 2000
Import of Medical Devices - A Workshop Manual (FDA 93-4228)	March 1, 1993	Do	February 8, 2000
Guidance for Medical Gloves - A Workshop Manual FDA 97-4257 (Replaced by Guidance for Industry and FDA-Medical Glove Guidance Manual Draft FDA 99-4257)	September 1, 1997	Do	Do
Part I-FDA Structure and Functions/Part II-Center for Devices and Radiological Health (CDRH) Structure and Functions/International Manual (Replaced by: U.S. FDA-Regulation of Medical Devices; Background Information for International Officials 4/14/99)	April 14, 1999	OHIP/DSMA	February 15, 2000
Part III-FDA's Regulation of Medical Devices/International Manual (Replaced by: U.S. FDA Regulation of Medical Devices; Background Information for International Officials 4/14/99)	April 14, 1999	OHIP/DSMA	Do
Part IV Electronic Access to FDA Guidance Documents and Information/International Manual (Replaced by: U.S. FDA-Regulation of Medical Devices; Background Information for International Officials 4/14/99)	April 14, 1999	OHIP/DSMA	Do
MDR Documents Access Information for CDRH Facts-On-Demand (FOD)	February 29, 1996	OSB	Do
MDR Documents Access Information for Industry Organizations	May 8, 1996	OSB	Do
Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements	February 22, 1999	OSB/DPS	January 17, 2000

CORRECTIONS

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Group	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance on Premarket Notification [510(k)] Submissions for Automated Endoscope Washers, Washer/Disinfectors, and Disinfectors Intended for Use in Health Care Facilities (This document was mistakenly listed as "withdrawn" in the March 14, 2000 FEDERAL REGISTER)	August 1, 1993	ODE/Division of General & Restorative Devices (DGRD)	Do

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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products	February 3, 2000	Generic Drug	Office of Training and Communication, Drug Information Branch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Internet access: http://www.fda.gov/cder/guidance/index.htm
IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls information	February 4, 2000	Chemistry Draft	Do
Special Protocol Assessment	February 9, 2000	Modernization Act Draft	Do
Draft guidance entitled "M4 Common Technical Document: Request for Comments on Initial Components"	February 11, 2000	ICH Draft - Joint Safety/Efficacy	Do
NDA: Impurities in Drug Substances	February 25, 2000	Chemistry	Do
Formal Meetings With Sponsors and Applicants For PDUFA Products	March 7, 2000	Modernization Act	Do
Formal Dispute Resolution: Appeals Above the Division Level	March 7, 2000	Do	Do
OTC Treatment of Herpes Labialis with Antiviral Agents	March 8, 2000	Clinical/Medical Draft	Do
Conjugated Estrogens, USP: LC-MS Method for Both Qualitative chemical characterization and Documentation of Qualitative Pharmaceutical Equivalence	March 9, 2000	Biopharmaceutic Draft	Do
Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products	March 10, 2000	Modernization Act Draft	Do
Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank: Availability	March 29, 2000	Do	Do
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act	March 30, 2000	Procedural	Do
Draft guidance entitled "E11: Clinical Investigation of Medicinal Products in the Pediatric Population"	April 12, 2000	ICH Draft - Efficacy	Do

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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs—Draft Guidance	January 2000	Animal Drug Industry	Communications Staff (HFV-12), FDA/CVM, 7500 Standish Pl., Rockville, MD 20855, 301-594-1755, Internet access: http://www.fda.gov/cvm FAX 301-594-1831
Guidance for Industry: Stability Testing for Medicated Premixes Guidance	March 2000	Do	Do

VI. Guidance Documents Issued by the Office of Regulatory Affairs (ORA)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research.	March 30, 2000	Regulated Industry	Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-857-0420 or Internet access at http://www.fda.gov/ora/compliance-ref/bimo_err_guide.htm
Compliance Policy Guide, Chapter 2, Sec.252.110, NEW: Volume Limits for Automated collection of Source Plasma	March 6, 2000	FDA Staff	Do Internet access at http://www.fda.gov/ora/compliance-ref/cpg/cpgbio/cpg252.110.htm
Compliance Policy Guide, Chapter 2, Sec. 257.100, REVISED: Deferral of source Plasma Donors Due to Red Cell Loss During collection of Source Plasma by Automated Plasmapheresis	March 22, 2000	Do	Do—Internet at http://www.fda.gov/ora/compliance-ref/cpg/cpgbio/cpg257.100.htm
Regulatory Procedures Manual, UPDATE/REVISION: Chapter 4, Subchapter/Warning Letters	March 21, 2000	Do	Do—Internet at http://www.fda.gov/ora/compliance-ref/rpm-new2/ch4.html
Investigations Operation Manual 2000	March 2000	Do	Division of Emergency and Investigational Operations (HFC-130) Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5636
Memorandum to Import Program Managers—Surveillance and Post Reconditioning Sampling of Bulk Spices for Pathogens	February 11, 2000	Do	Division of Import Operations and Policy (HFC-170), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 301-443-6553
Import Alerts	Continuously	Do	Freedom of Information staff (HFI-35), Food and Drug Administration, 5600 Fishers Lane, Rockville MD Internet at http://www.fda.gov/ora/fiars/ora-import-alerts.html

WITHDRAWALS

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	Date Withdrawn
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Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Compliance Policy Guide, Chapter 2, Sec. 215.100 (CPG 7134.07), IND Filings; Completion of Applicable Portions Prior to Final Action on License Applications or License Amendments	July 19, 1976	FDA Staff	March 28, 2000

Dated: 5/17/00
May 17, 2000.



Margaret M. Dotzel,
Acting Associate Commissioner for Policy.

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