9. What fair information practices should be implemented (e.g., ability to correct the record, notice of being put in registry to parent)?

10. How long should information be kept in a registry?

11. How will privacy issues affect the following groups: parents, immigrants, religious groups, HIV-positive and other immunocompromised health conditions, law enforcement, victims of domestic violence, and custodial parents?

12. How should registries ensure that privacy policies are followed?

13. Do you have any comment or recommendation for NVAC/CDC/HHS related to the implementation of the network of state and community-based registries and do you have any concerns?

14. Do you feel there is a need for the Federal Government to provide leadership in developing state and community-based immunization registries? What should the role of the Federal Government be in this effort?

15. Given the mandate of Health Insurance Portability and Accountability Act to create a unique health identifier, how should that goal be achieved while minimizing the probability of inappropriate use of the identifier?

16. What steps can be taken to prevent unauthorized re-disclosure of information already provided to an organization or person?

17. What legal barriers exist which prevent data sharing by MCOs and how can they be obviated?

18. What mechanism should be available to allow parents to opt out of the registry?

19. What agency/organization should be responsible for maintaining registry information?

20. How should consent for inclusion in an immunization registry be obtained? Should it be implicit or explicit?

21. What information should be included in an immunization registry?

22. Should registries include (and release) information on contraindications, adverse events, etc.?

23. Who should have access to immunization registry data and how can restricted access be assured?

24. What information should be available to persons other than the client/patient and the direct health care provider (e.g., schools)?

25. What is the best way to protect privacy and ensure confidentiality within a registry?

26. How should individuals/parents have access to registry information on themselves/their children?

27. Should data maintained in a state and community-based immunization registry be considered public information?

28. Would national privacy and confidentiality standards help ensure that data maintained in an immunization registry is protected?

Ensuring Provider Participation Questions to be Considered:

1. What type of resources (e.g., hardware, staff, etc.) are needed for you (provider/organization) to participate in a computerized registry?

2. What are the cost-related barriers that keep you (provider/organization) from participating in an immunization registry?

3. What cost should providers be responsible for, pertaining to participation in immunization registry systems?

4. What are the cost savings you would anticipate as a result of participating in a computerized registry (e.g., increased return visit form reminders, less personnel paperwork for preschool exams, etc.)?

5. How much time would you be willing to invest per patient visit (e.g., additional 1, 5, 7, 10 minutes) in the overall success of an immunization registry?

6. What type of user support would be needed in order for you (provider/organization) to participate in an immunization registry?

7. How would you (provider/organization) encourage providers and consumers in your community to participate in an immunization registry?

8. What community support would be necessary for you to participate in the immunization registry?

9. What benefits/value (e.g., immunization reminders, quick access to immunization histories, etc.) would a registry provide that would encourage your (provider/organization) participation?

10. What incentives should be offered to providers/organizations to participate in an immunization registry?

11. What barriers have you (provider/organization) encountered that have prevented you from participating in an immunization registry?

12. Is provider liability (e.g, disclosure of sensitive patient information) a barrier to participating in an immunization registry? Why?

13. How would an immunization registry impact your practice/organization?

14. Do you currently share immunization data with other providers electronically? For what purpose (e.g., billing, share group data, etc.)?

15. How (e.g., electronic record, paper record) is medical information maintained in your practice/organization?

16. Who should retain ownership of immunization records as they are distributed throughout an immunization registry?

17. How would you (provider/organization) use the data maintained in an immunization registry?

18. What type of quality control process would you (provider/organization) perform to ensure the accuracy and completeness of the immunization data entered into an immunization registry?

19. What type of security policies and procedures need to be in place for you to be confident that data are secure?

20. What functions should a registry perform in your office in order for you (provider/organization) to participate?

21. Do you have any advice or recommendations for NVAC/CDC/HHS related to the implementation of the network of state and community-based registries and do you have any concerns?

22. Do you feel that there is a need for the Federal Government to provide leadership in developing state and community-based immunization registries? What should the role of the Federal Government be in this effort?

23. Have you received training on the use and maintenance of computerized medical information? Do you feel this training is needed to fully support the development and maintenance of immunization registries?

Contact Person for More Information: Robb Linkins, M.P.H., Ph.D., Chief, Systems Development Branch, Data Management Division, NIP, CDC, 1600 Clifton Road, NE, M/S E–62, Atlanta, Georgia 30333, telephone (404) 639–8728, e-mail rxl3@cdc.gov.

Dated: June 29, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–17763 Filed 7–2–98; 8:45 am]

BILLING CODE 4163–18–P

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 the first quarterly update of all guidance documents issued and withdrawn since the compilation of the comprehensive list. FDA committed to publishing quarterly updates in its February 1997 ''Good Guidance Practices'' (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to inform the public of the existence and availability of guidance documents issued since the comprehensive list was compiled. This list also includes some guidance documents that were inadvertently not included on the comprehensive list mentioned previously.

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. Information on where to obtain single copies of listed guidance documents is provided for each agency center individually in the specific center's list of guidance documents.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its ''Good Guidance Practices'' (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publish 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 issued by FDA since the compilation of the February 26, 1998 (63 FR 9795) list and guidance documents inadvertently not included in the comprehensive list. The guidance documents are organized by the issuing Center or Office within FDA, and are further grouped by the intended users or regulatory activities to which they pertain. Dates provided in the following list refer to the date of issuance or, where applicable, the date of last revision of the document. Document numbers are provided where available.

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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Guidance for Industry: Industry-Supported Scientific and Educational Activities	November 1997	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 the United States) or 301–827–3844 (outside of the United States and local to Rockville, MD). Internet access: http://www.fda.gov/cber
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)	December 1997	Do	Do
Guidance for Industry: Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products	January 1998	Do	Do
Draft Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use	January 1998	Do	Do
Draft Guidance for Industry: Container and Closure Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products	January 1998	Do	Do
Draft Guidance for Industry: Clinical Development of Programs for Drugs, Devices and Biological Products Intended for Treatment of Osteoarthritis (OA)	February 1998	Do	Do
Draft Guidance for Industry: Environmental Assessment of Human Drug and Biologics Applications	November 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Guidance for Industry: Implementation of Section 126, Elimination of Certain Labeling Requirements of the Food and Drug Administration Modernization Act of 1997	February 1998	Do	Do
Guidance for Industry: Clinical Development Programs for Drugs, Devices and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	March 1998	Do	Do
Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)	March 1998	Do	Do
Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy	March 1998	Do	Do
Compliance Program Guidance Manual (Drugs and Biologics) (Publication No. 94–920699)	1994	FDA Personnel	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–605–6050

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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance on Medical Device Tracking (Docket #98D–0132)	February 19, 1998	OC	Division of Small Manufacturers Assistance, 1–800–638–2041 or 301–827–0111 or (Fax) Facts-on-Demand at 1–800–899–0381 or Internet at http://www.fda.gov/cdrh
Guidance on Lead Wires and Patient Cables	March 9, 1998	OC	Do
Draft Guidance to Industry and CDRH for PMA's and PMA Supplements: Use of Published Literature, Use of Previously Submitted Materials, and Priority Review	March 20, 1998	ODE	Do
PMA/510(k) Expedited Review—Guidance for Industry and CDRH Staff	March 20, 1998	ODE	Do
Guidance on Amended Procedures for Advisory Panel Meetings	March 20, 1998	ODE	Do
Guidance on IDE Policies and Procedures	January 20, 1998	ODE	Do
Early Collaboration Meetings Under the FDA Modernization Act (FDAMA), Guidance for Industry and CDRH Staff, Final Document (Docket #98D–0078) (FOD #310)	February 19, 1998	ODE	Do
Guidance on PMA Interactive Procedures for Day-100 Meetings and Subsequent Deficiencies—for Use by CDRH and Industry (Docket #98D–0079) (FOD #322)	February 19, 1998	ODE	Do
Determination of Intended Use for 510(k) Devices: Final Document (Docket #98D–0081) (FOD #857)	February 19, 1998	ODE	Do
30-Day Notices and 135-day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH (Docket #98D–0080) (FOD #795)	February 19, 1998	ODE	Do
New section 513(f)(2)—Evaluation of Automatic Class III Designation: Guidance for Industry and CDRH Staff (Docket #98D–0082) (FOD #199)	February 19, 1998	ODE	Do
Procedures for Class II Device Exemptions from Premarket Notification Guidance for Industry and CDRH Staff (Docket #98D–0083) (FOD #159)	February 25, 1998	ODE	Do
Electrocardiograph (ECG) Surface Electrode Tester—Version 1.0	February 11, 1997	ODE/DCRND	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guidance for the Submission of 510(k) Premarket Notifications for Cardiovascular Intravascular Filters	January 1, 1997	ODE/DCRND	Do
Guidance Document for Testing Bone Anchor Devices (FOD #915)	April 20, 1996	ODE/DGRD	Do
ORDB 510(k) Sterility Review Guidance (FOD #659)	July 3, 1997	ODE/DGRD	
Guidance for Testing MR Interaction With Aneurysm Clips (FOD #958)	May 22, 1996	ODE/DGRD	Do
Electroencephalograph Device Draft Guidance for 510(k) Content (FOD #767)	June 25, 1997	ODE/DGRD	Do
Ophthalmic Device Triage List	July 25, 1997	ODE/DOD	Do
Contact Lenses: The Better the Care the Safer the Wear (FDA Publication No. 91–4220)	April 1, 1991	ODE/DOD	Do
An FDA Survey of U.S. Contact Lens Wearers (Carol L. Herman) Reprinted from Contact Lens Spectrum	July 1, 1987	ODE/DOD	Do
Facts for Consumers from the Federal Trade Commission—Eyeglasses	April 1, 1986	ODE/DOD	Do
Important Information About Rophae Intraocular Lenses	August 20, 1992	ODE/DOD	Do
Intraocular Lens (IOL) Guidance Document	October 10, 1997	ODE/DOD	Do
FDA Guidance for Multifocal Intraocular Lens IDE Studies and PMA's	May 1996	ODE/DOD	Do
Premarket Notification[510(k)] Guidance Document on Class II Daily Wear Contact Lenses	May 12, 1994	ODE/DOD	Do
Electrocardiograph (ECG) Electrode—Version 1.0	February 11, 1997	ODE/DRAERD	Do
Electrocardiograph (ECG) Lead Switching Adapter—Version 1.0	February 11, 1997	ODE/DRAERD	Do
Tympanostomy Tubes, Submission Guidance for a 510(k) Premarket Notification	January 14, 1998	ODE/DRAERD	Do
Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents	February 5, 1998	ODE/DRAERD	Do
FDA Modernization Act of 1997: Guidance for the Device Industry on Implementation of Highest Priority Provisions; Availability	February 6, 1998	OHIP/Regs	Do
Policy Notebook in a Q/A Format (Update to existing document)	January 23, 1998	OHIP/DMQRP	Do
The Small Entity Compliance Guide	January 1998	OHIP/DMQRP	Do
Medical Device Appeals and Complaints: A Guidance on Dispute Resolution	February 19, 1998	OHIP/DSMA	Do
Medical Device Quality Systems Manual: A Small Entity Compliance Guide	December 1, 1996	OHIP/DSMA	Do
SMDA to FDAMA: Guidance on FDA's Transition Plan for Existing Postmarket Surveillance (FOD #318)	February 19, 1998	OSB/DPS	Do
Guidance on Procedures to Determine Application of Postmarket Surveillance Strategies (FOD #316)	February 19, 1998	OSB/DPS	Do
Guidance on Procedures for Review of Postmarket Surveillance Submissions (FOD #317)	February 19, 1998	OSB/DPS	Do
MDR/Policy/Guidance for Endosseus Implant Devices	December 1992	OSB/DSS	Do
MDR Guidance #4—External Defibrillators	September 1994	OSB/DSS	Do
MDR Guidance—Blood Loss Policy	December 1995	OSB/DSS	Do
Summary Reporting Approval for Adverse Events	July 1997	OSB/DSS	Do
Common Problems: Baseline Reports and MedWatch Form 3500A (letter to manufacturers updated)		OSB/DSS	Do
Guidance on the Recognition and Use of Consensus Standards	February 19, 1998	OST	Do
Withdrawn			

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 the Content of Preliminary Investigational Device Exemptions (Pre-IDE) Presentations: Teleconferences, Meetings and Written Submissions''	August 22, 1995	ODE/DCRND	Do
Preliminary Guidance for Ambulatory Electrocardiograph for Data to be Submitted to FDA in Support of Premarket Notification Applications	September 1, 1994	ODE/DCRND	Do
Preliminary Guidance for Data to be Submitted in Support of Premarket Notifications for Analyzing ECG's/Interpretive ECG's	December 1, 1994	ODE/DCRND	Do
Preliminary Guidance for Data to be Submitted to the FDA in Support of Premarket Notification Applications for External Cardioverters and Defibrillators	April 25, 1994	ODE/DCRND	Do
Reviewer Checklist for Monitors: EMC, Battery and Software	January 24, 1996	ODE/DCRND	Do
Medical Device Tracking: Questions and Answers Based on the Final Rule	August 26, 1993	OC/DOEI	Do
510(k) Diagnostic Ultrasound Guidance 4/91 Use of Medical Index in Place of Peak Intensity in Determining Substantial Equivalency for Diagnostic Ultrasound Equip/Access/Rel. Meas. Dev.	February 1993	ODE/DRAERD	Do
Review of ''YAG'' Lasers for Neurosurgery	N/A	ODE/DGRD	Do
FDA Public Health Advisory: Retinal Photic Injuries from Operating Microscopes During Cataract Surgery	October 16, 1995	ODE/DOD	Do
Sterilization: Questions and Answers from FDA, from Medical Device Diagnostic Industry for January, 1985, page 132	January 1985	OC/DOEII	Do
Corrections			
Rechargeable Battery Preliminary Guidance for Data to be Submitted to FDA in Support of Premarket Notification Applications (FOD #873)	January 1, 1994	ODE/DCRND	Do
Review Guidance for Anesthesia Conduction Catheter (FOD #783)	May 15, 1991	ODE/DCRND	Do
Guidance for Peak Flow Meters for Over-the-Counter Sale	June 1, 1993	ODE/DCRND	Do
Review Guidance for Oxygen Generators and Oxygen Equipment	Undated	ODE/DCRND	Do
Guidance for the Preparation and Content of Applications to the Food and Drug Administration for Ventricular Assist Devices and Total Artificial Hearts (draft)	December 4, 1987	ODE/DCRND	Do
Draft Premarket Notification Review Guidance for Evoked Response Somatosensory Stimulators	June 1, 1994	ODE/DGRD	Do
Draft Version—Guidance on Biocompatibility Requirements for Long Term Neurological Implants: Part 3—Implant Model	September 12, 1994	ODE/DGRD	Do
Draft Version 1—Biofeedback Devices—Draft Guidance for 510(k) Content	August 1, 1994	ODE/DGRD	Do
Draft Version Cranial Perforator Guidance	July 13, 1994	ODE/DGRD	Do
Draft Version Guidance for Clinical Data to be Submitted for Premarket Approval Application for Cranial Electrotherapy Stimulators	August 20, 1992	ODE/DGRD	Do
Draft Version Guide for Cortical Electrode 510(k) Content	August 10, 1992	ODE/DGRD	Do
Draft Version Neuro Endoscope Guidance	July 7, 1994	ODE/DGRD	Do
Galvanic Skin Response Measurement Devices—Draft Guidance for 510(k) Content	August 23, 1994	ODE/DGRD	Do
Guidance for Studies for Pain Therapy Devices—General Considerations in the Design of Clinical Studies for Pain-Alleviating Devices	May 12, 1988	ODE/DGRD	Do
Guide for 510(k) Review of Processed Human Dura Mater	June 26, 1990	ODE/DGRD	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail or Internet)
Guide for TENS 510(k) Content (Draft)	August 1, 1994	ODE/DGRD	Do
Guidelines for Reviewing Premarket Notifications that Claim Substantial Equivalence to Evoked Response Stimulators	N/A	ODE/DGRD	Do
Protocol for Dermal Toxicity Testing for Devices in Contact With Skin (Draft)	N/A	ODE/DGRD	Do
Premarket Notification 510(k) Guidance for Contact Lens Care Products	May 1, 1997	ODE/DOD	Do
Amendment 1: Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses	June 28, 1994	ODE/DOD	Do
Premarket Approval (PMA) Manual (FDA 97–4214)	July 1, 1997	OHIP/DSMA	Do
Required Postmarket Surveillance Section 522(a) Initial Device Categories Revised	September 30, 1997	OSB/DPS	Do
Guidance to Manufacturers on the Development of Required Postmarket Surveillance Study Protocols Under Section 522(a)(1) of the Federal Food, Drug, and Cosmetic Act	July 16, 1996	OSB/DPS	Do
Variance from Manufacturer Report Number Format	August 12, 1996	OSB/DSS	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)
Level 1 Guidances			
Environmental Assessment of Human Drugs and Biologics Applications	February 12, 1998	Chemistry	Office of Training and Communications, Drug Information Branch, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573 or Internet at http://www.fda.gov/cder/guidance/index.htm
PAC-ALTS: Postapproval Changes—Analytical Laboratory Testing Sites	April 28, 1998	Do	Do
SUPAC IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum	April 28, 1998	Do	Do
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	March 18, 1998	Clinical	Do
Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis (OA)	February 18, 1998	Do	Do
Manufacture, Processing or Holding of Active Pharmaceutical Ingredients	April 17, 1998	Compliance	Do
S1B Testing for Carcinogenicity in Pharmaceuticals	February 23, 1998	International Conference on Harmonization	Do
Implementation of Section 126, Elimination of Certain Labeling Requirements, of the FDA Modernization Act of 1997	February 18, 1998	FDA Modernization Act	Do
National Uniformity for Nonprescription Drugs Ingredient Labeling for OTC Drugs	May 5, 1998	Do	Do
Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act	February 5, 1998	Do	Do
Level 2 Guidances			
Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro	April 7, 1997	Clinical	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)
Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application	April 7, 1997	Generic Drug	Do
Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling	January 12, 1998	Advertising	Do
Withdrawn			
Biopharmaceutic Considerations in Designing and Evaluating Novel Drug Delivery Systems	November 1, 1983	Biopharmaceutic	
Clinical Evaluation of Drugs to Prevent Dental Caries	November 2, 1978	Clinical	
Clinical Evaluation of Drugs to Prevent, Control and/or Treat Periodontal Disease	November 1, 1978	Do	
Conjugated Estrogens (Tables) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 21, 1991	Biopharmaceutic	
Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products	April 22, 1997	Compliance	
Diphenhydramine Hydrochloride Capsules/Elixir	June 1, 1986	Labeling	
Ergotamine Tartrate and Caffeine Tablets and Suppositories	December 1, 1981	Do	
Glyburide Tablets	April 1, 1993	Do	
Haloperidol Tablets/Oral Solution (Concentrate)	February 1, 1990	Do	
Regulatory Aspects Pertinent to the Development of Transdermal Drug Delivery Systems	February 2, 1985	Biopharmaceutic	
Supplements to New Applications, Abbreviated Antibiotic Applications for Nonsterile Drug Products	December 12, 1994	Compliance	
Terfenadine (Tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 11, 1995	Biopharmaceutic	
Positron Emission Tomography Questions and Answers 1	October 24, 1996	Generic Drug	
Positron Emission Tomography Questions and Answers 2	April 18, 1997	Do	
Submission of an Environmental Assessment in Human Drug Applications and Supplements	November 13, 1995	Chemistry	
Submission of an Environmental Assessment in Human Drug Applications and Supplements	November 13, 1995	Do	
Acetohexamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 1, 1988	Biopharmaceutic	
Allopurinol (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 15, 1985	Do	
Amiloride Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 29, 1985	Do	
Aminophylline (suppositories) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 5, 1983	Do	
Amitriptyline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 5, 1983	Do	
Amoxicillin (capsules, tablets and suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	June 10, 1988	Do	
Baclofen (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 5, 1988	Do	
Cefadroxil (capsules, tablets and suspension) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 7, 1988	Do	
Cephalexin (tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 19, 1987	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)
Cephradine (Capsule and Suspension) In-Vivo Bioequivalence Studies	September 10, 1986	Do	
Chlordiazepoxide and Chlordiazepoxide HCl Bioavailability and Dissolution Studies	July 5, 1983	Do	
Chlorpropamide In-Vivo Bioavailability Studies	July 5, 1983	Do	
Chlorthalidone (Tablets)	July 5, 1983	Do	
Clinical Evaluation of Drugs for the Treatment of Peripheral Vascular Disease		Do	
Clofibrate In Vivo Bioavailability Studies	April 7, 1986	Do	
Clonidine Hydrochloride Drug Products In Vivo Bioequivalence Study and In Vitro Dissolution Testing	December 5, 1984	Do	
Clorazepate In Vivo Bioequivalence Study and In Vitro Dissolution Testing	February 17, 1987	Do	
Cyclobenzaprine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 25, 1988	Do	
Desipramine Hydrochloride (Tablets) In Vivo Bioequivalence Studies	September 22, 1987	Do	
Dicyclomine Hydrochloride Drug Products In Vivo Bioequivalence	August 10, 1984	Do	
Dissolution Testing (General)	April 1, 1978	Do	
Estropipate Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing (I)	August 26, 1992	Do	
Flurazepam Hydrochloride (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	October 15, 1985	Do	
Hydrochlorothiazide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 28, 1987	Do	
Hydroxyzine Hydrochloride (tablets) (dissolution only)	March 4, 1986	Do	
Indomethacin (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 27, 1988	Do	
Isopropamide Iodide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 12, 1982	Do	
Loxapine Succinate (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 10, 1987	Do	
Maprotiline Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 27, 1987	Do	
Meclofenamate Sodium (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 12, 1986	Do	
Metaproterenol Sulfate (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	March 18, 1986	Do	
Metoclopramide Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 27, 1984	Do	
Nalidixic Acid In Vivo Bioequivalence and In Vitro Dissolution Testing	August 19, 1987	Do	
Nitrofurantion Macrocrystalline (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	January 10, 1986	Do	
Nitroglycerin Ointment In Vivo Bioequivalence Studies	December 17, 1986	Do	
Perphenazine (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 27, 1987	Do	
Perphenazine/Amitriptyline (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 27, 1987	Do	
Phenylbutazone Oxyphenbutazone (capsules and tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 28, 1987	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)
Prazepam (capsules and tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 26, 1988	Do	
Prednisone (tablets) (dissolution only)	July 10, 1985	Do	
Probenecid Drug Products Bioavailability Study	July 26, 1983	Do	
Propoxyphene Napsylate With Acetaminphen (Tablets)	March 26, 1980	Do	
Propranolol Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 1, 1984	Do	
Propylthiouracil (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 13, 1986	Do	
Quinidine Gluconate (tablets, controlled release) In Vivo Bioequivalence and In Vitro Dissolution Testing	September 22, 1987	Do	
Ritodrine Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 27, 1987	Do	
Sulfinpyrazone (Capsules and Tablets)	September 25, 1987	Do	
Sulfones (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	November 7, 1986	Do	
Temazepam In Vivo Bioequivalence Studies and In Vitro Dissolution Testing	August 8, 1985	Do	
Tolazamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	May 30, 1986	Do	
Tolbutamide (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	December 1, 1983	Do	
Trimipramine Maleate (capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing	August 18, 1987	Do	
Verapamil Hydrochloride (tablets) In Vivo Bioequivalence and In Vitro Dissolution Testing	July 18, 1985	Do	

V. Guidance Documents Issued by the Center for Food Safety and Applied Nutrition

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)
Level I Guidance Documents Not Included in the February 1998 Comprehensive List			
Draft Working Guide to Minimize Microbial Hazards for Fresh Fruits and Vegetable	1998	Farmers and Food Packers	Lou Carson, Food Safety Initiative (HFS–3), FDA–CFSAN, 200 C St. SW., Washington, DC 20204 or jsaltsman@bangate.fda.gov
Iron-containing Supplements and Drugs: Label Warning and Unit Dose Packaging; Small Entity Compliance Guide	1997	Dietary Supplement Manufacturers; Small Entities	Office of Special Nutritionals (HFS–450), FDA–CFSAN, 200 C St. SW., Washington, DC 20204
Level 2 Guidance Documents			
Partial List of Enzyme Preparations That Are Used in Foods	1998	FDA Regulated Industry	Office of Premarket Approval (HFS–200), FDA–CFSAN, 200 C St. SW., Washington, DC 20204
Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food	1998	Do	Do
Fish and Fishery Products Hazards and Controls Guide, 2nd Ed.	January 1998	Do	Office of Seafood (HFS–400), FDA–CFSAN, 200 C St. SW., Washington, DC 20204
HACCP Regulations for Fish and Fishery Products: Questions and Answers	1997	Do	Do

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

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Validation of Analytical Procedures; Definition and Terminology; Draft	December 1997	Regulated Industry	Center for Veterinary Medicine (HFV–12), Communications Staff, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755.
Validation of Analytical Procedures; Methodology; Draft	December 1997	Do	Do
Industry-Supported Scientific and Educational Activities	November 1997	Do	Do
Professional Flexible Labeling of Antimicrobial Drugs; Draft	January 1998	Do	Do
Small Entities Compliance Guide for Renderers	February 1998	Do	Do
Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors	February 1998	Do	Do
Small Entities Compliance Guide for Feeders of Ruminant Animals With On-Farm Feed Mixing Operations	February 1998	Do	Do
Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations	February 1998	Do	Do
CVM Program Policy and Procedures Manual; Index (Guide No. 1240.0000)	March 19, 1998	Do	Do
CVM Guidance on Media Inquiries (Guide No. 1240.2325)	December 17, 1997	Do	Do
Requirements for Importation of Investigational New Animal Drugs (Guide No. 1240.3032)	March 27, 1992	Do	Do
Animal Drug Applications Expedited Review (Guide No. 1240.3135)	December 3, 1997	Do	Do
CVM Research Activities (Guide No. 1240.3700)	January 6, 1998	Do	Do
Initiation and Approval of Research Projects (Guide No. 1240.3710)	January 6, 1998	Do	Do
Ownership Transfer or Corporate Identity Change of an Application (Guide No. 1240.4150)	March 19, 1998	Do	Do
CVM Makes the Analysis of Comments on the Fluoroquinolone and Glycopeptide Prohibition Available to the Public	January 15, 1998	Do	Do
Withdrawn			
CVM Program Policy and Procedures Manual; Index (Guide No. 1240.0000)	October 29, 1997		
CVM Guidance on Media Inquiries (Guide No. 1240.2325)	July 1, 1997		
CVM Research Activities (Guide No. 1240.3700)	November 3, 1993		
Initiation and Approval of Research Projects (Guide No. 1240.3710)	November 3, 1993		
Criteria for the Approval of Euthanasia Products (Guide No. 1240.4112)	February 13, 1990		
Sterility of Ophthalmic Products (Guide No. 1240.4120)	December 7, 1993		
Sterility and Pyrogen Requirements for Injectable Drug Products (Guide No. 1240.4122)	November 27, 1989		
Overformulation in Animal Drug Products (Guide No. 1240.4130)	January 2, 1992		
Continuous Use Production Drugs and Short-Term Therapeutic Treatments in Feeds (Guide No. 1240.4145)	April 16, 1990		
Policy on Sterilization of New Animal Drug Products and Containers by Irradiation (Guide No. 1240.4160)	September 10, 1997		
CVM Medically Necessary Veterinary Drug Product Shortage Management (Guide No. 1240.4170)	June 30, 1994		

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)
Small Entities Compliance Guide on Animal Proteins Prohibited from Animal Feed	June 1997		

VII. Guidance Documents Issued by the Office of Regulatory Affairs

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Investigations Operations Manual (PB98–913399)	January 1998	FDA Staff Personnel	National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, or via Internet at www.fda.gov/ora/ inspect—ref/iom/iomtc.html
Mammography Quality Standards Act (MQSA) Auditors Guide (PB98–127178)	January 1998	Do	NTIS or via Internet at www.fda.gov/ora/inspect—ref/igs/iglist.html
Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems (PB98–127152)	December 1997	Do	Do
Guide to Inspections of Grain Product Manufacturers	March 1998	Do	Division of Emergency and Investigational Operations (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857
Guide to Bioresearch Monitoring Inspections of In Vitro Devices	February 1998	Do	Do
Guide to Inspections of Viral Clearance Processes for Plasma Derivatives	March 1998	Do	Do
Guide to Inspections of Computerized Systems in the Food Processing Industry	March 1998	Do	Do
Regulatory Procedures Manual; Update/New Subchapter; Application Integrity Policy	March 1998	Do	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 or via Internet at www.fda.gov/ora/compliance__ref/rpm/rpmtc.html
Regulatory Procedures Manual; Update Subchapter; Warning Letters	March 1998	Do	Do
Regulatory Procedures Manual: Update/Revised Subchapter; Import Procedures	April 1998	Do	Do
Regulatory Procedures Manual: Updated/Revised Subchapter; Priority Enforcement Strategy for Problem Importers	April 1998	Do	Do
Regulatory Procedures Manual: Updated/Revised Subchapter; Import Procedures	April 1998	Do	Do
Regulatory Procedures Manual: Updated/Revised Subchapter; Notice of Sampling	April 1998	Do	Do
Regulatory Procedures Manual: Updated/Revised Subchapter; Supervisory Charges	April 1998	Do	Do
Regulatory Procedures Manual: Update/New Subchapter; Granting and Denying Transportation and Exportation (T&E) Entries	May 1998	Do	Do
Import Alerts	Continuously	Do	Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or via Internet at www.fda.gov/ora/fiars/ora__imports__alerts.html
Guidance Documents Not Included in the February 1998 Comprehensive List			
Guideline for the Monitoring of Clinical Investigations	January 1998	Regulated Industry	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 or via Internet at www.fda.gov/ora/compliance__ref/rpm/rpmtc.html
Computerized Systems Used in Clinical Trials	June 18, 1997	Do	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Compliance Program 7348.808; Bioresearch Monitoring; Good Laboratory Practices (GLP) (Nonclinical)	August 8, 1994	FDA Staff Personnel	Do
Food Laboratory Practice Program (Nonclinical Laboratories) 7348.808A: EPA Data Audit Inspections	October 1, 1991	Do	Do
Compliance Program 7348.810: Sponsors, Contract Research Organizations and Monitors	August 18, 1994	Do	Do
Compliance Program 7348.809: Bioresearch Monitoring; Institutional Review Board	August 18, 1994	Do	Do
Compliance Program 7348.811: Bioresearch Monitoring; Clinical Investigations	August 18, 1994	Do	Do

VIII. International Conference on Harmonization Guidances (CDER)

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Hard Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
E2B Data Elements for Transmission of Individual Case Safety Reports	January 15, 1998	Regulated Industry	Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573 or 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 the United States)or 301–827–3844 (outside of the United States and local to Rockville, MD). Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm
E8 General Considerations for Clinical Trials	December 17, 1997	Do	Do
M3 Timing of Nonclinical Studies for the Conduct of Human Clinical Trials of Pharmaceuticals	November 25, 1997	Do	Do
QC3 Impurities; Residual Solvents	December 24, 1997	Do	Do
S1B Testing for Carcinogenicity of Pharmaceuticals	February 23, 1998	Do	Do
S1C(R) Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes	December 4, 1997	Do	Do

Dated: June 25, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–17702 Filed 7–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted