Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

H. Evaluation Criteria

Each application should document the existence of an operational distance-based learning, graduate-level, degree program in the applicant institution. Each qualifying application will be evaluated individually against the following criteria by an independent review panel appointed by CDC.

1. Background, Need, and Capability (30 Percent)

The extent to which the applicant describes current and previous related experience.

a. The extent to which the applicant is currently an internationally recognized, accredited graduate-level program in public health.

b. The extent to which the applicant operates an internationally recognized, accredited graduate-level program in public health.

c. The extent to which the applicant already has existing academic testing centers throughout the world, which are currently maintained, so that a student's academic progress can be objectively monitored at regular intervals without his/her having to go outside his/her country of residence.

2. Goals and Objectives (15 Percent)

The extent to which the goals and objectives are relevant and feasible to be accomplished during the project period, and which address all activities necessary to accomplish the purpose of the proposal.

3. Methods (20 Percent)

The extent to which the applicant provides a detailed description of proposed activities which are likely to achieve each objective and overall program goals and which includes designation of responsibility for each action undertaken. The extent to which the applicant provides a reasonable and complete schedule for implementing all activities. The extent to which concurrence with the applicant's plans by all other involved parties is specific and documented.

4. Evaluation (20 Percent)

The extent to which the proposed evaluation system is detailed and will document program process, effectiveness, impact, and outcome. The extent to which the applicant demonstrates potential data sources for evaluation purposes, and documents staff availability, expertise, and capacity to perform the evaluation. The extent to which a feasible plan for reporting evaluation results and using evaluation information for programmatic decisions is included.

5. Personnel and Staffing (15 Percent)

The extent to which position descriptions, CVs and lines of command are appropriate to accomplish the program goals and objectives.

6. Budget and Justification (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of:

1. Semi-annual reports;

2. Financial status report no more than 90 days after the end of each budget period; and

3. Final financial status and performance reports no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in ''Where To Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable:

AR–10: Smoke-Free Workplace Requirement

AR–11: Healthy People 2000 Requirement

AR–12: Lobbying Restrictions

J. Authority and Catalog of Federal International Assistance

This program is authorized under the Sections 307 of Public Health Service Act, [42 U.S.C. section 242l], as amended. The Catalog of Federal International Assistance number is 93.283.

K. Where To Obtain Additional Information

To receive additional information, please go to the CDC home page on the Internet: www.cdc.gov and click on the word ''funding.''

If you do not have Internet access, you can request an application kit by calling 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all documents, business assistance can be obtained from: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 00014, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341–4146, telephone (770) 488–2717, E-mail address: jcw6@cdc.gov

For program technical assistance, contact Ms. Elliott Churchill, M.S., M.A., Senior Communications Specialist, Division of International Health, Epidemiology Program Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop C–08, Atlanta, GA 30333, telephone: (404) 639–2231, E-mail address: rec1@cdc.gov

Dated: July 29, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–19970 Filed 8–3–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0046]

Update 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 an update of all guidance documents issued and withdrawn since the compilation of the previous quarterly list that published on January 6, 1999, and the annual comprehensive list that published on June 10, 1999. 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 for the first part of this year. This list also includes some guidance documents that were inadvertently not included on previously published lists.

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: For general information regarding GGP's: Lisa M. Helmanis, Regulations Policy and Management Staff (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its 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. Because the agency has fallen behind in issuing its quarterly updates, this document covers guidance documents issued and withdrawn since the publication of the last quarterly list on January 6, 1999 (64 FR 888), and the annual comprehensive list on June 10, 1999 (64 FR 31228).

On June 1, 1998, the President instructed all Federal agencies to ensure the use of ''plain language'' in all new documents. As part of this initative, FDA is taking steps to ensure that the principles of ''plain language'' set forth by the President are being incorporated into its guidance documents. The agency invites public comment on the clarity of its guidances.

The following list of guidance documents represents all guidances issued or withdrawn by FDA since the compilation of the January 6, 1999, quarterly list and the June 10, 1999, annual comprehensive list and any guidance documents inadvertently not included on previously published lists. 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: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	December 1998	FDA—Regulated Industry	Office of Communication, Training, and Manufacturers Assistance (HFM–40), 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, 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: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling	January 1999	Do	Do
Guidance for Industry: Population Pharmacokinetics	February 1999	Do	Do
Guidance for Industry: Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) February 1999	Do	Do	Do
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	February 1999	Do	Do
Draft Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products	February 1999	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)
Draft Guidance for Industry: Formal Dispute Resolution: Appeals Above the Division Level	February 1999	Do	Do
Draft Guidance for Industry: IND's for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products, Chemistry Manufacturing and Controls Content and Format	February 1999	Do	Do
Draft Guidance for Industry: Accelerated Approval Products—Submission of Promotional Materials	March 1999	Do	Do
Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product	March 1999	Do	Do
Update on Abbokinase (Urokinase)	March 16, 1999	Healthcare Providers	Do
Update on Abbokinase (Urokinase)	March 22, 1999	Do	Do
Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans	April 1999	FDA—Regulated Industry	Do
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	April 1999	Do	Do
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''	May 1999	Do	Do
Guidance for Industry for Platelet Testing and Evaluation of Platelet Substitute Products	May 1999	Do	Do
Guidance for Industry: Efficacy Studies to Support Marketing of Fibrin Sealant Products Manufactured for Commercial Use	May 1999	Do	Do
Dear Colleague Letter—Hypotension and Bedside Leukocyte Reduction Filters	May 5, 1999	Healthcare Providers	Do

III. Guidance Documents Issued by the Center for Devices and Radiological (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 for Industry on Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects	March 25, 1999	Office of Compliance (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
Document for Special Controls for Erythropoietin Assay Premarket Notifications (510(k))	April 28, 1999	Office of Device Evaluation (ODE)/Division of Clinical Laboratories Devices (DCLD)	Do
In Vitro Diagnostic Fibrin Monomer Paracoagulation Test	April 27, 1999	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)
Recommended Clinical Study Design for Ventricular Tachycardia Ablation	May 7, 1999	ODE/Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND)	Do
Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh	March 2, 1999	ODE/Division of General and Restorative Devices (DGRD)	Do
Guidance for the Submission of a Premarket Notification for a Dermabrasion Device	March 2, 1999	Do	Do
Accountability Analysis for Clinical Studies for Ophthalmic Devices	March 15, 1999	ODE/Division of Ophthalmic Device (DOD)	Do
Guidance on 510(k) Submissions for Keratoprostheses	March 31, 1999	Do	Do
The Mammography Quality Standards Act Final Regulations Compliance Guidance—Document 2 (Draft)	March 5, 1999	Office of Health of Industry Program (OHIP)/Division of Mammography Quality and Radiation Programs (DMQRP)	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Motion of Tube-Image Receptor Assembly	March 23, 1999	Do	Do
The Mammography Quality Standards Act Final Regulations Facility Survey and Medical Physicist Qualification Requirements	May 5, 1999	Do	Do
Guidance to Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements (Draft)	February 23, 1999	Office of Surveillance and Biometrics (OSB)/Division of Postmarket Surveillance (DPS)	Do
MDR Reporting Guidance for Date-Related Problems Including Y2K	April 16, 1999	OSB/Division of Surveillance Systems (DSS)	Do
Variance From Manufacturer Report Number Format (Variance No. 5)	August 12, 1996	Do	Do
Immunotoxicity Testing Guidance	May 6, 1999	Office of Science and Technologies (OST)/Division of Life Sciences (DLS)	Do
Replacements			
Guidance for Industry—Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators (Replaces: In Vitro Diagnostic Calibrators)	February 22, 1999	ODE/DCLD	Do
Guidance for Spinal System 510(k)'s (Replaces: Draft Guideline for Reviewing Spinal Fixation Device Systems)	May 7, 1999	ODE/DGRD	Do
Electro-Optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA (Replaces: In Vivo Devices for the Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE Draft Document)	May 12, 1999	ODE/Division of Reproductive, Abdominal, Ear, Nose, and Throat Devices Branch (DRAERD)	Do
Home Uterine Activity Monitors: Guidance for the Submission of 510(k) Premarket Notifications (Replaces: Premarket Testing Guidelines for Home Uterine Activity Monitors)	May 12, 1999	Do	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulation—Document 1 (Replaces: Compliance Guidance: The Mammography Quality Standards Act Final Regulation)	March 4, 1999	OHIP/DMQRP	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 Request and Issuance of Interim Notice Letters for Mammography Facilities Under the Mammography Quality Standards Act (42 U.S.C. 263(b)) (Replaces: Guidance for Request and Issuance of Interim Notice Letters for Mammography Facilities Under the Mammography Quality Standards Act (42 U.S.C. 263(b))	May 4, 1999	Do	Do
Compliance Guidance: The Mammography Quality Standards Act Final Regulations—Preparing for MQSA Inspections (Replaces: ''What a Mammography Facility Should Do to Prepare for an MQSA Inspection'' and ''Addendum to What a Mammography Facility Should Do To Prepare for an MQSA Inspection''	May 5, 1999	Do	Do
Regulations of Medical Devices Background Information for International Officials (Replaces: Regulations of Medical Devices Background Information for Foreign Officials)	April 14, 1999	OHIP/Division of Small Manufacturers Assistance (DSMA)	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 Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Accelerated Approval Products—Submission of Promotional Materials	March 26, 1999	Advertising Draft	Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573, or via the Internet at http://www.fda.gov/cder/guidance/index.htm
ANDA's: Impurities in Drug Products	January 5, 1999	Generic Drug Draft	Do
BACPAC 1: Intermediates In Drug Substance Synthesis (Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation)	November 30, 1998	Chemistry Draft	Do
Bioanalytical Methods Validations for Human Studies	January 5, 1999	Biopharmaceutic Draft	Do
Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action	June 1999	Do	Do
Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA)	February 17, 1999	Clinical Medical	Do
Content and Format of Geriatric Labeling	January 21, 1999	Labeling Draft	Do
Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act	November 23, 1998	Procedural	Do
Establishing Pregnancy Registries	June 4, 1999	Clinical Medical Draft	Do
Evaluation of Human Pregnancy Outcome Data; Draft Guidance for Reviewers	June 4, 1999	Do	Do
Fast Track Drug Development Programs: Designation, Development, and Application Review	November 18, 1998	Procedural	Do
FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products	December 1998	Clinical Medical	Do

Name of Document	Date of Issuance	Grouped by Intended User or Regulatory Activity	How to Obtain a Copy of the Document (Name and Address, Phone, FAX, E-mail, or Internet)
Formal Meetings With Sponsors and Applicants for PDUFA Products	March 19, 1999	Procedural Draft	Do
Formal Dispute Resolution: Appeals Above the Division Level	March 19, 1999	Do	Do
General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products	November 30, 1998	Clinical Pharmacological Draft	Do
In Vivo Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling	November 19, 1998	Do	Do
IND's for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format	April 20, 1999	Chemistry Draft	Do
Metered Dose Inhalers (MDI's) and Dry Powder Inhalers (DPI's) Drug Products; Chemistry, Manufacturing, and Controls Documentation	November 19, 1998	Do	Do
Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products	May 1999	Do	Do
NDA's: Impurities in Drug Substances	January 21, 1999	Do	Do
Noncontraceptive Estrogen Drug Products—Physician and Patient Labeling	January 8, 1999	Labeling Draft	Do
Organization of an ANDA	March 2, 1999	Generic Drug	Do
Population Pharmacokinetics	February 10, 1999	Clinical Pharmacology	Do
Product Name, Placement, Size, and Prominence in Advertising and Promotional Labeling	March 12, 1999	Advertising Draft	Do
Regulatory Submissions in Electronic Format; General Considerations	January 28, 1999	Electronic Submissions	Do
Regulatory Submissions in Electronic Format; New Drug Applications	January 28, 1999	Do	Do
Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products	February 26, 1999	Generic Drug Draft	Do
SUPAC IR/MR: Immediate-Release and Modified-Release Solid Oral Dosage Forms; Manufacturing Equipment Addendum	February 26, 1999	Chemistry	Do
SUPAC—SS: Nonsterile Semisolid Dosage Forms	January 5, 1999	Chemistry Draft	Do
Therapeutic Equivalence Code Placement on Prescription Drug Labels and Labeling	January 28, 1999	Labeling Draft	Do
Variations in Drug Products that May Be Included in a Single ANDA	January 27, 1999	Generic Drug	Do
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Containing Certain Active Moieties/Active Ingredients Based on a Biopharmaceutics Classification System	February 17, 1999	Biopharmaceutic Draft	Do
Withdrawn			
Archiving Submissions in Electronic Format—NDA's	September 23, 1997		
Clinical Evaluation of Drugs to Prevent, Control and/or Treat Periodontal Disease	November 1, 1978		
Content and Format of Investigational New Drug Applications (IND's) for Phases 2 and 3 Studies of Drugs, Including Specific Therapeutic Biotechnology-Derived Products; Preliminary Draft	December 10, 1997		
Providing Regulatory Submissions in Electronic Format—NDA's	April 6, 1998		

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

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)
Withdrawn			
Preparing Environmental Assessments: General Suggestions	August 1990		
Step-by-Step Guidance for Preparing Environmental Assessments	March 1987		
Partial List of Enzyme Preparations That are Used in Foods	1998		
Partial List of Microorganisms and Microbial-Derived Ingredients That Are Used in Food	1998		
FDA Nutrition Labeling Guide for Using Data Bases NOTE: ONLY DELETE THE 1993 VERSION	1993		
New Guidances			
Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions NOTE: REISSUED DUE TO QUALITY FOOD PROTECTION ACT JURISDICTION OVER FOOD CONTACT SUBSTANCES FOR A MORE LIMITED PURPOSE	1993	Petitioners for Food Contact Applications	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3100, or via the Internet at http://vm.cfsan.fda.gov/~dms/opa-cg3a.html
Statement of Identity Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Small Entity Compliance Guide	January 4, 1999	Dietary Supplement Manufacturers	Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5251
Corrections			
Statement of Policy: Foods Derived From New Plant Varieties: Notice	May 29, 1992	Developers of New Plant Food Varieties	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW. , Washington, DC 20204, 202–418–3100
Guidance for Submitting Requests under 21 CFR 170.39, Threshold of Regulation for Substances Used in Food Articles	1996	Food Packaging Industry	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-gg2.html
Guidelines for the Preparation of Petition Submissions	1996	Food Ingredient or Packaging Industry	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-prep.html
Guidelines for Approval of Color Additives in Contact Lenses Intended as Colors	1996	Color or Contact Lens Industry	Do
FDA Recommendations for Submission of Chemical and Technological Data on Color Additives for Food, Drugs, or Cosmetics Use	February 1993	Color Additives Industry	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-col1.html
Points to Consider for the Use of Recycled Plastics in Food Packaging: Chemistry Considerations	December 1992	Food Packaging Industry	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-cg3.html
Recommendations for Submission of Chemical and Technological Data for Direct Food Additive and GRAS Food Ingredient Petitions	May 1993	Do	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-cg4.html
Recommendations for Chemistry Data for Indirect Food Additive Petitions	June 1995	Do	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-cg5.html
Enzyme Preparations: Chemistry Recommendations for Food Additive and GRAS Affirmation Petitions	January 1993	Food Enzyme Industry	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-cg7.html
Estimating Exposure to Direct Food Additive and Chemical Contaminants in the Diet	September 1995	Food and Food Ingredient Industry	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-cg8.html

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)
Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food (also known as Redbook I)	1982	Petitioners for Food or Color Additives	National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161, Publication No. PR–83–170696
Environmental Assessment Technical Handbook	March 1987	Do	Do—Publication No. PB87175345–AS, A–01
Environmental Assessment of Food-Packaging Materials With Enhanced Degradation Characteristics	February 1994	Do	Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3100
Color Additive Petitions Information and Guidance	1996	Do	Do
Toxological Testing of Food Additives (Updated 1997)	1983	Do	Do—Internet at http://vm.cfsan.fda.gov/~dms/opa-tg1.html
FDA's Policy for Foods Developed by Biotechnology	1995	Food Industry	Internet at http://vm.cfsan.fda.gov
Food Additive Petition Expedited Review	January 1999	Guidance for Industry and CFSAN	Robert L. Martin, Office of Premarket Approval (HFS–215), 200 C St. SW., Washington, DC 20204, 202–418–3074, or e-mail premarkt@cfsan.fda.gov, or via the Internet at http://vm.cfsan.fda.gov/~dms/opa-expe.html
Use of Antibiotic Resistance Marker Genes in Transgenic Plants	September 1998	Do	Nega Beru, Office of Premarket Approval (HFS–206), 200 C St. SW., Washington, DC 20204, 202–418–3097, or e-mail premarkt@cfsan.fda.gov or via the Internet at http://vm.cfsan.fda.gov/~dms/opa-armg.html

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)
Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals	January 1999	Animal Drug Industry	Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1755, FAX 301–594–1831 or via the Internet at http://www.fda.gov/cvm
Guidance for Industry: Submitting a Notice of Claimed Investigational Exemption in Electronic Format to CVM via E-mail	January 1999 (Revised)	Do	Do
Draft Guidance for Industry: Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling	March 1999	Do	Do
Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species	April 1999 (Revised)	Do	Do

VII. 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)
Compliance Policy Guide, Chapter 1, Sec. 160.850: NEW, Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17)	May 13, 1999	FDA Personnel	Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0420 or via the Internet at http://www.fda.gov/ora/compliance__ ref/cpg/cpggenl/cpg160–180.htm
Compliance Policy Guide, Chapter 1, Sec. 160.800, NEW: Year 2000 (Y2K) Computer Compliance	April 26, 1999	Do	Do—Internet at http://www.fda.gov/ ora/compliance__ref/cpg/cpggenl/cpg160–800/html
Compliance Policy Guide, Chapter 5, Sec. 555.425, NEW: Foods—Adulteration Involving Hard or Sharp Foreign Objects	March 23, 1999	Do	Do—Internet at http://www.fda.gov/ ora/compliance__ref/cpg/cpgfod/cpg555–425.htm
Compliance Policy Guide, Chapter 1, Sec.140.100, REVISION/DRAFT: Regulatory Policy on the Disposition of Publications that Constitute Labeling (CPG 7153.13)	April 26, 1999	Do	Do—Internet at http://www.fda.gov/ ora/compliance__ref/cpg/cpgfod/draftrev-cpg715313.htm
Compliance Policy Guide, Chapter 2, Sec. 230.140, NEW, Evaluation and Processing of Post Donation Information Reports	July 9, 1999	Do	Do—Internet at http://www.fda.gov/ora/compliance__ref/default.htm
Computerized Systems Used in Clinical Trials	April 1999	FDA—Regulated Industry	Do—Internet at http://www.fda.gov/ora/compliance__ref/bimo/ffinalcct.htm
Draft Guidance Policy Statement: Draft Civil Money Penalty Reduction Policy for Small Entities	May 18, 1999	FDA Personnel and Regulated Industry	Do—Internet at http://www.fda.gov/ohrms/Dockets/98fr/051899f.txt
Medical Device Warning Letter Pilot	March 8, 1999	Do	Do—Internet at http://www.fda.gov/ohrms/Dockets/98fr/030899e.pdf
Guidelines for Entry Review of Radiation-Emitting Electronic Devices	March 12, 1999	FDA Personnel	Division of Import Operations and Policy (HFC–170), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–1218
Import Alerts	Continuously	Do	Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or via the Internet at http://www.fda.gov/ora/fiars/ora__import—alerts.html
Inspectional Policy Regarding Y2K Issues	February 11, 1999 (Revised March 29, 1999)	Do	Division of Emergency and Investigational Operations (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645
Laboratory Procedures Manual, NEW Chapter X, Method Validation Samples	May 1999	Do	Division of Field Science (HFC–140), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7605
Investigations Operations Manual, Chapter 5, Subchapter 520, Section 523.2, REVISION, Photo/Video Identification and Submission	June 1999	Do	Division of Emergency Operations (HFC–130), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5636 or via the Internet at http://fda.gov/ora/inspect__ref/iom/IOMCoverPg.html
Guide to International Inspections and Travel, REVISION (Formerly: FDA/ORA International Inspection Manual and Travel Guide)	July 1999	Do	Do—Updated version not yet available on Internet

Withdrawn

Compliance Policy Guide, Chapter 2, Sec. 205.100, Standards and Minimum Requirements for Biologic Products (CPG 7134.03)	December 21, 1998		
Compliance Policy Guide, Chapter 3, Sec. 300.200, Reconditioners/Rebuilders of Medical Devices (CPG 7124.28),	January 4, 1999		

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. 210.100, Licensing—Changes To Be Reported to the Office of Biologics (CPG 7134.05)	April 26, 1999		
Compliance Policy Guide, Chapter 4, Sec. 460.200, Manufacture, Distribution, and Promotion of Adulterated, Misbranded, or Unapproved New Drugs for Human Use by State-Licensed Pharmacies (CPG 7132.16)	January 8, 1999		

Dated: July 27, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2171]

Medical Devices; Draft Guidance for the Accountability Analysis for Clinical Studies for Ophthalmic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled, ''Accountability Analysis for Clinical Studies for Ophthalmic Devices.'' This guidance is intended to provide general information about the analysis of accountability of subjects in clinical studies in ophthalmic device investigational device exemption applications and marketing applications and notifications. By providing a reference point for the reporting of accountability information, FDA hopes that terminology and methods of presentation can be standardized so that the agency and sponsors can more effectively analyze these data. This guidance is not final nor is it in effect at this time.

DATES: Written comments concerning this guidance must be submitted by November 2, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Accountability Analysis for Clinical Studies for Ophthalmic Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 301–443–8818. Submit written comments on the document to the Dockets Management Branch, (HFA–305), Food and Drug Administration, rm 1061, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Donna R. Lochner, Center for Devices and Radiological Health (HFZ–463), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Accountability Analysis for Clinical Studies for Ophthalmic Devices.'' This guidance document provides background information that FDA and the sponsor can use in preparing accountability analyses for subjects enrolled in clinical studies of ophthalmic devices. It provides definitions of common terminology used in describing accountability, considerations for presentation of a ''lost to follow-up''analysis, and sample formats for presentation of accountability. FDA has noted that there is often a misunderstanding in the meaning of certain terms used to describe accountability, which can confuse the presentation of the accountability data. Further, sponsors have frequently requested that FDA provide them with sample formats for presentation of accountability data. This guidance document attempts to provide some clarity in these areas.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the accountability analysis for ophthalmic devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the draft guidance entitled ''Accountability Analysis for Clinical Studies for Ophthalmic Devices'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1350) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Accountability Analysis for Clinical Studies for Ophthalmic Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information.