CHAPTER 10 - REFERENCE MATERIALS

SUBCHAPTER 1000 - LAW, REGULATION AND GUIDANCE

This chapter will help you to locate regulatory references and FDA staff.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act),the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the FDA Modernization Act of 1997, (FDAMA), the International Conference on Harmonization (ICH), the Mutual Recognition Agreement (MRA), national emergencies and initiatives, and other forces continue to impact FDA inspectional operations as changes in law, regulation, guidance and internal procedures issue. As ICH members (Japan, U.S. and European Union) reach consensus agreements, ICH guidelines are adopted by all three governments. In the United States, they may replace outstanding FDA guidance in the medical device, human and animal drug areas. Unless exempted, the Bioterrorism Act and implementing regulations require most domestic food facilities and foreign food facilities who export to the U.S. to register as of December 12, 2003; FDA began accepting registrations on October 16, 2003. The Bioterrorism Act requires that FDA receive prior notice of food imported into the United States, beginning on December 12, 2003. The 2002 MDUFMA authorizes FDA to charge user fees for medical device premarket review; it allows third party medical device inspections, sets out new regulatory requirements for single-use devices, and directs FDA to establish the Office of Combination Products. FDA drug GMP initiative and Process Analytical Technology (PAT) efforts are underway.

In conducting inspections and investigations according to changing policies, in order to be effective, FDA regulators must understand the difference between regulatory requirements and guidance.

Laws or statutes, enacted by Congress, and regulations or rules, promulgated by Federal agencies, contain regulatory requirements.

FDA's guidance documents, on the other hand, have a different legal status and serve purposes different from laws and regulations. The purposes of guidance documents are to:

1. Provide assistance to the regulated industry by clarifying requirements that have been imposed by Congress or issued in regulations by FDA, and by explaining how industry may comply with those statutory and regulatory requirements, and

2. Provide specific review and enforcement approaches to help ensure that FDA's employees implement the agency's mandate in an effective, fair, and consistent manner.

The term "guidance documents" includes documents prepared for FDA staff, applicants/sponsors, and the public that: (1) relate to the processing, content, and evaluation/approval of submissions; (2) relate to the design, production, manufacturing, and testing of regulated products; (3) describe the agency's policy and regulatory approach to an issue; or (4) establish inspection and enforcement policies and procedures.

Guidance documents do not include documents relating to internal FDA procedures, agency reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms. FDA procedures issued for staff to follow, such as the IOM, are internal procedures intended to direct your activities and you are to follow them.

Guidance documents for industry do not establish legally enforceable rights or responsibilities and are not legally binding on the public or the agency. Rather, they explain how the agency believes the statutes and regulations apply to certain regulated activities. For a more detailed explanation of the background to the development, issuance and use of guidance documents see the preamble to the February 27, 1997 Federal Register Volume 62 Number 39. To access 21CFR115 Good Guidance Practices, see http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfrv1_01.html. Also see http://www.fda.gov/cdrh/ohip/guidance/1323.pdf to access the CDRH Manual for the Good Guidance Practices (GGP) Regulation - Final Guidance for FDA Staff (2/01). For a comprehensive list of FDA current guidance documents, see http://www.fda.gov/opacom/morechoices/industry/guidedc.htm

The Federal Register is the official daily publication for rules, proposed rules, and Notices of federal agencies and organizations as well as Executive Orders and other Presidential documents. The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive Departments and agencies of the Federal Government. Most regulations enforced by FDA are located in Title 21 of the CFR. For a listing of all titles in the U.S Code, see http://www4.law.cornell.edu/uscode/#TITLES.

SUBCHAPTER 1010 - SOURCES OF INFORMATION

1011 - INVESTIGATOR TRAINING AND CERTIFICATION

ORA's Investigator certification program provides a focused training plan for the ongoing professional development of agency investigators. The program is designed to address the specific needs of agency District Offices by providing a structured mechanism for investigators to maintain the required levels of competency.

Performance certification promotes uniformity in investigator training and experience. The program is designed to promote the efficient use of (ORA) training resources. Investigators who complete the program will be formally recognized as meeting the competencies required at the specific certification level achieved.

Additional information on ORA's Investigator Certification program, including procedure documents and forms for certification in specific commodity areas, is available on the ORA U . See http://web.ora.fda.gov/dhrd/Certification/certification.htm.

In addition to managing the investigator certification program through ORAU, the Division of Human Resource Development (DHRD) (HFC-60) manages and coordinates with Regions and Districts, the ORA staff's overall ongoing professional development training through in person and web-based courses, broadcasts, and video conferences. For more information on available training on the ORAU see http://web.ora.fda.gov/dhrd/.

1012 - CONTACTING FDA EMPLOYEES

Easily finding colleagues you need to contact can make your work life more productive. See IOM Chapter 2 the organization of FDA offices, including a directory of ORA field offices and program managers. The Office of Regulatory Affairs organizational directory (blue pages) is available in electronic format. See http://www.fda.gov/ora/inspect_ref/iom/IOMORADIR.html. At the end of the blue pages, find a listing of District program monitors. For FDA Center staff directories:

CFSAN - See http://www.cfsan.fda.gov/~dms/srchbfd.html.

CBER - See http://www.fda.gov/cber/inside/org.htm

CDRH - See http://www.fda.gov/cdrh/organiz-info.html. For a list of resource staff by topic of specialization in the Division of Small Manufacturers, Consumer and International Affairs, see http://www.fda.gov/cdrh/dsma/dsmastaf.html#DSMICA_Staff

CVM - See http://www.fda.gov/cvm/aboutcvm/aboutcvm.html

CDER - See http://www.fda.gov/cder/directories/reference_guide.htm. For a list of resource staff by topic of specialization, in the CDER Division of Manufacturing and Product Quality, (HFD-320) see http://www.fda.gov/cder/dmpq/csotable.htm

To obtain contact information for an FDA employee in your e-mail directory, find the name, then click on "properties" for telephone number and office designation. If the telephone number listed is inaccurate for an FDA employee you wish to contact, call the FDA Personnel Locator at telephone number (301) 443-1544 for an update.

You may also search the Department of Health and Human Services electronic employee directory, which includes FDA and all other HHS staff. See http://directory.psc.gov/employee.htm. See IOM Chapter 3 for other Federal agency and State contact information, or to check the Directory of State and Local Officials on the FDA web site, see http://www.fda.gov/ora/fed_state/directorytable.htm.

1013 - INTERNET AND INTRANET

The FDA Internet Web site at http://www.fda.gov provides access to FDA references in electronic format: laws,

regulations, policy, guidance, correspondence, reports and other publications. From the FDA home page link to laws enforced by FDA and related statutes at www.fda.gov/opacom/laws . From there you can access the Code of Federal Regulations, the Federal Register, and FDA Manuals and Publications. Under the heading "FDA Manuals and Publications" is a link to a comprehensive list of current FDA guidance documents at http://www.fda.gov/opacom/morechoices/industry/guidedc.htm.

Two features will facilitate your navigation of the FDA website, For the FDA "Website Index", see www.fda.gov/opacom/hpchoice.html. To access the FDA "Website Map", see www.fda.gov/sitemap.html.

Subscribe to various FDA e-mail lists for updates on web postings. See www.fda.gov/emaillist.htm.

To access FDA libraries see http://intranet.fda.gov/library/. To access the FDA intranet homepage see http://intranet.fda.gov/index.cfm?index=2.

1014 - FDA ON DISK

The FDA Gold Disk is an electronic source of regulatory references maintained on CD-ROM by the Office of Enforcement, Division of Compliance Information and Quality Assurance (HFC-240) Steven Kendall (510) 337-6840. To order a Gold Disk, contact San Francisco District, Gwen Wong, (510) 337-6890. FDA personnel who do not have access to an FDA network server can use the Gold Disk in an off-line mode. It may also be available on your local district server. Check with your computer support personnel. The FDA gold disk is a convenient source of FDA regulatory references in electronic format when Internet access is not available. It contains, for example, the Federal Food Drug and Cosmetic Act, Title 21 CFR, Compliance Policy Guides, Enforcement Reports, Talk Papers, Import Alerts, Investigations Operations Manual, Regulatory Procedures Manual, selected Compliance Programs, the Food Code, and listings of approved drug products. The Gold Disk is not releasable under FOI and is not available to the public. It is for FDA use only. The subset of the Gold Disk available to state and local agencies (but not releasable under FOI) is the Eureka Disk. To order this, contact Paul Raynes in the ORA Division of Federal-State Relations (DFSR) at (301) 827-2910.

1015 - ELECTRONIC-FAX INFORMATION SYSTEMS

The FDA Medical Devices fax information system issues documents twenty-four hours a day, seven days a week on request to (800) 899-0381. Follow the directions by the automated attendant to receive a faxed list of references and their order numbers. Next, request specific documents by number as indicated on the index.

Biologics, Human/Animal Drugs and Foods do not have fax information systems.

1016 - FDA/ORA MANUALS AND REPORTS

ORA headquarters and the OC Office of Information Resources Management support a change to electronic manuals, not paper manuals, because electronic manuals are easier to issue, revise and distribute. As part of the ORA Quality Management System, ORA HQ supports electronic manual dissemination through developing Intranet master lists or indices for directives used by ORA. See http://web.ora.fda.gov/qms/ or contact Patricia Maroni-Benassi at (301) 827-0389 or pmaroney@ora.fda.gov for more information. During transition from paper to electronic manuals, a limited selection and number of paper manuals will be available as follows:

1. Compliance Policy Guides (CPGs): Limited number of 2003 paper manuals available by contacting Lana Ogram at (301) 827-0393 or at dvasbind@ora.fda.gov;
2. Compliance Program Guidance Manual (CPGM): No paper manuals;
3. Data Codes Manual: No paper manuals; for electronic lists of program assignment codes and establishment type codes contact ORM/Division of Program Evaluation and Management
4. Enforcement Reports: No paper reports;
5. Field Management Directives (FMDs) - No paper manual;
6. Guide to International Inspections and Travel - For paper manuals contact ORA/DFI 301-827-5653;
7. Inspection Technical Guides - No paper manuals;
8. International Cooperative Agreements Manual - No paper manuals;
9. Investigations Operations Manual (IOM) - Current edition paper manuals available by contacting Alan Gion, ORA/ORO/Division of Field Investigations at (301) 827-5649.
10. Laboratory Procedures Manual (LPM) - No paper manuals;
11. Laboratory Information Bulletins (LIB) - No paper copies
12. Regulatory Procedures Manual (RPM) - Limited number of 2002 paper manuals by contacting Office of Enforcement at 301-827-0386, Scott MacIntire;
13. Recalls and Safety Alerts - No paper copies;
14. Staff Manual Guide: No paper manuals;
15. State and Federal Cooperative Agreements: No paper copies.

1017 - FORMS AND OTHER PUBLICATIONS

The FDA on line Public Forms Catalog contains a list of FDA forms and the information necessary to order them.

Order paper copies of FDA forms from the USDA Consolidated Forms and Publications Distribution Center, Beltsville Service Center at 6351 Ammendale Road in Beltsville, MD 20705. Phone or fax orders will not be accepted. Forms may be ordered electronically. To obtain a customer number necessary to order forms electronically, or for other questions concerning FDA forms, contact:

FDA/Office of the Commissioner/Office of Information Resources Management/Division of Information Services and Policy
Elizabeth Sands, Forms Management Officer, (HFA-250)
5600 Fishers Lane, Room 16B-26

Rockville, MD 20857
(301) 827-1480
FAX (301) 594-0060
Or e-mail to esands@oc.fda.gov.

The Department of Health and Human Services (DHHS) Program Support Center, 16071 Industrial Drive, Gaithersburg, MD 20877 also maintains a limited selection of FDA forms and publications. To access the PSC forms download site, see http://forms.psc.gov/. To search their catalog, see https://propshop.psc.gov/shopping/formspubs.asp#/. For questions, contact Danny Saum at PSC at (301) 443-7634.

The INTRANET FDA's Electronic Forms Catalog is another resource. Internal forms related to field operations are located at that site. For example, you can find seals, affidavits, Form FDA 482 Notice of Inspection, and many other forms on which FDA documents its activities related to investigations, inspections and sample collection and analysis. Forms are organized alphabetically as well as by form number.

1018 - REGULATORY REFERENCES AND THE GENERAL PUBLIC

The general public must make a request under the Freedom of Information Act (FOIA) in order to obtain certain FDA documents requiring redaction. See IOM 134 (Freedom of Information Act) and IOM 135 (internal Documents) for additional information on FOIA. For instructions to the public on how to file an FOIA request, see www.fda.gov/foi/foia2.htm.

Many FDA documents are available to the public without an FOIA request. To obtain forms, direct the public to the FDA Public Use Forms web page. The public can purchase paper editions of various agency manuals, such as the Food Code and Compliance Program Manuals if ordered by NTIS item number from the National Technical Information Service (NTIS). Instruct the person seeking a publication to first locate the NTIS item number by calling the NTIS sales department at 800-553-6847. The next step is to enter the NTIS item number in the search box at the NTIS website at www.ntis.gov , and follow directions on ordering the publication. For additional information on NTIS publications, direct the public to contact:

National Technical Information Service
Technology Administration
U.S. Department of Commerce
Springfield, VA 22161
Order Desk: (703) 605-6585
Fax: (703) 605-6900

The public may also obtain federal publications from the U.S. Government Bookstore on-line or on site. See http://bookstore.gpo.gov/locations/index.html for locations of on-site U.S. government bookstores.

The public may also obtain FDA documents from the CDRH automated FAX information service listed in section 1015 of Subchapter 1010. FDA references are also available to the public in electronic format from the FDA website. From the FDA homepage, link to special information for consumers, industry, health professionals, patients, state and local officials. For example, direct industry to the FDA industry web page.

Those regulated by FDA may contact their ORA Regional Small Business Representative (SBR) for an explanation of how FDA requirements apply to specific circumstances. SBRs also locate relevant references, make referrals, conduct or participate in workshops and conferences, or make non-regulatory audits on request. See http://www.fda.gov/ora/fed_state/Small_Business/regional.htm for a list of SBRs and the regions they serve.

Direct industry inquiries in accordance with District policy either to appropriate District personnel, to the ORA Small Business Representative for your region, to an FDA industry assistance office or the Center Ombudsman, or to the Office of the Commissioner. In CDRH, the Division of Manufacturers, International and Consumer Affairs (DSMICA) staff specializes in industry assistance. For FDA drug manufacturing queries, a list of resource staff in the CDER Division of Manufacturing and Product Quality, (HFD-320) identifies each staff member by area of knowledge. Refer questions about post approval changes to the CDER post approval changes e-mail box at pac314_70@cder.fda.gov . Refer questions about good clinical practice requirements to the FDA's GCP staff .

Refer consumer inquiries to the appropriate District Public Affairs Specialist .

Try to refer appropriately to make your government work more effectively for all concerned.

1019 - ACRONYMS

To access explanations for some of the hundreds of acronyms in FDA references, try the following:

1. CDER Acronym list compiled by the CDER Division of Biometrics III
2. CVM Related Acronyms and Abbreviations
3. CFSAN Abbreviations and Acronyms from the CFSAN Risk Analysis Working Group Report "Initiation and Conduct of All Major Risk Assessments within a Risk Analysis Framework" (3/02)
4. Draft Listeria monocytogenes Risk Assessment report: Abbreviations and Acronyms
5. ORA Glossary of Computerized System and Software Development Terminology
6. Fiscal Year 2001 Performance Plan, FY 2000 Final Performance Plan, and FY 1999 Performance Report Glossary of Acronyms
   http://www.fda.gov/ope/FY01plan/glossary01.html
7. Fiscal Year 2004 Annual Performance Plan, FY2003 Revised Performance Plan, FY 2002 Annual Performance Plan see Appendix F Glossary of Acronyms at http://www.fda.gov/ope/fy04plan/2004ppmainpage.html

SUBCHAPTER 1020 - SPECIAL REGULATORY BY PRODUCT CATEGORY

1021 - FOOD AND COLOR ADDITIVES

1021.01 - Food Additives Status List

The Food Additives Status List in the IOM Appendix A is a quick look up of a number of food additives and their use limitations as specified in regulations 21CFR 170-199 and 21 CFR 570-589 promulgated under the FD&C Act, under Sections 401 (Food Standards) 409 (Food Additives) and 512 (Animal Drugs). You may encounter additives which are not in the IOM Appendix A but are still acceptable because they are:

1. Obviously safe substances although not on the list of items generally recognized as safe (GRAS), and not published in the regulations;
2. Synthetic flavoring substances because of their indefinite status;
3. Those pending administrative determination;
4. Substances granted prior sanction for specific use prior to enactment of the Food Additives Amendment;
5. Food contact substances (including secondary direct additives) that are the subject of an effective notification. For the inventory of effective notifications for food contact substances, see http://www.cfsan.fda.gov/~dms/opa-fcn.html

In addition to the IOM Appendix A, there are several FDA additive databases available on the FDA website. The FDA has published the EAFUS (Everything Added to Food in the United States) database. This list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS. Nevertheless, it contains only a partial list of all food ingredients that may in fact be lawfully added to food, because under federal law some ingredients may be added to food under a GRAS determination made independently from the FDA. The list contains many, but not all, of the substances subject to independent GRAS determinations. For information about the GRAS notification program, consult the Inventory of GRAS Notifications.

See also food additive publications available from the FDA/CFSAN/Office of Food Safety.

1021.02 - Color Additives Status List

The Color Additives Status List in Appendix A provides the current status and use limitations of most colors likely to be found in food, drug, device, or cosmetic establishments. To access Color Additives for Medical Devices (11/95), see http://www.fda.gov/cdrh/ode/575.pdf. To access the FDA Color Additives web page see http://www.cfsan.fda.gov/%7Edms/col-toc.html.

1022 - FOOD

For up to date references on food, food additive and cosmetic requirements and guidance, periodically check the Center for Food Safety and Applied Nutrition's web site. See http://vm.cfsan.fda.gov/list.html.

For food and cosmetic guidance documents, see http://www.cfsan.fda.gov/~dms/guidance.html.

1022.01 - Food - General

1. Action Levels for Poisonous or Deleterious Substances in Human Food and Animal FeedAction Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed (Revised 8/00): Lists action levels for unavoidable poisonous or deleterious substances, which are established by the FDA to control levels of contaminants in human food and animal feed.
2. Allergens: CPG 555.250 FDA Statement of Policy on Labeling and Preventing Cross-Contact of Food Allergens (4/01)
3. BSE: Guidance for Industry: The Sourcing and Processing of Gelatin to Reduce the Potential Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA Regulated Products for Human Use (9/97)
4. Botanicals: Letter to Manufacturers Regarding Botanicals and Other Novel Ingredients in Conventional Foods (1/01)
5. Defect Action Levels (Revised 5/98) - Lists levels of natural or unavoidable defects in foods that present no health hazards for humans
6. Filth in Food - Sec. 555.600 - Filth from Insects, Rodents, and Other Pests in Foods (CPG 7120.18) (12/02).
7. Food Code (Revised 2001): a compendium of model food safety guidelines for retail operations and institutions that is based on the latest science. The Food Code is used as a reference by the more than 3,000 state and local regulatory agencies that oversee food safety in restaurants, grocery stores, nursing homes, and other institutional and retail settings.
8. Fruits and Vegetables: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; (10/98)
9. Frozen Dessert Processing Guidelines (10/89) - Available from CFSAN/Office of Field Programs/ Division of Cooperative Programs/Milk Safety Branch (HFS-626), Bob Hennes at 301-436-2175.
10. Health Claims: Guidance for Industry: Qualified Health Claims in Labeling of Conventional Foods and Dietary Supplements (12/02)
11. Labeling: Food Labeling Guide (6/99 update)
12. Labeling: Food Labeling Questions and Answers Volume 1
13. Labeling: Food Labeling Questions and Answers Volume 2
14. Labeling: NLEA Small Business Exemption Criteria
15. Pesticides: Glossary of Pesticide Chemicals (10/01) lists Title 40 CFR tolerances of pesticide chemicals in food and animal feed -
16. Pesticides: Pesticide Residues in Food and Feed - Enforcement Criteria Sec. 575.100 (CPG7141.01) (Rev. 3/95)
17. Registration of Food Facilities

18. Security: Guidance for Industry — Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance (3/03)
19. Security: Guidance for Industry — Importers and Filers: Food Security Preventive Measures Guidance (3/03)
20. Security and Safety: FDA publications on CFSAN Food Safety and Security web page

1022.02 - Hazard Analysis Critical Control Points (HACCP)

1. Hazard Analysis and Critical Control Point (HACCP) Principles and Application Guidelines (8/97) See http://vm.cfsan.fda.gov/~comm/nacmcfp.html#exec-sum
2. HACCP Overview CFSAN web page http://www.cfsan.fda.gov/~comm/haccpov.html
3. Juice HACCP regulation - Questions and Answers, (8/01) See http://www.cfsan.fda.gov/~comm/juiceqa.html
4. Juice HACCP regulation - Additional Questions and Answers (9/03)
5. Juice HACCP Regulator Training (9/02) See http://www.cfsan.fda.gov/~comm/juiceman.html
6. Juice - Draft Guidance for Industry: Standardized Training Curriculum for Application of HACCP Principles to Juice Processing (6/03) See http://www.cfsan.fda.gov/~dms/juicgui5.html
7. Juice - Guidance for Industry: Bulk Transport of Juice Concentrate and Certain Shelf Stable Juices (4/03)
8. Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidances, First Edition (9/02) See http://www.cfsan.fda.gov/~dms/juicgui3.html
9. Guidance for Industry: Exemptions from the Warning Label Requirements for Juice - Recommendations for Effectively Achieving a 5-Log pathogen Reduction (updated 10/02) See http://www.cfsan.fda.gov/~dms/juicgui6.html
10. Juice HACCP Small Entity Compliance Guide (4/03)
11. Juice HACCP CFSAN web page: for additional FDA juice HACCP publications, see http://www.cfsan.fda.gov/~comm/haccpjui.html#regulation
12. Seafood HACCP Guidance Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, see http://www.cfsan.fda.gov/~comm/haccp4.html
13. Seafood HACCP Questions and Answers: HACCP Regulations for Fish and Fishery Products, See http://www.cfsan.fda.gov/~dms/qa2haccp.html
14. Seafood HACCP Transition Guidance (12/99) See http://www.cfsan.fda.gov/~comm/seaguide.html
15. Seafood HACCP Refusal of Inspection or Access to HACCP Records Pertaining to Safe and Sanitary Processing of Fish and Fishery Products Guidance (7/01) See http://www.cfsan.fda.gov/~comm/seaguid3.html
16. Seafood HACCP Domestic Seafood HACCP report, See http://www.cfsan.fda.gov/~dms/sea3501a.html
17. Seafood HACCP CFSAN web page: See http://www.cfsan.fda.gov/~comm/haccpsea.html
18. Seafood Information and Resources: CFSAN web page http://www.cfsan.fda.gov/seafood1.html#haccp

1022.03 - Bioengineered Foods

1. Center for Food Safety and Applied Nutrition, Biotechnology Home Page, See http://vm.cfsan.fda.gov/~lrd/biotechm.html
2. Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering - Draft Guidance (1/01) See http://vm.cfsan.fda.gov/~dms/biolabgu.html
3. Federal Register of 1/18/01, Premarket Notice Concerning Bioengineered Foods (1/01) See http://www.cfsan.fda.gov/~lrd/fr010118.html
4. Federal Register of 5/29/92, Statement of Policy: Foods Derived From New Plant Varieties, pp. 22984-23005 (10/00) See http://vm.cfsan.fda.gov/~lrd/bio1992.html
5. FDA's Policy for Foods Developed by Biotechnology; CFSAN Handout 1995 see http://www.cfsan.fda.gov/~lrd/biopolcy.html
6. FDA's Statement of Policy: Foods Derived from New Plant Varieties Questions & Answers 6/92 see http://vm.cfsan.fda.gov/~lrd/bioqa.html

1022.04 - Seafood

1. Seafood HACCP Guidance Fish and Fisheries Products Hazards and Controls Guidance, Third Edition (6/01) See http://www.cfsan.fda.gov/~comm/haccp4.html
2. Questions and Answers: HACCP Regulations for Fish and Fishery Products (1/99) See http://www.cfsan.fda.gov/~dms/qa2haccp.html
3. Seafood HACCP Transition Guidance (12/99) see http://www.cfsan.fda.gov/~comm/seaguide.html
4. Seafood HACCP Refusal of Inspection or Access to HACCP Records Pertaining to Safe and Sanitary Processing of Fish and Fishery Products Guidance (7/01) See http://www.cfsan.fda.gov/~comm/seaguid3.html
5. Domestic Seafood HACCP Report, Revised Instructions FDA Form 3501 (2/01) see http://www.cfsan.fda.gov/~dms/sea3501a.html
6. For more information on seafood HACCP see http://www.cfsan.fda.gov/~comm/haccpsea.html
7. Guidance Document for Trace Elements in Seafood - Arsenic, Cadmium, Chromium, Lead, Nickel (1993) see http://www.cfsan.fda.gov/~frf/guid-sf.html
8. National Shellfish Sanitation Program Model Ordinance (11/00): represents the Agency's current thinking on the safe and sanitary control of the growing, processing, and shipping of molluscan shellfish for human consumption, see http://vm.cfsan.fda.gov/~ear/nsspotoc.html
9. Interstate Certified Shellfish Shippers List, see http://vm.cfsan.fda.gov/~ear/shellfis.html
10. Seafood HACCP CFSAN web page: See http://www.cfsan.fda.gov/~comm/haccpsea.html

11. Seafood Information and Resources: CFSAN web page http://www.cfsan.fda.gov/seafood1.html#haccp

1022.05 - Food Inspection Guides

Food inspection guides are available from DFI. Also, see http://www.fda.gov/ora/inspect_ref/igs/iglist.html. They include:

1. Guidance on Inspections of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients (8/01) See http://www.fda.gov/ora/inspect_ref/igs/allergy_inspection_guide.htm
2. Food Allergen Inspection Training for Regulators (10/01) see http://www.cfsan.fda.gov/~dms/alrgtrn.html
3. Guide to Nutritional Labeling and Education Act (NLEA) Requirements (2/95) See http://www.fda.gov/ora/inspect_ref/igs/nleatxt.html
4. Guide to Inspections of Computerized Systems in the in the Food Processing Industry (3/98) See http://www.fda.gov/ora/inspect_ref/igs/foodcomp.html
5. Guide to Inspections of Grain Product Manufacturers (7/03)
6. Guide to Inspections of Interstate Carriers and Support Facilities (4/95) See http://www.fda.gov/ora/inspect_ref/igs/icsf.html
7. Guide to Inspections of Miscellaneous Food Products Volume I (5/95) See http://www.fda.gov/ora/inspect_ref/igs/foodsp.html
8. Guide to Inspections of Manufacturers of Miscellaneous Food Products, Volume II (9/96) See http://www.fda.gov/ora/inspect_ref/igs/foodsp2.html
9. Guide to Inspections of Dairy Product Manufacturers (4/95) See http://www.fda.gov/ora/inspect_ref/igs/dairy.html
10. Guide to Inspections of Acidified Food Manufacturers (5/98) See http://www.fda.gov/ora/inspect_ref/igs/acidfgde.htm
11. Guide to Inspections of Low Acid Canned Food Manufacturers, Part 1 (11/96) Administrative Procedures and Scheduled Processes See http://www.fda.gov/ora/inspect_ref/igs/lacfpt1/lacfpt101.html
12. Guide to Inspections of Low Acid Canned Food Manufacturers, Part 2 Processes and Procedures (4/97) See http://www.fda.gov/ora/inspect_ref/igs/lacfpt2/lacfpt201.html
13. Guide to Inspections of Low Acid Canned Food Manufacturers, Part 3 Containers/Closures (11/98) http://www.fda.gov/ora/inspect_ref/igs/iglist.html
14. Guide to the Inspection of Aseptic Processing and Packaging for the Food Industry (02/01), currently only available in hardcopy
15. Guide to Trace Back of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations (7/03) See http://www.fda.gov/ora/inspect_ref/igs/epigde/epigde.html

1022.06 - CFSAN Databases

1. Everything Added to Food in the United States (EAFUS) see http://www.cfsan.fda.gov/~dms/eafus.html
2. List of Indirect Additives Used in Food Contact Substances, see http://www.cfsan.fda.gov/~dms/opa-indt.html
3. Inventory of Effective Premarket Notifications for Food Contact Substances see http://www.cfsan.fda.gov/~dms/opa-fcn.html
4. Food Contact Substance Cumulative Daily Intake/ Acceptable Daily Intake database, see http://www.cfsan.fda.gov/~dms/opa-edi.html. This database cites the regulation where a food contact substance appears.
5. Summary of all GRAS notices - see http://www.cfsan.fda.gov/~rdb/opa-gras.html
6. Partial List of Enzyme Preparations Used in Food (7/01) see http://www.cfsan.fda.gov/~dms/opa-enzy.html
7. Partial List of Microbial Derived Ingredients Used in Food (7/01) see http://www.cfsan.fda.gov/~dms/opa-micr.html
8. Summary of Color Additives Used in Foods, Drugs, Cosmetics, and Medical Devices

CFSAN Office of Management Systems (HFS-676) maintains an internal database of Low Acid Canned Food/Acidified Food registered establishments and scheduled processes. To gain access and further information about this database, ORA personnel should contact Sharon Macuci ORA/ORM at 301-436-1865.

1023 - DIETARY SUPPLEMENTS

To access the FDA's dietary supplement web site, see http://www.cfsan.fda.gov/~dms/supplmnt.html. References there include:

1. Dietary Supplement Health and Education Act of 1994 (12/95) synopsis
2. Dietary Supplement Overview of Dietary Supplements (4/99)
3. Ingredients: Premarket Notification for a New Dietary Ingredient (Federal Register, 9/23/97)
4. Ingredients: New Ingredients - Explanation including: definition, notification process, and table of notifications received (2/01)
5. Labeling Guidance for Industry: Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements (1/99)
6. Labeling Defining Structure/Function Claims That Can Be Used for Dietary Supplements, final Rule: Final Rule: Statements Made for Dietary Supplements Concerning the Effect of a Product on the Structure or Function of the Body (Federal Register, 01/06/2000)
7. Labeling Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements and Interim Evidence-based Ranking System for Scientific Data (7/03)

8. Labeling Guidance for Industry - Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements (1/99)
9. Labeling Guidance for Industry: Iron Containing Supplements and Drugs: Label Warning Statements (10/03)
10. Labeling Requirements to Use the Nutrient Content Claims "High Potency" and "Antioxidants". Final Rule: Food Labeling; Nutrient Content Claims: Definition for "High Potency" and Definition of "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods (Federal Register 9/23/97)
11. Labeling Letter Regarding Dietary Supplement Health Claim for Antioxidant Vitamins and Risk of Certain Cancers (4/03)
12. Consolidated Information on Ephedrine Alkaloids

1024 - COSMETICS

1024.01 - Cosmetic References

For FDA's Cosmetic web site see http://www.cfsan.fda.gov/~dms/cos-toc.html. Specific cosmetic references include:

1. Cosmetics Handbook (1992): FDA requirements and policies for safe production and accurate labeling of cosmetics
2. Cosmetic Good Manufacturing Practice Guidelines
3. FDA's Cosmetic Labeling Manual (10/91): Contains information on FDA's requirements and policies for safe production and accurate labeling of cosmetics.
4. Information Materials for the Food and Cosmetics Industries: A catalogue of cosmetic publications
5. Memorandum of Understanding (MOU) (6/03): Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Food Safety and Applied Nutrition to Assist FDA in Implementing the Drug and Cosmetic Provision of the Federal Food, Drug and Cosmetic Act for Products that Purport to be Cosmetics But Meet the Statutory Definition of a Drug
6. Microbiological Methods for Cosmetics (from FDA's Bacteriological Analytical Manual 8/01)

1024.02 - Cosmetic Inspection Guides

1. Cosmetic Guide to Inspections of Cosmetic Product Manufacturers (2/95) See http://www.fda.gov/ora/inspect_ref/igs/cosmet.html

1025 - DEVICES

1025.01 - CDRH Regulatory References

The Center for Devices and Radiological Health (CDRH), Division of Small Manufacturers Assistance (DSMA) (HFZ-220) maintains Fax Back, a fax on demand system to provide medial device related FDA references. The telephone numbers to access this system are (800) 899-0381 or (301) 827-0111. For up-to-date medical device references, see http://www.fda.gov/cdrh/index.html. See www.fda.gov/ora, the ORA home page for up-to-date medical device publications and guidance materials. For an alphabetized index of CDRH references, including product specific references, see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/topicindex/topindx.cfm. One selection in the index is a list of Good Guidance Practices Documents, organized by issuing CDRH Office/Division/Branch.

References available from the CDRH fax information system or the CDRH web site include:

1. 510(k): 510(k) Manual Premarket Notification Regulatory Requirements for Medical Devices (8/95)
2. 510(k): Deciding When to Submit a 510(k) for a Change to an Existing Device (1/97)
3. 510(k) Sterility Review Guidance K90-1 Final Guidance for Industry and FDA (8/02)
4. 510(k): Medical Device Exemptions 510(k) and GMP Requirements (11/00)
5. 510(k): Guidance or the Content of Premarket Submissions for Software Contained in Medical Devices (5/29/98)
6. Classification of Medical Devices: FDA Classification of Medical Devices
7. Classification of Medical Devices: Medical Device Product Code Classification Database
8. Consensus Standards: Guidance on the Recognition and Use of Consensus Standards (6/01)
9. Design: Design Control Guidance for Medical Device Manufacturers (3/97)
10. Design: Do it By Design an Introduction to Human Factors in Medical Devices See http://www.fda.gov/cdrh/humfac/doit.html (9/93)
11. Design: Device Use Safety: Incorporating Human Factors in Risk Management (7/00) See http://www.fda.gov/cdrh/humfac/1497.html
12. Design: New Model Medical Device Development Process (7/98)
13. Import Alerts on Medical Devices
14. IVD: Guideline for the Manufacture of In Vitro Diagnostic Products (1/94)
15. Labeling: Regulatory Requirements for Medical Device Manufacturers (8/89)
16. Labeling: Guidance for Industry: Alternative to Certain Prescription Device Labeling Requirements (1/00)
17. Labeling: Human Factors Principles for Medical Device Labeling (9/93)
18. MDR: Medical Device Reporting for Manufacturers (amended 3/00)
19. MDR: Medical Device Reporting for User Facilities (4/96)
20. MDR: Medical Device Reporting Forms and Instructions
21. MDR: Medical Device Reporting Alternative Summary Reporting (ASR) Program (10/00)
22. MDR: User Facility Reporting Bulletins
23. PMA: Premarket Approval Process
24. Quality Systems: Medical Device Medical Device Quality Systems Manual: A Small Entity Compliance Guide First Edition

25. Quality Systems: The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices". compiled by FDA/CDRH' Kimberly Trautman. The book offers guidance on the medical device QS/GMPs and shows their relationship to ISO 9001.
26. Registration: Guidance for Industry: Instructions for Completion of Medical Device Registration and Listing Forms 2891, 2891a and 2892
27. Registration and Listing: FOIA Releasable Registration and Listing Files
28. Re-use of Single Use: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (8/00) and Appendix A updates (4/03)
28. Software: Final Guidance for Industry and FDA: General Principles of Software Validation (1/02)
30. Software: Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices (9/99)
31. Tracking: Guidance for Industry and FDA Staff on Medical Device Tracking (1/00)

1025.02 - Device Inspection Guides

Inspection guides covering medical devices are available from DFI (HFC-130) at 301-827-5653. Also see http://www.fda.gov/ora/inspect_ref/igs/iglist.html for guides to inspections of medical devices such as:

1. Guide to Inspections of Medical Device Manufacturers(12/97). See http://www.fda.gov/ora/inspect_ref/igs/med_dev_mnfct/toc.html
2. Guide to Inspections of Quality Systems (8/99) See http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm
3. Guide to Inspections of Foreign Medical Device Manufacturers (9/95) See http://www.fda.gov/ora/inspect_ref/igs/fordev.html
4. Guide to Inspections of Electromagnetic Compatibility Aspects of Medical Device Quality Systems (12/97) See http://www.fda.gov/ora/inspect_ref/igs/elec_med_dev/emc1.html
5. Mammography Quality Standards Act (MQSA) Auditor's Guide (1/98) See http://www.fda.gov/ora/inspect_ref/igs/mqsa.html
6. Guide to Bioresearch Monitoring Inspections of In Vitro Diagnostic Devices (3/98) See http://www.fda.gov/ora/inspect_ref/igs/bimoivd.html
7. Glossary of Computerized System and Software Development Terminology (8/95) See http://www.fda.gov/ora/inspect_ref/igs/gloss.html

1025.03 - CDRH Databases

For a list of and links to CDRH public access databases, see http://www.fda.gov/cdrh/databases.html. They include a searchable database of CDRH guidance documents, a listing of medical devices in commercial distribution, a database of registered firms, a listing of FDA - recognized consensus standards, and a product classification database. To access the CDRH public database of medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1997, see http://www.fda.gov/cdrh/mdrfile.html. The web site also contains a public database of the Device Experience Database (MAUDE) for a reports of adverse events involving medical devices since June 1993. To access the FDA internal registration and listing 510(k), PMA, MDR and Maude databases through the CDRH Information Retrieval System (CIRS) you must acquire an individual account by contacting your District CIRS liaison. See the ORA Field Program Monitors listing in the Chapter 2 of the IOM to locate your District CIRS liaison. To access the CDRH internal M204 data system on radiation-emitting electronic products, request the District computer liaison to contact the CDRH Office of Compliance for an account and instructions.

1026 - BIOLOGICS

1026.01 - CBER Regulatory References

A current listing of the Center for Biologics Evaluation and Research (CBER) regulatory references is available through CBER's web site.

For the topic index of CBER references, see http://www.fda.gov/cber/cberac.htm. For an index sorted by type of CBER publication, see http://www.fda.gov/cber/publications.htm. These references include:

1. IND Exemptions: Guidance for Industry: IND Exemptions for Studies of Drug or Biological Products for Treatment of Cancer (9/03)
2. Bioengineered Plants: Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals (9/02) see http://www.fda.gov/cber/gdlns/bioplant.htm
3. Container Closure Systems: Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics-Chemistry Manufacturing Controls Documentation (7/99) see http://www.fda.gov/cber/gdlns/cntanr.htm
4. Human Tissue: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt Jakob Disease (CJD) and Variant Creutzfeld-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)(6/02) see http://www.fda.gov/cber/gdlns/cjdvcjd0602.htm
5. Human Tissue: Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation (3/02) see http://www.fda.gov/cber/gdlns/tissval.htm
6. Postmarket Adverse Experiences: Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products including Vaccines March 2001 See http://www.fda.gov/cder/guidance/4177dft.pdf
7. Sterile Products: Draft Guidance for Industry Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Process (8/03)

1026.02 - Blood and Blood Products Inspection

Guides and Industry Guidance

For a complete list of inspectional guides available from DFI, see http://www.fda.gov/ora/inspect_ref/igs/iglist.html. Blood and blood products inspection guides are:

1. Blood Bank Inspections (9/94) - See http://www.fda.gov/ora/inspect_ref/igs/blood.html
2. Source Plasma Establishments (4/01) - See http://www.fda.gov/ora/inspect_ref/igs/Source_Plasma/default.htm
3. Infectious Disease Marker Testing Facilities (10/96) See http://www.fda.gov/ora/inspect_ref/igs/infdis.html

CBER has mailed many guidance documents relative to Blood Banks directly to Blood Establishments. These guidance documents are listed in the Compliance Program Guidance Manual, Inspection of Licensed and Unlicensed Blood Banks. Also, to access these on the CBER Blood web page. They include:

1. Blood Components: Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components (10/02) See http://www.fda.gov/cber/gdlns/circbld.htm
2. Blood Components: Draft Guidance for Industry: A Modified Lot-Release Specification for Hepatitis B Surface Antigen (HBSAg) Assays Used to Test Blood, Blood Components, and Source Plasma Donations (4/02) see http://www.fda.gov/cber/gdlns/hbslotrel.htm
3. Donors: Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients (12/02) See http://www.fda.gov/cber/gdlns/smpoxdefquar.htm#
4. Donors: Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection (5/03)
5. Donors: Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires (7/03)
6. Donors: Draft Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples of Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV (3/02) see http://www.fda.gov/cber/gdlns/hivhcvnatbld.htm
7. Donors: Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Produce Recipients and Their Contacts (12/99) see http://www.fda.gov/cber/gdlns/zooxeno.htm

1026.03 - Other Biologics Inspection Guides

1. Guide to Inspections of Viral Clearance Processes for Plasma Derivatives (3/98) See http://www.fda.gov/ora/inspect_ref/igs/viralcl.html
2. Biotechnology Inspection Guide (11/91) See http://www.fda.gov/ora/inspect_ref/igs/biotech.html

1026.04 - CBER Databases

Vaccine Adverse Event Report System (VAERS): a public access database of adverse events that occur after the administration of US licensed vaccines. Reports are received from: patients, parents, health care providers, pharmacists, and vaccine manufacturers

The Adverse Event Reporting System (AERS): a public access database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The FDA receives adverse drug reaction reports from manufacturers as required by regulation. Health care professionals and consumers send reports voluntarily through the MedWatch program

1027 - DRUGS

1027.01 - CDER Regulatory References

CDER regulatory references including a complete list of CDER Guidance Documents are available on the CDER Regulatory Guidance web site, see http://www.fda.gov/cder/regulatory/default.htm and from the Drug Information Branch at 301-827-4573. Go to International Conference on Harmonization (ICH) web site to learn more about quality references under development by the U.S., European Union (EU) and Japan.

1. Botanical Drug Products: Guidance for Industry: Botanical Drug Products (Draft 8/00) See http://www.fda.gov/cder/guidance/1221dft.htm
2. Computerized Systems Used in Clinical Trials (4/99) See http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.PDF
3. Container Closure Systems for Packaging Human Drugs and Biologics (5/99) See http://www.fda.gov/cder/guidance/1714fnl.htm
4. Dioxin: Possible Contamination of Drugs and Biological Products - Guidance for Industry (8/99) See http://www.fda.gov/cder/guidance/3310fnl.pdf
5. Drug Master Files Guideline (9/89) See http://www.fda.gov/cder/guidance/dmf.htm
6. Drug Master Files for Bulk Antibiotic Drug Substances Guidance (11/99) See http://www.fda.gov/cder/guidance/3276fnl.pdf
7. Expiration Dating of Solid Oral Dosage Forms Containing Iron (6/97) See http://www.fda.gov/cder/guidance/1807fn1.pdf
8. Gelatin: Guidance for Industry: The Sourcing and Processing of Gelatin to Reduce the Risk Posed by Bovine Spongiform Encephalopathy (BSE) in FDA regulated Products for Human Use (9/97)
9. ICH Q1A Stability Testing of New Drug Substances and Products Rev. 1 (8/01) See http://www.fda.gov/OHRMS/DOCKETS/98fr/930139gd.pdf
10. ICH Q1D Guidance for Industry: Bracketing and

Matrixing Designs for Stability Testing of New Drug Substances and Products (1/03) See http://www.fda.gov/cder/guidance/4985fnl.pdf

11. ICH Q1E Draft Consensus Guideline - Evaluation of Stability Data, see http://www.fda.gov/OHRMS/DOCKETS/98fr/02d-0237-gdl0001-vol1.pdf
12. ICH Q1F Draft Consensus Guideline - Stability Data for Registration in Climactic Zones 3 and 4, (2/02) see http://www.ich.org/pdfICH/Q1Fstep2.pdf
13. ICH Q3AR Final Guidance on Impurities in New Drug Substances (2/03) Published in the Federal Register, Vol, 68, No. 68, Tuesday February 11, 2003; p. 6924-6925
14. ICH Q3BR: Impurities in New Drug Products (Revised Guideline) (2/03)
15. ICH Q3C Guidance for Industry on Impurities: Residual Solvents (12/97) or see FR Vol. 62, NO. 247, December 24, 1997, page 67377, http://www.fda.gov/cder/guidance/Q3Cfinal.htm
16. ICH Q5A Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin in FR Vol. 63, No. 185, 9/24/98 see http://www.fda.gov/ohrms/dockets/98fr/092498c.txt
17. ICH Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances, in FR Vol. 65, No. 251 on 12/29/00, see http://www.fda.gov/OHRMS/DOCKETS/98fr/122900d.htm
18. ICH Q6B Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products in FR Vol. 64 No. 159 on 8/18/99, see http://www.fda.gov/OHRMS/DOCKETS/98fr/081899a.txt
19. ICH Q7A Guidance for Industry: Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (8/01) See http://www.fda.gov/cder/guidance/4286fnl.htm
20. Inhalation Drug Products: Guidance for Industry: Nasal Spray and Inhalation, Solution, Suspension and Spray Drug Products Chemistry, Manufacturing and Controls Documentation (7/02)
21. Medical Gases Guideline (2/89) See http://www.fda.gov/cder/guidance/cmgg89.htm
22. Medical Gas: Fresh Air 2000, A Look at FDA's Medical Gas Requirements, see http://www.fda.gov/cder/dmpq/freshair.htm
23. Medical Gas Mix-Ups: Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities: FDA Public Health Advisory (3/01)
24. Orange Book: Approved Drug Products with Therapeutic Equivalents See http://www.fda.gov/cder/ob/default.htm
25. Out of Specification Test Results: Guidance for Industry: Investigation of Out of Specification Test Results for Pharmaceutical Production (Draft 9/98) See http://www.fda.gov/cder/guidance/1212dft.pdf
26. Post-approval Changes: Guidance for Industry: Changes to an Approved NDA or ANDA (11/99) See http://www.fda.gov/cder/guidance/2766fnl.pdf
27. Post-approval Changes: Guidance for Industry: Bulk Actives Post-approval Changes: BACPAC I Intermediates in Drug Substance Synthesis: Chemistry, Manufacturing, Controls and Documentation (2/01)
28. Post-approval Changes: Guidance for Industry: SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post Approval Changes: Chemistry, Manufacturing Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation (11/95) See http://www.fda.gov/cder/guidance/cmc5.pdf
29. Post-approval Changes: Guidance for Industry: SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalency Documentation (9/97) See http://www.fda.gov/cder/guidance/1214fnl.pdf
30. Post-approval Changes: Guidance for Industry: SUPAC-IR/MR Immediate Release and Modified Release Solid Oral Dosage Forms Manufacturing Equipment Addendum (1/99) See http://www.fda.gov/cder/guidance/1721fnl.pdf
31. Post-approval Changes: Guidance for Industry: SUPAC-IR: Questions and Answers about SUPAC-IR Guidance (2/97) See http://www.fda.gov/cder/guidance/qaletter.htm
32. Post-approval Changes: Guidance for Industry: SUPAC-SS: Nonsterile Semisolid Dosage Forms: Scale-UP and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation (5/97) see http://www.fda.gov/cder/guidance/1447fnl.pdf
33. Post-approval Changes: Guidance for Industry: SUPAC-SS Manufacturing Equipment Addendum (Draft 12/98) See http://www.fda.gov/cder/guidance/1722dft.pdf
34. Postmarket Adverse Experiences: Guideline for Postmarketing Reporting of Adverse Drug Experiences [Docket No. 85D-0249] March 1992 See http://www.fda.gov/medwatch/safety/ade/t_cder.htm
35. Postmarket Adverse Experiences: Guidance for Industry: Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products - Clarification of What to Report August 1997 See http://www.fda.gov/medwatch/report/guide2.htm
36. Postmarket Adverse Experiences: Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products including Vaccines March 2001 See http://www.fda.gov/cder/guidance/4177dft.pdf
37. Sterile Drug Products Produced by Aseptic Processing: Current Good Manufacturing Practice Draft Guidance (8/03)
38. Sterile Drug Products: Guideline on Sterile Drug Products Produced by Aseptic Processing (6/87, reprinted 6/91)
39. Validation: Guideline on the Preparation of Investigational New Drug Products (Human and Animal) (3/91) see www.fda.gov/cder/guidance/old042fn.pdf

40. Validation: Guideline on General Principles of Process Validation (5/87) See http://www.fda.gov/cder/guidance/pv.htm
41. Validation: Compliance Policy Guide 7132c.08 (8/93) Process Validation Requirements for Drugs Subject to Premarket Approval See http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg490-100.html
42. Validation: Guidance for Industry: Submission Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products (11/94) see http://www.fda.gov/cder/guidance/cmc2.pdf
43. Validation: Guideline on Validation of the Limulus Amebocyte Lysate Test as an End Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices (12/87) See http://www.fda.gov/cder/guidance/old005fn.pdf
44. Validation: Guidance for Industry: Analytical Procedures and Methods Validation Chemistry, Manufacturing, and Controls Documentation (Draft 8/00) See http://www.fda.gov/cder/guidance/2396dft.htm
45. Validation: Final Guidance for Industry and FDA: General Principles of Software Validation (1/02) See http://www.fda.gov/cdrh/comp/guidance/938.html

1027.02 - Human Drug Inspection Guides

Inspectional guides covering human and animal drug manufacturing and testing that are available from DFI. See www.fda.gov/ora, Inspectional References, include:

1. Guide to Inspection of Computerized Systems in Drug Processing (2/83) See http://www.fda.gov/ora/inspect_ref/igs/csd.html
2. Glossary of Computerized System and Software Development Terminology See http://www.fda.gov/ora/inspect_ref/igs/gloss.html
3. Guide to Inspections of High Purity Water Systems (7/93) See http://www.fda.gov/ora/inspect_ref/igs/high.html
4. Guide to Inspections of Lyophilization of Parenterals (7/93) See http://www.fda.gov/ora/inspect_ref/igs/lyophi.html
5. Guide to Inspections of Microbiological Pharmaceutical Quality Control Laboratories (7/93) See http://www.fda.gov/ora/inspect_ref/igs/micro.html
6. Guide to Inspections of Pharmaceutical Quality Control Laboratories (7/93) See http://www.fda.gov/ora/inspect_ref/igs/pharm.html
7. Guide to Inspections of Validation of Cleaning Processes (7/93) See http://www.fda.gov/ora/inspect_ref/igs/valid.html
8. Guide to Inspections of Dosage Form Drug Manufacturers - CGMP's (10/93) See http://www.fda.gov/ora/inspect_ref/igs/dose.html
9. Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval Issues for Development and Validation (1/94) See http://www.fda.gov/ora/inspect_ref/igs/solid.html
10. Guide to Inspections of Sterile Drug Substance Manufacturers (7/94) See http://www.fda.gov/ora/inspect_ref/igs/subst.html
11. Guide to Inspections of Topical Drug Products (7/94) See http://www.fda.gov/ora/inspect_ref/igs/topic.html
12. Guide to Inspections of Oral Solutions and Suspensions (8/94) See http://www.fda.gov/ora/inspect_ref/igs/oral.html
13. Guide to Inspections of Foreign Pharmaceutical Manufacturers (5/96) See http://www.fda.gov/ora/inspect_ref/igs/fordrug.html
14. Guide to Inspections of Bulk Pharmaceutical Chemicals (9/91) See http://www.fda.gov/ora/inspect_ref/igs/bulk.html
15. Biotechnology Inspection Guide (11/91) See http://www.fda.gov/ora/inspect_ref/igs/biotech.html
16. Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations See http://www.fda.gov/cder/aers/chapter53.htm

1027.03 - Veterinary Regulatory References

The Center for Veterinary Medicine (CVM) regulatory and informational references are available on the CVM website. See http://www.fda.gov/cvm/default.htm CVM web site references include guidance documents - See http://www.fda.gov/cvm/guidance/published.htm#documents, and Compliance Policy Guides (CPGs) as well as an index of topics. Copies of regulatory references may also be obtained from the CVM's Communications Staff (HFV-12), MPN IV, 7519 Standish Place, Rockville, MD 20855, or by calling (301) 827-3800. CVM references include:

1. Drug Stability Guideline No.5: (4th Revision 12/90) See http://www.fda.gov/cvm/guidance/guide5part1.html
2. Guideline No. 23: Medicated Free Choice Feeds: Manufacturing Controls (7/85) See http://www.fda.gov/cvm/guidance/guide23.html
3. CPG Sec. 608.400 (7125.40) Compounding of Drugs for use in Animals, See http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg608-400.html
4. Animal Drug Manufacturing Guidelines No. 42 A series of 4 guidelines revised 1994) See http://www.fda.gov/cvm/guidance/admguidelinetoc.html
5. Guidance for Industry No. 48: Submission of Documentation for Sterilization Process Validation in Applications for Human and Veterinary Drug Products (11/94)
6. Guidance for Industry No. 57: Preparation and Submission of Veterinary Master Files (1/95) see http://www.fda.gov/cvm/guidance/guide57.html
7. Guidance for Industry No. 64: Validation of Analytical Procedures: Methodology (7/99) See http://www.fda.gov/cvm/guidance/guida64.doc
8. Guidance for Industry No. 67: Small Entities Compliance Guide for Renderers (2/98) See http://www.fda.gov/cvm/guidance/guidance67.pdf
9. Guidance for Industry No. 68: Small Entity Compliance Guide for Protein Blenders, Feed Manufacturers and Distributors (2/98) See http://www.fda.gov/cvm/guidance/guidance68.pdf

10. Guidance for Industry No. 69: Small Entities Compliance Guide No. for Feeders of Ruminant Animals With On-Farm Feed Mixing Operations (2/98) See http://www.fda.gov/cvm/guidance/guidance69.pdf
11. Guidance for Industry No. 70: Small Entity Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations (2/98) See http://www.fda.gov/cvm/guidance/guidance70.pdf
12. Guidance for Industry No. 72: GMPs for Medicated Feed Manufacturers Not Required to Register and be Licensed with FDA (5/98) See http://www.fda.gov/cvm/guidance/guideline72.html
13. CPG Sec. 689.100 (7126.41) Direct Fed Microbial Products See http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg689-100.html
14. Guidance for Industry No. 73: Stability Testing of New Veterinary Drug Substances and Medicinal Products" VICH GL3 (9/99) See http://www.fda.gov/cvm/guidance/guide73.doc
15. Guidance for Industry No. 74: Stability Testing of New Veterinary Dosage Forms VICH GL4 (9/99) See http://www.fda.gov/cvm/guidance/guide74.doc
16. Guidance for Industry No. 75: Stability Testing: Photostability Testing of New Veterinary Drug Substances and Medicinal Products VICH GL5 (9/99) See http://www.fda.gov/cvm/guidance/guide75.doc
17. Guidance for Industry No. 76: Questions and Answers BSE Feed Regulations (7/98) See http://www.fda.gov/cvm/guidance/guida76.htm
18. Guidance for Industry No. 83: Chemistry, Manufacturing and Controls Changes to an Approved NADA or ANADA: Draft Guidance (6/99) See http://www.fda.gov/cvm/guidance/dguide83.pdf
19. Guidance for Industry No. 85: Good Clinical Practices (VICH GL9) (5/01) See http://www.fda.gov/cvm/guidance/guide85.doc
20. Guidance for Industry No. 91: Stability Testing for Medicated Premixes (VICH GL8) (3/00) See http://www.fda.gov/cvm/guidance/fguide91.doc
21. Guidance for Industry No. 92: Impurities In New Veterinary Drug Substances (7/99) See http://www.fda.gov/cvm/guidance/fguide92.doc
22. Guidance for Industry No. 93: Impurities In New Veterinary Medical Products (7/99) See http://www.fda.gov/cvm/guidance/fguide93.doc
23. Guidance for Industry No. 99: Stability Testing Of Biotechnological/Biological Veterinary Medicinal Products VICH GL17: (3/01) See http://www.fda.gov/cvm/guidance/fguide99.doc
24. Guidance for Industry No. 100: Impurities: Residual Solvents in New Veterinary Medicinal Products VICH GL18: (5/01) See http://www.fda.gov/cvm/guidance/guide100.doc
25. CPG Sec. 689.100 (7126.41) Direct Fed Microbial Products See http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg689-100.html
26. Guidance for Industry No. 105: Computerized Systems Used in Clinical Trials (4/99) See http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.htm
27. Guidance for Industry No. 120: Veterinary Feed Directive Regulation (3/01) See http://www.fda.gov/cvm/guidance/guide120.doc
28. Guidance for Industry No. 126: BACPAC I: Intermediates in Drug Substance Synthesis Bulk Actives Post approval Changes: Chemistry, Manufacturing, and Controls Documentation (2/01) See http://www.fda.gov/cder/guidance/3629fnl.htm
29. Guidance for Industry No. 158: Use of Material from Deer and Elk in Animal Feed | doc | | pdf | (9/03)

Refer to these documents for additional guidance applicable to veterinary drug manufacture:

1. Guideline on General Principles of Process Validation (5/87) See http://www.fda.gov/cder/guidance/pv.htm
2. Guideline on Sterile Drug Products Produced by Aseptic Processing (reprinted 6/91) See http://www.fda.gov/cder/guidance/old027fn.pdf
3. Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice [HTML] [PDF] [Word] (9/03)
4. Compliance Policy Guide 7132c.08 (8/93) Process Validation Requirements for Drugs Subject to Premarket Approval See http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg490-100.html

1027.04 - Veterinary Drug Inspection Guides

Drug Inspection Guides listed in IOM subchapter 1027.02 apply to inspections of both human and veterinary drugs with regard to application of 21 CFR 211 Current Good Manufacturing Practice for Finished Pharmaceuticals.

1027.05 - CDER and CVM Databases

1. CDER public access drug firm annual registration status: see www.fda.gov/cder/dfars/default.htm
2. CDER public access National Drug Code Query (NDCQ) System: The NDCQ contains human drug products that have completed the listing process in accordance with the applicable federal law. The information is as reported by the listing firm. See http://www.fda.gov/cder/ndc/database/Default.htm
3. The Adverse Event Reporting System (AERS) is a public access database designed to support the FDA's post-marketing safety surveillance program for all approved drug and therapeutic biologic products. The FDA receives adverse drug reaction reports from manufacturers as required by regulation. Health care professionals and consumers send reports voluntarily through the MedWatch program.
4. Orange Book - public access database provides searches for approved human drug products by proprietary name, active ingredient, applicant holder, or application number. See www.fda.gov/cder/ob/default.htm
5. Green Book - public access database provides search

for approved animal drug products by application number, sponsor. See http://www.fda.gov/cvm/greenbook/greenbook.html

6. Inactive Ingredient Database - searchable database of inactive drug ingredient sin FDA-approved drug products, see http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm

1028 - BIORESEARCH MONITORING PROGRAM

1028.01 - Bioresearch Monitoring Regulatory References

See The FDA Good Clinical Practice in FDA Regulated Clinical Trials web page and the ORA Bioresearch Monitoring web page to access FDA bioresearch monitoring regulations and guidance, proposed regulations, draft guidance, policy and procedures including:

1. Application Integrity Policy Information
2. Bioresearch related Compliance Policy Guides
3. Clinical Investigators and IRBs: FDA Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators (1998)
4. Clinical Investigators and IRBs: Dear Colleague Letter on 1998 update of FDA Information Sheets (2/99)
5. Human Cloning: FDA Letter to Institutional Review Boards on Human Cloning (10/26/98)
6. Clinical Investigators: Disqualified/Restricted/ Assurances List for Clinical Investigators
7. Computerized Systems: Guidance for Industry: Computerized Systems Used in Clinical Trials (4/99)
8. Debarment: List of Debarred Individuals
9. Good Laboratory Practice: Guidance for Industry Good Laboratory Practice Regulations Management Briefings Post Conference Report (8/79 - updated 11/98)
10. Nonclinical Laboratories Inspected under the GLP Regulations since FY 1990
11. Good Laboratory Practice: Guidance for Industry: Good Laboratory Practices Questions and Answers (6/81)
12. Good Laboratory Practice Program (Nonclinical Laboratories) Compliance Program 7348.808
13. Good Laboratory Practice Program (EPA Data Audit Inspections) Compliance Program 7348.808A
14. Good Laboratory Practice (GLP), Proposed Rule, 11/19/1976
15. Good Laboratory Practice (GLP) Final Rule, 12/22/1978
16. Good Laboratory Practice (GLP), Proposed Rule, 10/29/1984
17. Good Laboratory Practice (GLP), Amendment, Final Rule, 9/4/1987
18. HIPAA (Health Insurance Portability and Accountability Act of 1996)authorizations: Guidance for Industry: IRB Review of Stand Alone HIPAA Authorizations Under FDA Regulations (10/03)
19. ICH E6: Good Clinical Practice (4/96) Guidance for Industry
20. ICH E8: Guidance on General Considerations for Clinical Trials published in FR Vol. 62 No. 42 12/17/97
21. Informed Consent: Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research, (3/00)
22. Monitoring Clinical Investigations: Guidance for Industry: Guideline for the Monitoring of Clinical Investigations (1/88 - updated 11/98)
23. Veterinary Clinical Trials: Guidance for Industry No. 58: Good Target Animal Study Practices: Clinical Investigators and Monitors (5/97)
24. Veterinary Clinical Trials: Guidance for Industry No. 85: VICH GL9 (5/01) Good Clinical Practice

1028.02 - Bioresearch Inspection Guides

1. Techniques for Detecting False Data During Bioresearch Monitoring Inspections (1/03) is available from DFI (HFC-130) at 301-827-5653.

1029 - MISCELLANEOUS

1029.01 - Computer References

1. Clinical Trials: Guidance for Industry: Computerized Systems Used in Clinical Trials (4/99) See http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.htm
2. Consensus Standard: Recognized Consensus Standard - Software Lifecycle Processes, see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=233
3. Drug Manufacturing: Compliance Policy Guide Section 425. 100 (7132a.17) Computerized Drug Processing: CGMP Applicability to Hardware and Software (9/87) See http://www.fda.gov/ora/compliance_ref/cpg/cpg-drg/cpg425-100.html
4. Drug Manufacturing: Compliance Policy Guide Section 425. 200 (7132a.12) Computerized Drug Processing: Vendor Responsibility (9/87) See http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg425-200.html
5. Drug Manufacturing: Compliance Policy Guide Section 425. 300 (7132a.15) Computerized Drug Processing: Source Code for Process Control Application Programs (4/87) See http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg425-300.html
6. Drug Manufacturing: Compliance Policy Guide Section 425. 400 (7132a.07) Computerized Drug Processing; Input/Output Checking (9/87) See http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg425-400.html
7. Drug Manufacturing: Compliance Policy Guide Section 425.500 (7132.08) Computerized Drug Processing: Identification of Persons on Batch Production and Control Records (9/87) See http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg425-500.html
8. Electronic Records: Guidance for Industry, Part 11,

Electronic Records; Electronic Signatures - Scope and Application (8/03)

9. FDA Draft Policy for the Regulation of Computer Products (11/89) See http://www.fda.gov/cdrh/ode/351.pdf
10. Glossary of Computerized System and Software Development Terminology (8/95) See http://www.fda.gov/ora/inspect_ref/igs/gloss.html
11. Medical Device: 510(k)s, PMAs: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (5/98) See http://www.fda.gov/cdrh/ode/57.html
12. Medical Device: Computer-Controlled Potentially High-Risk Medical Devices - List of Device Types (8/99) See http://www.fda.gov/cdrh/yr2000/cdrh/phrds/phrds.html
13. Medical Device: Guidance for Industry, FDA Reviewers and Compliance: Off-the-Shelf Software Use in Medical Devices (9/99) See http://www.fda.gov/cdrh/ode/guidance/585.html
14. Validation: Final Guidance for Industry and FDA: General Principles of Software Validation (1/02) See http://www.fda.gov/cdrh/comp/guidance/938.html

For a compilation of FDA regulatory and informational references on 21CFR Part 11 Electronic Records; Electronic Signatures, see http://www.fda.gov/ora/compliance_ref/part11.

1029.02 - Computer Inspection Guides

Guide to Inspections of Computerized Systems in Drug Processing (2/83) See http://www.fda.gov/ora/inspect_ref/igs/csd.html

Guide to Inspections of Computerized Systems in the Food Processing Industry (3/98) See http://www.fda.gov/ora/inspect_ref/igs/foodcomp.html

Guidance for FDA Investigators: Application of Medical Device GMPs to Computerized Devices and Manufacturing Processes (5/92) See http://www.fda.gov/cdrh/comp/guidance/247.pdf

1029.03 - Combination Products

The Medical Device User Fee and Modernization Act of 2002 directed FDA to establish the Office of Combination Products (OCP) to better regulate those products which do not fall neatly into only one of the drug, device, biologic or food categories. For example, a product may be both a device and a drug, such as a bone cement containing an antimicrobial agent. The OCP assigns review responsibility for combination products, in accordance with section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(g)(l)). The agency is required to assign premarket review responsibility for combination products based on the product's "primary mode of action." For information on how FDA determines product jurisdiction and regulates combination products through intercenter agreements, visit the OCP website and read intercenter agreements between (CBER-CDRH), (CDRH-CDER), (CBER-CDER) and (CFSAN-CDER).

1029.04 - Health Fraud References

To access the FDA CFSAN website on health fraud, see http://www.cfsan.fda.gov/~dms/wh-fraud.html.

To obtain Health Fraud Bulletins in the following list, contact your district health fraud monitor listed in the IOM blue pages:

1. Request for Limited Inspection Re: Homeopathic Products (Drug Study Bulletin #l - 10/26/84)
2. Removal of Caffeine and Phenylpropanolamine Combination Products from the OTC Market (Drug Study Bulletin #2 - 11/9/84)
3. Homeopathic Drugs (Drugs & Biologics Fraud Bulletin #3 - 12/11/84)
4. Class Action Cholecystokinin (CCK) (Drugs & Biologics Fraud Bulletin #4 - 2/22/85)
5. Implementation of class action to issue Regulatory Letters to all firms marketing DHEA (Drugs & Biologics Fraud Bulletin #5 - 3/28/85)
6. OTC products on the market offered for Oral Chelation Therapy (Drugs & Biologics Fraud Bulletin #6 - 7/1/85)
7. Marine Lipids (Health Fraud Bulletin #7 - 3/25/88 revision)
8. Products containing Nonoxynol-9 which claim to prevent AIDS - request for investigation and recommendations (Drugs & Biologics Fraud Bulletin #8 - 8/30/85)
9. "Colostrum" Products (Health Fraud Bulletin #9 - 1/15/87)
10. Fraudulent AIDS Products (Health Fraud Bulletin #10 - 7/15/87)
11. Immune System Products (Health Fraud Bulletin #11 - 8/17/87)
12. Beta-Carotene for Cancer (Health Fraud Bulletin #12 - Undated)
13. Transdermal Patches (Health Fraud Bulletin #13 - 2/3/89)
14. Products for the Treatment of Systemic Candida infections (Health Fraud Bulletin #14 - 5/l9/89)
15. Vitamin & Mineral Products for the Prevention or Treatment of Diseases of the Eye (Health Fraud Bulletin #15 - 7/13/90)
16. Products containing nonoxynol-9 as a single entity; nonoxynol-9 and para-chlorametaxylenol (PCMX) as a combination (Health Fraud Bulletin #16 - 5/14/91)
18. Prescription Homeopathic Products Marketed Over-the-14. Counter (Health Fraud Bulletin #17 - 6/9/92)
18. Cholesterol Related to Cardiovascular Disease (Health 14. Fraud Bulletin #18 - 3/22/93)
19. Colloidal Silver (Health Fraud Bulletin #19 - 10/7/94)
20. OTC Treatments for Benign Prostatic Hypertrophy (Non-Traditional Drug Bulletin #20 - 3/18/97)
21. Attention Deficit Hyperactivity Disorder (Non-Traditional 14. Drug Bulletin #21 6/27/97)
22. Herbal Alternatives to Fen-Phen (Non-Traditional Drug Bulletin #22 - 10/8/97)
23. OTC Drug Products for Impotence and Sexual Dysfunction (Non-Traditional Drug Bulletin #23 - 6/11/98)

1029.05 - International Inspection Guides

1. Guide to International Inspections and Travel (11/02)

SUBCHAPTER 1030 - CFR'S

1031 - LIST OF PARTS OF TITLE 21 CFR

This subchapter lists the parts of Title 21 Code of Federal Regulations: Food and Drugs, Chapter I, Food and Drug Administration. Title 21 contains nine volumes as follows:

Page citations in the following lists refer to Title 21 CFR revised as of April 1, 2003.

21 CFR SUBCHAPTER A - GENERAL

Bolded list entrees indicate those regulations reprinted in their entirety in IOM Appendix B.

Volume 1

21 CFR SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION

Volume 2

21 CFR SUBCHAPTER B - FOOD FOR HUMAN CONSUMPTION (CON'T.)

Volume 3

21 CFR SUBCHAPTER C - DRUGS: GENERAL

Volume 4

21 CFR SUBCHAPTER D - DRUGS FOR HUMAN USE

Volume 5

21 CFR SUBCHAPTER E - ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

Volume 6

21 CFR SUBCHAPTER F - BIOLOGICS

Volume 7

21 CFR SUBCHAPTER G - COSMETICS

21 CFR SUBCHAPTER H - MEDICAL DEVICES

Volume 8

21 CFR SUBCHAPTER I - MAMMOGRAPHY QUALITY STANDARDS ACT

SUBCHAPTER J - RADIOLOGICAL HEALTH

21 CFR SUBCHAPTER K - [RESERVED]

21 CFR SUBCHAPTER L - REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

21 CFR CHAPTER II DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

Volume 9

1032 - CFR SECTIONS AFFECTING OTC

1032.01 - Alphabetical Listing of Sections Affecting OTC Drugs

1032.02 - OTC Final Monographs: Alphabetical Listing

Note: See the FDA OTC Monograph web site for monographs issued since 4/1/03.