

Rockville, MD 20857. Telephone: 301-443-8843. Fax: 301-594-2336. E-mail: Vkim@samhsa.gov

Food and Drug Association (FDA)

FDA provides a wealth of written and electronic information to assist small business compliance with FDA regulatory requirements.

FDA has published hundreds of guidelines to assist regulated industry, including small business, in complying with the laws and regulations that FDA administers. These guidelines cover virtually all areas that FDA regulates, from new drug and medical device premarket review, to product import and export issues, to issues that relate to the manufacture of foods, drugs, devices, and biological products.

FDA has also published and made widely available guidelines that the agency has developed for its own enforcement and compliance staff. These guidelines describe the general standards for compliance action and set forth the procedures to be followed in conducting investigational and enforcement activities. Essentially all of these written materials are available through FDA's many web-sites. FDA has also prepared "plain language" versions of some of the more technical documents to assist small businesses and others in understanding FDA's expectations.

FDA has created a number of small business and industry assistance "homepages" on its web-sites that bring together an array of useful regulatory and compliance information.

For example, the Center for Devices and Radiological Health has created a "Device Advice" Web page, a self-service interactive site for obtaining information about medical devices. The human pharmaceutical program has created a comparable Web page, "Small Business Assistance".

FDA's Small Business Representatives (SBRs) are a significant resource for the small business community. Each of FDA's five regional offices is assigned an SBR to provide small business educational outreach and training.

FDA regional offices represent another significant informational resource for the small business community. The regional offices answer thousands of questions, conduct scores of training programs, and organize many "grassroots" meetings to educate the regulated industry, especially small businesses, about emerging regulatory topics of interest.

In addition, FDA's public affairs specialists (PASs), who are assigned to many of the agency's field offices, are able to respond to questions about

FDA's programs, policies, and procedures.

Finally, FDA has appointed ombudsmen in the Office of the Commissioner, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Veterinary Medicine, and the Center for Devices and Radiological Health. These officials not only provide compliance assistance, but also help regulated companies explore available options in resolving disputes with the agency.

Guidelines

Technical guides. FDA has issued hundreds of guides to assist manufacturers in meeting premarket approval and other regulatory requirements. Among these guidelines a number of guidelines expressly directed to the concerns and needs of small businesses.

Inspectional guides. FDA has made publicly available the agency's manuals and written procedures governing the conduct of inspectional and investigational activities.

Policy Guides

FDA has issued many guidelines to help regulated industry understand the laws, policies, and regulations that FDA administers. Many of these documents are issued in "plain language" versions to assist small businesses and others in understanding FDA's expectations.

All of the above-cited guidance materials may be accessed through the following Web sites:

- Center for Drug Evaluation and Research Guidance Documents: <http://www.fda.gov/cder/guidance/index.htm>
- Center for Devices and Radiological Health Guidance Documents for Industry: <http://www.fda.gov/cdrh.guidance.htm>
- Center for Food Safety and Applied Nutrition Food and Cosmetic Guidance Documents: <http://www.cfsan.fda.gov/~dms/guidance.html>
- Office of Regulatory Affairs Inspection References: http://www.fda.gov/ora/inspect_ref/default.htm

Web Assistance

The following small business and industry-assistance homepages also bring together an array of useful regulatory and compliance information:

- Center for Drug Evaluation and Research (CDER) Small Business Assistance: <http://www.fda.gov/cder/about/smallbiz/default.htm>—This site provides a listing of various programs, laws, regulations, and organizations that pertain to the drug development and

approval process. This site is specifically geared to small businesses; however, general information relating to both small and large businesses is also available here (*i.e.*, guidance documents, CDER calendar, etc.).

- Information on Devices: <http://www.fda.gov/cdrh/devadvice/>—This is an interactive, self-service site. It contains information on "How to Market Your Device" as well as an overview of the regulations, guidance documents, consumer information, and more.

- Veterinary Products: <http://www.fda.gov/cvm/faqs/faqs.html>—This site answers "Frequently Asked Questions" about veterinary products. It includes links to sites that provide information and requirements for topics such as "New Animal Drug Approval" and "Marketing a Pet Food Product," as well as others.

- Center for Biologic Evaluation and Research (CBER): <http://www.fda.gov/CBER/manufacture.htm>—This Web site from the Center for Biologic Evaluation and Research explains the manufacturers assistance program, which provides assistance and training to companies, both large and small, regarding CBER policies and procedures. This site also contains links to other sites that may be of values to the small business owner.

- Office of Regulatory Affairs Information on Small Business: http://www.fda.gov/ora/fed_state/small_business/default.htm.

- Office of Regulatory Affairs Small Business Guide to FDA: http://www.fda.gov/ora/fed_state/Small_Business/sb_guide/default.htm.—This site is from the FDA's Office of Regulatory Affairs. It offers links to a number of useful sites such as "What to do when marketing a new product," "recalling a product," "undergoing an FDA inspection," etc. It also provides an introduction to the **Federal Register**, information on obtaining FDA documents, frequently called numbers, and much more information.

- Center for Food Safety and Applied Nutrition Guide to Starting a Food Business: <http://www.cfsan.fda.gov/~comm/foodbiz.html>—Advice on "Starting A Food Business" which may be of interest for the (potential) small business owner. This site provides links to federal and state regulatory agencies, import & export information, as well as several other helpful sites.

Small Business and Industry Assistance Offices. Each major FDA component has its own industry assistance office. Staff in these offices provide program-specific information