

Small Business Guide to FDA

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INTRODUCTION

The Food and Drug Administration (FDA) recognizes that dealing with a large organization can frequently be a time consuming, frustrating experience. Although there is no acceptable panacea, FDA has instituted a number of activities aimed at easing this problem for regulated small businesses. These include the establishment of the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) in the Center for Devices and Radiological Health, Small Business Assistance Programs in the five FDA regional offices, and the creation of small business assistance offices in each of the Centers. These units provide technical assistance to small companies, hold exchange meetings to hear the views and perspectives of small businesses, conduct educational workshops, develop informational materials, and provide an accessible, efficient channel through which small businesses can acquire information from the FDA. The primary purpose of these activities is to increase our communication with the small business community. This, in turn, opens the door for improved understanding and a better working relationship. Because FDA regulates a wide range of products - from aspirin to x-ray equipment - we could not tailor this booklet to exactly fit everyone's operation. Instead, we have compiled some basic yet important information about FDA that, when put to use, will facilitate your interactions with the Agency. If you want to know about FDA's organization, procedures, policies, and regulations, we suggest that you keep this booklet handy. It contains a lot of good information for firms like yours.

THE FEDERAL REGISTER - WHAT IT IS AND HOW TO USE IT

The Federal Register is one of the most important sources for information on what FDA -- or for that matter, what any government agency is doing. Published daily, Monday through Friday, the Federal Register carries all proposed and finalized regulations and many significant legal notices issued by the various agencies, as well as presidential proclamations and executive orders.

Subscriptions to the Federal Register can be purchased from the Superintendent of Documents. For price and order information, call (888) 293-6498 or (202) 512-1530 for online subscriptions. As an alternative, copies can usually be found in local libraries, county courthouses, federal buildings or on the Internet at <http://www.gpoaccess.gov/fr/index.html>. The following are examples of how the Federal Register can be used to keep informed of FDA issues and activities:

ADVANCE NOTICE - Often, FDA will publish "Notices of Intent" in the Federal Register to give you the earliest possible opportunity to participate in its decisions. These notices inform you that FDA is considering an issue and that your views are welcome before a formal proposal is made.

PROPOSED REGULATIONS - When a formal proposal is developed, FDA publishes a "Notice of Proposed Rulemaking" in the Federal Register. The notice gives the timeframe in which you have to submit written comments about the proposed action. If you do not feel you have enough time to study the proposal and comment on it, you can submit a written request that Agency officials extend the comment period. If FDA extends the period, a notice of the extension is published in the Federal Register. Occasionally, a second or third proposal is published in the Federal Register because of the nature of the comments received. Each time a proposal is substantively revised or amended, a notice is published in the Federal Register.

FINAL REGULATIONS - Ultimately, a "Final Rule" is published, and the rule specifies the date when the new regulatory requirements or regulations become effective.

REGULATORY AGENDA - Twice a year -- in April and October - FDA, along with the entire Department of Health and Human Services, publishes an agenda in the Federal Register that summarizes policy-significant regulations, regulations that are likely to have a significant economic impact on small entities, and other actions under development. This agenda will help you identify actions of interest early to plan your participation. Each item listed includes the name, address and telephone number of an Agency official to contact if you need more information.

MEETINGS AND HEARINGS - Notices are published in the Federal Register announcing all meetings of the Agency's advisory committees (see public hearings) and all public meetings that provide an information exchange between FDA and industry, health professionals, consumers, and the scientific and medical communities. The notice contains the date, time and place of the meeting, as well as its agenda. The Federal Register also announces administrative hearings before the Agency and public hearings to gain citizen input into Agency activities (see citizen petition). Information about meetings of advisory committees is also available by calling (1-800) 741-8138.

HOW TO COMMENT ON PROPOSED REGULATIONS

Before you comment on regulations proposed by FDA, you may obtain more information about a proposal by contacting the person designated in the Federal Register statement. A Comprehensive list of proposed regulations open for comment from all federal agencies may be viewed at <http://www.regulations.gov>. At this website you may enter and directly send your comments on any proposed regulation. Whether you agree or disagree with the proposed regulations, you will want to communicate your comments in the most effective way possible. The following points will help you do this:

- Give the title, date of publication, and docket number for the proposal.
- State who you are and how the proposal affects you. (Economic costs and back-up data are more compelling than generalities.)
- Give supporting statements for your position and present new data and scientific findings, if possible.
- Whether you agree or disagree, you may suggest alternatives to the proposal or to requirements that are part of the proposal.
- The more substantive your comments, the more weight they will carry. The same thing is true for petitions (see petition content and format). When FDA considers comments from the public, it's not a simple matter of counting up "for" or "against" options.

Send your comments on proposed regulations to Dockets Management Branch, Room 1-23, 12420 Parklawn Dr., Rockville, MD 20857; (301) 827-6860.

HOW TO OBTAIN AGENCY DOCUMENTS

A Handbook for Requesting Information and Records from FDA (BG 97-6)

(<http://www.fda.gov/opacom/backgrounders/foiahand.html>)

Obtaining Public Information

Certain documents that are prepared for public distribution--such as press releases, consumer publications, speeches, and congressional testimony--are available from FDA without having to file a Freedom of Information Act (FOIA) request. Many of these documents are available on FDA's Internet site (www.fda.gov). We encourage you to browse the site for documents you want to look at. Public information may also be obtained by contacting the appropriate FDA information officer.

Obtaining Information Through FOIA

FOIA allows anyone to request copies of records not normally prepared for public distribution. FOIA pertains to existing records only and does not require agencies to create new records to comply with a request. It also does not require agencies to collect information they do not have or to do research or analyze data for a requestor. In addition, FOIA requests must be specific enough to permit an FDA employee who is familiar with the subject matter to locate records in a reasonable period of time. Under FOIA, certain records may be withheld in whole or in part from the requestor if they fall within FOIA exemptions.

HOW TO OBTAIN FDA STATUTES AND REGULATIONS

The Federal Food, Drug, and Cosmetic Act, as Amended, sections of the Public Health Service Act pertaining to biological products, the Radiation Control for Health and Education Act, the Safe Medical Devices Act, the Mammography Quality Standards Act, the Fair Packaging and Labeling Act, the Infant Formula Act, the Nutrition Labeling and Education Act, and the Dietary Supplement Health and Education Act are among the statutes enforced by the FDA. They are compiled in one booklet, "Federal Food, Drug, and Cosmetic Act as Amended and Related Laws," which is available from the Superintendent of Documents. The regulations over which FDA has jurisdiction are codified under Title 21, Code of Federal Regulations (CFR). These are updated on April 1 of each year and are available for sale approximately four months later. Nine volumes are applicable to FDA and may be purchased singly or as a set from the Superintendent of Documents. These regulations are accessible on the Internet at <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>. The contents of each volume are listed below:

- Parts 1 to 99. General regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Color additives.
- Parts 100 to 169. Food standards, good manufacturing practice for foods, low-acid canned foods, acidified foods, and food labeling.
- Parts 170 to 199. Food additives.
- Parts 200 to 299. General regulations for drugs.
- Parts 300 to 499. Drugs for human use.
- Parts 500 to 599. Animal drugs, feeds, and related products.
- Parts 600 to 799. Biologics and cosmetics.
- Parts 800 to 1299. Medical devices and radiological health. Regulations under the Federal Import Milk Act, the Federal Tea Importation Act, the Federal Caustic Poison Act, and for control of communicable diseases and interstate conveyance sanitation.
- Parts 1300 through end. Drug Enforcement Administration regulations and requirements.

HOW TO PETITION THE FDA

Anyone may request or petition FDA to change or create an Agency policy or regulation under 21 CFR Part 10.30. If you believe this type of action is necessary, direct your request to FDA's Dockets Management Branch <http://www.fda.gov/ohrms/dockets/>. When submitting a petition, keep these points in mind:

- Clearly state what problem you think the Agency needs to address.
- Propose specifically what the Agency's action should be. Your proposal should be based on sound, supportable facts.
- Submit the petition, an original and three (3) copies, unless otherwise stipulated in the Federal Register announcement, to:

Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857
(301) 827-6860

FDA carefully considers every petition and must respond within 180 days by either approving or denying it (in whole or in part), or providing a tentative response indicating why FDA has been unable to reach a decision. All petitions will be subject to public examination and copying as governed by the rules in 21 CFR 10.20(j). If FDA approves the petition, it may be published in the Federal Register. Your petition could eventually be incorporated into Agency policy. An example showing how to prepare a citizen's petition follows:

Petition Content and Format

(Date) _____

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

CITIZEN PETITION

The undersigned submits this petition under _____ (relevant statutory sections, if known) of the _____ Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to _____ (issue, amend, or revoke a regulation or order to take or refrain from taking any other form of administrative action).

A. ACTION REQUESTED

1. If the petition requests the Commissioner to issue, amend or revoke a regulation, give the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.
2. If the petition requests the Commissioner to issue, amend or revoke an order, include a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.
3. If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, state the specific action or relief requested.

B. STATEMENT OF GROUNDS

A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.

C. ENVIRONMENTAL IMPACT STATEMENT

Give an environmental impact analysis report in the manner specified in 21 CFR 25.42. (Claim for categorical exclusion under 21 CFR 25.30, 25.31, 25.32, 25.33, or 25.34 or an environmental assessment under Sec. 25.40 of this chapter.)

D. ECONOMIC IMPACT STATEMENT

The following information is to be submitted only when requested by the Commissioner following review of the petition: a statement of the effect of the requested action on 1) cost (and price) increases to industry, government, and consumers; 2) productivity of wage earners, businesses, or government; 3) competition; 4) supplies of important materials, products, or services; 5) employment; and 6) energy supply or demand.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature)

Name of Petitioner

(Mailing Address)

(Phone)

HOW TO PARTICIPATE IN AGENCY DECISION-MAKING

In addition to commenting on Federal Register documents and petitioning the Agency, there are a number of ways that can interact with FDA to make your viewpoint known. Here are a few examples:

Public Meetings or Conferences

FDA uses public meetings and conferences to discuss significant issues with the public. The Agency may schedule public meetings, sometimes referred to as "exchange meetings," before developing a proposal, or after proposing a program change. The meetings offer a chance for you and FDA managers to discuss issues informally before the rulemaking process begins. FDA announces meetings in the Federal Register and trade publications.

Industry Information/Education Meetings

Many meetings and workshops are conducted in which key representatives from industry, government, academia, and professional, consumer, ethnic, and patient groups discuss subjects of vital concern to industry and the FDA.

Public Hearings

A hearing is an opportunity for you to take part in a rule-making proceeding. FDA always announces hearings in the Federal Register and usually in other publications (e.g., industry newsletters) related to the topic of the hearing. Depending on the subject of the hearing, you can testify on specific issues that are included in an Agency proposal, or you can present your views about general issues on Agency programs. At all hearings, your testimony, whether it is presented orally or in writing, will become part of an official record of evidence which will help the Agency make policy decisions.

Public Advisory Committees and Panels

FDA routinely looks for qualified people to serve on a variety of public advisory committees and panels. Many of the Agency's committees and panels include members representing consumer and industry interests. FDA requests nominations for these members through announcements in the Federal Register. The committees generally study current scientific work and make recommendations to the Agency on product approvals, regulations, and other actions. Membership on most committees requires a scientific background. A free copy of "FDA Public Advisory Groups" or further information about FDA advisory committees, can be obtained by contacting the Office of Committee Management (HFA-306), Food and Drug Administration, Room 4B-17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; (301) 827-5496 or FAX (301) 827-5891. For current information or information updates on FDA advisory committee meetings, call the Advisory Committee Information Line by dialing (1-800) 741-8138 or (301) 443-0572, and the five digit number assigned to each advisory committee. This number will appear in each notice of meeting.

How Regulated Industry Can Communicate with FDA

Main FDA Address and Phone Number (for general inquiries):

U.S. Food and Drug Administration
5600 Fishers Lane (HF-40)
Rockville, MD 20857
Phone: (301) 827-4450
(888) INFO-FDA (1-888-463-6332)
FAX: (301) 443-1863

WHAT TO DO WHEN

Marketing a New Product

FDA must give the manufacturer, distributor or importer clearance to market certain products before they can be sold in interstate commerce. For example:

- New human and veterinary drugs ["New" drugs = those with new intended uses or new chemical entities] and certain medical devices [examples = stair-climbing wheelchair, contact lens, heart pacemaker] must be approved for safety and effectiveness, and their labeling reviewed for accuracy and thoroughness.
- Substances added to food must meet the requirements of the food additive regulations that are based on FDA's review of scientific data of safety and utility that have been submitted to FDA.
- All domestic and foreign facilities that manufacture/process, pack, or hold food (and dietary supplements) for human or animal consumption in the United States must register with the FDA. For more information on starting a food business see <http://www.cfsan.fda.gov/~comm/foodbiz.html>.
 - In addition, manufacturers of low-acid canned foods* packaged in air-tight bottles, plastic bags, and cans and acidified foods** must register with FDA and submit detailed information about heat-treatments to destroy bacteria (and acidification, if necessary to prevent growth of bacterial spores).
- Specific premarket controls apply to biological products that are required to be licensed under Federal law.

Marketing these kinds of products or conducting experimental investigations with them in human clinical trials, requires that one or more applications be filed with FDA and that certain procedures be followed.

In addition, although some products [such as cosmetics and some radiation-emitting items] do not need premarket approval from FDA, there are regulatory standards and regulations applicable to their manufacture and labeling that fall under FDA's jurisdiction. Therefore, to avoid unnecessary delay in bringing new products to market, it would be helpful to talk with an FDA product specialist early in your planning. (See Who to Contact for Assistance for the most appropriate contact).

PRODUCTS THAT REQUIRE REGISTRATION, LISTING, FILING OF A COOKING PROCESS, OR LICENSING PRIOR TO MARKETING:

- All domestic and foreign facilities that manufacture/process, pack, or hold food (and dietary supplements) for human or animal consumption in the United States must register with the FDA to satisfy the Bioterrorism Act of 2002. The agency highly recommends on line registration at <http://www.cfsan.fda.gov/~dms/fsbtact.html>. You must register using Form 3537. If you do not have reasonable access to the Internet, you may obtain a copy of this form by writing to the U.S. Food and Drug Administration, HFS-681, 5600 Fishers Lane, Rockville, MD 20857, or by requesting the form by phone at 800-216-7331 or 301-575-0156.
- Low Acid Canned Foods [LACF]* such as traditional vegetables, or any other food requiring aseptic processing to control the growth of pathogens must register all manufacturing establishments and file all scheduled processes. [To order forms 2541, 2541c: via phone 202-205-5282 or via Internet at <http://forms.psc.gov/forms/FDA/FDA-2541.pdf>, <http://forms.psc.gov/forms/FDA/FDA-2541c.pdf>]
 - Acidified Foods** such as salsas, hot sauces, certain salad dressings, relishes, barbecue sauces, or any other food that use acidification [addition of vinegar, lemon juice, etc.] to control the growth of pathogens must register all manufacturing establishments and file all scheduled processes. [To order forms 2541 or 2541a: Via phone: 202-205-5282 or via Internet at <http://forms.psc.gov/forms/FDA/FDA-2541.pdf>, <http://forms.psc.gov/forms/FDA/FDA-2541a.pdf>]
- Drugs including medical gases, human and veterinary prescription drugs, over-the-counter [OTC] drugs, and certain biologics must register all establishments and list all drug products. [To order forms 2656, 2657, or 2658: Via phone at 301-594-1086 or via Internet at <http://forms.psc.gov/forms/FDA/FDA-2656.pdf>, <http://forms.psc.gov/forms/FDA/FDA-2657.pdf>, <http://forms.psc.gov/forms/FDA/FDA-2658.pdf>]
 - **In addition**, many drugs require an Investigational New Drug [IND] application, New Drug Application [NDA], an Abbreviated New Drug Application [ANDA], New Animal Drug Application [NADA], or an Abbreviated New Animal Drug Application [ANADA]. [To order forms: Via phone at 301-827-3937 or via Internet <http://forms.psc.gov/forms/FDA/FDA-1571es.pdf>, <http://forms.psc.gov/forms/FDA/FDA-1572.pdf>] *
- Devices - human and animal devices must register all establishments and list all drug products. [To order forms 2891 or 2892: Via FAX: 301-443-8818 or via Internet (2891 only) <http://www.fda.gov/cdrh/comp/fda2891.pdf>]
 - **In addition**, many devices require Premarket Notification [510(k)] or Premarket Approval [PMA]
- Biologics and Blood Banks - human biologics may also be considered a drug or device and subject to the requirements of a drug or device. [Phone for forms: 301-827-3546]* USDA regulates biologics for animals. Many biologics establishments require licensing as well.

*Some forms only available by mail from [NO phone/FAX orders]:
Consolidated Forms and Publications Distribution Center [CFPDC]
Beltsville Service Center
6351 Ammendale Road
Beltsville, MD 20705

HANDLING AN FDA INSPECTION

FDA may conduct an inspection of your operation for a variety of reasons, such as a routinely scheduled investigation, a survey, or a response to a reported problem. The investigator will present his/her credentials and "Notice of Inspection" upon arriving at your plant. A knowledgeable person in your firm, such as the plant or production manager, preferably designated ahead of time, should accompany the investigator at all times. It is in your best interest to fully understand FDA's inspection procedures. When you are unsure of certain actions taken by the investigator, don't hesitate to ask questions.

Usually, the investigator will examine your production process, look at certain records and collect samples. At the conclusion of the inspection, the investigator will discuss with your firm's management any significant findings and concerns; and leave with your management a written report of any conditions or practices, which, in the investigator's judgment, indicate objectionable conditions, or practices. This list of "Inspectional Observations," also called an FDA-483, can be used by your firm's management as a guide for corrective action, since the FDA representative will not usually recommend specific corrective measures. Your firm can and should respond to the FDA-483 during the discussion with the investigator. In fact, corrective actions or procedural changes that were accomplished immediately in the presence of the investigator are regarded as positive indications of your concern and desire to voluntarily correct discrepancies.

If you do not agree with the actions being taken by the FDA or if you have a question about the jurisdiction of the agency in a particular matter, you can contact the FDA's Office of the Ombudsman to seek a resolution.

- Office of the Ombudsman
Food and Drug Administration
5600 Fishers Lane
Room 14B03, HF-7
Rockville, MD 20857
Telephone: 301-827-3390
FAX: 301-480-8039
E-mail: ombudsma@oc.fda.gov [*Sending confidential information by electronic mail is not recommended.*]

See the FDA Center Small Business Contacts for the Ombudsman in the various FDA Centers. *If FDA takes regulatory action against your firm, the Small Business Representatives are not available for guidance, since their activities are nonregulatory in nature.* You should contact a district Compliance Officer for advice (see FDA District Offices) under those circumstances.

Recalling Violative Products

A "recall" is a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which FDA would initiate a regulatory action such as seizure of the product. During a recall, a firm can expect to work more closely with FDA than under almost any other circumstance. In fact, the first step, when a product must be recalled, is for the manufacturer or distributor to call the nearest FDA field office and talk with the Recall Coordinator. See list of FDA District Offices.

FDA's main concerns during a recall are that the firm has determined the location of the product and organized the prompt removal from commerce of any suspect lots. FDA will then work with the firm to identify the cause of the problem and the corrections needed to prevent a recurrence. FDA is also concerned about the final disposition of the recalled product. Final disposition may be in the form of destruction, with appropriate regard for local laws concerning waste removal or incineration. Other possible conclusions to recalls include reconditioning (relabeling, repacking, reworking, etc.) or exportation, if permitted. Any method used must first be discussed with the FDA District Office, as FDA may wish to witness the effort, and the firm must maintain proper documentation.

Also with device recalls, the firm must report to the FDA District Office any Corrections or Removals in accordance with 21 CFR 806.10 as soon as the firm becomes aware of the problem.

Essentially, the procedures for a product recall are determined by the individual company; however, a proper recall system will include provisions for record-keeping, handling product returns, liaison with FDA, and public information. The efficiency of tracking and removing a product depends on the completeness of the records maintained throughout the production and distribution process.

Information on Recalls of FDA Regulated Products:
http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html

Professional Demeanor of FDA Employee:
If you are concerned about the professional demeanor of any FDA employee during an inspection or during their performance of other official duties, you should contact the District Director in the nearest FDA field office to resolve your concerns. See LIST OF DISTRICT DIRECTORS.

WHO TO CONTACT FOR ASSISTANCE

Knowing whom to contact is the first step in obtaining information you need. It may be helpful to keep in mind that FDA has five Centers, five Regions, and 21 District Offices within those regions. Reaching the right office and, more importantly, the right person who has the information you need, can sometimes be frustrating. This list of contacts should help guide you in the right direction.

Whether you need information related to getting your product approved and on the market, wanting an FDA speaker for your industry meeting, or just need copies of FDA regulations, there are a number of sources to which you can go for general assistance:

Small Business Representatives (SBRs) - FDA has Small Business Representatives who help small businesses whose products are regulated by FDA. They are located in five regions of the country: New York, Philadelphia, Atlanta, Dallas, and Oakland.

OTHER LINKS WITH INFORMATION OR ASSISTANCE FOR INDUSTRY:

DRUGS - [CDER] - <http://www.fda.gov/cder/about/smallbiz/default.htm>

FOODS, DIETARY SUPPLEMENTS, COSMETICS - [CFSAN] - <http://www.cfsan.fda.gov/~dms/industry.html>

DEVICES - [DSMICA in CDRH] - <http://www.fda.gov/cdrh/industry-asst.html> or "DEVICE ADVICE" - <http://www.fda.gov/cdrh/devadvice>

BIOLOGICS - [CBER] - <http://www.fda.gov/cber/manufacture.htm>

ANIMAL PRODUCTS - [CVM] - <http://www.fda.gov/cvm/contactcvm/contactCVM.html>

These sites are available to deal with the special concerns and/or provide helpful information to small firms and new businesses. They provide information that clarifies how Agency laws and regulations apply to various products or specific circumstances and suggest methods of meeting these requirements. The SBRs can respond to your inquiries, conduct or participate in workshops and conferences, or visit your plant, at your request, to offer assistance.

All FDA speaker requests must be submitted through:

Food and Drug Administration
Office of Public Affairs
Program and Speaker Coordination Staff
5600 Fishers Lane, Room 15A-08
Rockville, MD 20857
FAX 301-827-2823

SMALL BUSINESS REPRESENTATIVES (SBRs)

Small Business Representative (HFR-NE17) Marilyn Corretto

FDA, **Northeast Region (CT, MA, ME, NH, NY, RI, VT)**

158-15 Liberty Avenue

Jamaica, NY 11433-1034

Phone (718) 662-5618

FAX (718) 662-5434

Email: oranersbr@ora.fda.gov

Small Business Representative (HFR-CE5) Marie T. Falcone

FDA, **Central Region (DC, DE, IL, IN, KY, MD, MI, MN, ND, NJ, OH, PA, SD, VA, WI, WV)**

U.S. Customhouse

200 Chestnut St., Room 900

Philadelphia, PA 19106

Phone (215) 597-2120, ext. 4003

FAX (215) 597-5798

Email: mfalcone@ora.fda.gov

Small Business Representative (HFR-SE17)

FDA, **Southeast Region (AL, FL, GA, LA, MS, NC, PR, SC, TN, VI)**

60 Eighth St., N.E.

Atlanta, GA 30309

Phone (404) 253-2238

FAX (404) 253-1207

Email: orasesbr@ora.fda.gov

Small Business Representative, (HFR-SW17) David Arvelo

Small Business Technician, Sue Thomason

FDA, **Southwest Region (AR, CO, IA, KS, MO, NE, NM, OK, TX, UT, WY, US-Mexico Border Imports)**

4040 N. Central Expressway, Suite 900

Dallas, TX 75204

Phone (214) 253-4952 or (214) 253-4951

FAX (214) 253-4970

Email: oraswrsbr@ora.fda.gov

Small Business Representative, (HFR-PA17) Marcia Madrigal

FDA, **Pacific Region (AK, AZ, CA, HI, ID, MT, NV, OR, WA)**

Oakland Federal Building

1301 Clay Street, Suite 1180-N

Oakland, CA 94612-5217

Phone (510) 637-3980

FAX (510) 637-3977

Email: mmadriga@ora.fda.gov

**REGIONS AND DISTRICTS
FOOD AND DRUG ADMINISTRATION**

REGION and DISTRICT	STATES SERVED	DIRECTOR
<p>NORTHEAST REGION: <u>New York Regional Office</u> 158-15 Liberty Avenue Jamaica, NY 11433-1034 Phone - (718) 662-5416 FAX - (718) 662-5434</p>	<p>CT, MA, ME, NH, NY, RI, VT</p>	<p>DIANA J. KOLAITIS REGIONAL DIRECTOR</p>
<p><u>New York District Office</u> 158-15 Liberty Avenue Jamaica, N.Y. 11433-1034 Phone - (718) 662-5447 FAX - (718) 662-5665</p>	<p>NY</p>	<p>Jerome G. Woyshner District Director</p>
<p><u>New England District Office</u> One Montvale Ave. Stoneham, MA 02180 Phone - (781) 596-7717 FAX - (781) 596-7896</p>	<p>CT, MA, ME, NH, RI, VT</p>	<p>Gail T. Costello District Director</p>
<p>CENTRAL REGION: <u>Philadelphia Regional Office</u> U.S. Customhouse 200 Chestnut St., Room 900 Philadelphia, PA 19106 Phone - (215) 597-4390 FAX - (215) 597-5798</p>	<p>DC, DE, IL, IN, KY, MD, MI, MN, ND, NJ, OH, PA, SD, VA, WI, WV</p>	<p>SUSAN M. SETTERBERG REGIONAL DIRECTOR</p>
<p><u>Philadelphia District Office</u> U.S. Customhouse 2nd and Chestnut Sts., Room 900 Philadelphia, PA 19106 Phone - (215) 597-4390 FAX - (215) 597-4660</p>	<p>DE, PA</p>	<p>Thomas Gardine District Director</p>
<p><u>Central Region Office - Chicago</u> 20 North Michigan Ave. Suite 510 Chicago, IL 60602 Phone - (312) 353-9400 ext. 120 FAX - (312) 886-1682</p>	<p>DC, DE, IL, IN, KY, MD, MI, MN, ND, NJ, OH, PA, SD, VA, WI, WV</p>	<p>Andrew Bonanno Deputy Regional Director</p>

REGION and DISTRICT

STATES SERVED

DIRECTOR

Chicago District Office

550 W. Jackson Blvd.
Suite 1500 South
Chicago, IL 60661
Phone - (312) 353-5863
FAX - (312) 596-4187

IL

Vacant
District Director

Baltimore District Office

6000 Metro Dr. Suite 101
Baltimore, MD 21215
Phone - (410) 779-5454
FAX - (410) 779-5707

DC, MD, VA, WV

Lee Bowers
District Director

Cincinnati District Office

6751 Steger Drive
Cincinnati, OH 45237-3097
Phone - (513) 679-2700
FAX - (513) 679-2771

KY, OH

Carol A. Heppe
District Director

New Jersey District Office

Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
Phone - (973) 526-6000
FAX - (973) 526-6069

NJ

Douglas I. Ellsworth
District Director

Detroit District Office

300 River Place Drive
Suite 5900
Detroit, MI 48207-4457
Phone - (313) 393-8100
FAX - (313) 393-8105

IN, MI

Joann M. Givens
District Director

Minneapolis District Office

212 3rd Ave., South
Minneapolis, MN 55401-2532
Phone - (612) 334-4100
FAX - (612) 334-4134

MN, ND, SD, WI

W. Charles Becoat
District Director

SOUTHEAST REGION:

Atlanta Regional Office

60 Eighth St. N.E.
Atlanta, GA 30309
Phone - (404) 253-1171
FAX - (404) 253-1207

**AL, FL, GA, LA, MS,
NC, PR, SC, TN, VI**

**GARY J. DYKSTRA
REGIONAL DIRECTOR**

REGION and DISTRICT

STATES SERVED

DIRECTOR

Atlanta District Office

60 Eighth St. N.E.
Atlanta, GA 30309
Phone - (404) 253-1161
FAX - (404) 253-1202

GA, NC, SC

Mary H. Woleske
District Director

New Orleans District Office

6600 Plaza Drive Suite 400
New Orleans, LA 70127
Phone - (504) 240-2401
FAX - (504) 240-6360

AL, LA, MS, TN

Carl Draper
District Director

Florida District Office

555 Winderly Place. Suite 200
Maitland, FL 32751
Phone - (407) 253-1161
FAX - (407) 253-1202

FL

Emma R. Singleton
District Director

San Juan District Office

466 Fernandez Juncos Avenue
San Juan, PR 00901-3223
Phone - (787) 474-9500
FAX - (787) 729-6851

PR, VI

Donald J. Voeller
District Director

SOUTHWEST REGION:

Dallas Regional Office

4040 N. Central Expressway, Suite 900
Dallas, TX 75204
Phone - (214) 253-4901
FAX - (214) 253-4960

**AR, CO, IA, KS, MO,
NE, NM, OK, TX,
UT, WY, US-Mexico
Border Imports**

**DENNIS BAKER
REGIONAL DIRECTOR**

Dallas District Office

4040 N. Central Expressway, Suite 300
Dallas, TX 75204
Phone - (214) 253-5200
FAX - (214) 253-5313

AR, OK, TX

Michael A. Chappell
District Director

Southwest Import District

4040 N. Central Expressway, Suite 300
Dallas, TX 75204
Phone – (214) 253-5330
Toll-free – (800) 991-4881
FAX – (214) 253-5316

AR, AZ, CA, CO, IA,
KS, MO, NE, NM,
OK, TX, UT, WY,
US-Mexico Border
Imports

Robert Deininger
District Director

REGION and DISTRICT	STATES SERVED	DIRECTOR
<u>Denver District Office</u> 6th & Kipling Sts., Denver Federal Ctr Bldg. 20, Entrance W-10 Denver, CO 80225-0087 Phone - (303) 236-3000 FAX - (303) 236-3099 (Mailing Address: P.O. Box 25087 Denver, CO 80225-0087)	CO, NM, UT, WY	Belinda Collins District Director
<u>Kansas City District Office</u> 11510 West 80th St. Lenexa, KS 66214 Phone - (913) 752-2144 FAX - (913) 752-2136 (Mailing Address: P.O. Box 15905 Lenexa, KS 66285-5905)	IA, KS, MO, NE	Charles W. Sedgwick District Director
PACIFIC REGION: <u>Oakland Regional Office</u> Oakland Federal Building 1301 Clay St. Suite 1180 - N Oakland, CA 94612-5217 Phone - (510) 637-3960 FAX - (510) 637-3976	AK, AZ, CA, HI, ID, MT, NV, OR, WA	BRENDA HOLMAN REGIONAL DIRECTOR
<u>Los Angeles District Office</u> 19701 Fairchild Irvine, CA 92612-2506 Phone - (949) 608-2900 FAX - (949) 608-4498	AZ ,CA	Alonza E. Cruse District Director
<u>Seattle District Office</u> 22201 23rd Dr. S.E. Bothell, WA 98021 Phone - (425) 486-8788 FAX - (425) 483-4996	AK, ID, MT, OR, WA	Charles Breen District Director
<u>San Francisco District Office</u> 1431 Harbor Bay Parkway Alameda, CA 94502-7096 Phone - (510) 337-6700 FAX - (510) 337-6859	CA, HI, NV	Vacant District Director

FDA CENTERS' SMALL BUSINESS CONTACTS

Center Small Business Contact Person - When you have an inquiry that requires highly specialized assistance, such as information to be submitted in a new drug application, or if you are requesting a meeting with someone in headquarters, you may save time by directly calling the small business contact person in the appropriate center. The people listed below can also send you a wide variety of informational materials or audiovisuals:

Center for Drug Evaluation and Research
Office of Training and Communication (HFD-210)
Ron Wilson, Director
Small Business Assistance
E-mail wilsonr@cder.fda.gov
5600 Fishers Lane, Room 12B45
Rockville, MD 20852
Phone - (301) 827-1694
FAX - (301) 827-3056

CDER Ombudsman
Warren Rumble (Acting)
Phone - 301-594-5490
FAX - 301-827-4312
E-mail - ombudsman@cder.fda.gov

Small Business Assistance for drug firms can be accessed from the Center for Drug Evaluation and Research at <http://www.fda.gov/cder/about/smallbiz/default.htm> or by calling the Division of Drug Information, listed above.

Center for Biologics Evaluation and Research
Division of Manufacturers Assistance and Training (HFM-42), matt@cber.fda.gov
1401 Rockville Pike, Suite 200N
Rockville, MD 20857-1448
Phone - (301) 827-2000
FAX 301-827-3079
Voice Information System - (301) 827-1800 (1-800-835-4709)
Office FAX - (301) 827-3843

CBER Ombudsman
Sheryl Lard Whiteford
Phone - 301-827-0373
FAX - 301-827-0440
E-mail - LARD@CBER.FDA.GOV

Center for Food Safety and Applied Nutrition
Graciela Iguina, giguina@cfsan.fda.gov
Industry Activities Staff (HFS-565)
5100 Paint Branch Parkway
College Park, MD 20740-3835
Phone - (301) 436-1730
FAX - (301) 436-2621

Center for Devices and Radiological Health
John F. Stigi, Director, dsmica@cdrh.fda.gov
Division of Small Manufacturers, International and Consumer Assistance (HFZ-220),
www.fda.gov/cdrh/devadvice/
Room 130C
1350 Piccard Dr.
Rockville, MD 20850
Phone - (1-800) 638-2041
FAX - (301) 443-8818

CDRH Ombudsman
Les Weinstein
Phone - 301-827-7991
FAX - 301-827-2565
Email - OMBUDSMAN@CDRH.FDA.GOV

Center for Veterinary Medicine
Joanne M. Kla, jkla@cvm.fda.gov
Consumer Safety Officer
Communication Staff (HFV-12)
Room N428 Metro Park North #2
7519 Standish Place
Rockville, MD 20855-2773
Phone - (301) 827-3806
FAX - (301) 594-4512

CVM Ombudsman
Marcia K. Larkins
Phone - 301-827-4535
FAX - 301-827-3957
E-mail - mlarkins@cvm.fda.gov

In addition, the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), established in the Center for Devices and Radiological Health, provides technical and other non-financial assistance to small medical device manufacturers. Although DSMICA personnel are located in headquarters, they routinely provide field assistance to firms by conducting workshops and, at the request of the manufacturer, making onsite visits.

HOW TO OBTAIN ASSISTANCE FOR FDA'S PROCUREMENT AND CONTRACT ACTIVITIES

FDA has a special program that helps small companies participate in the Agency's procurement and contract activities. The program's goal is to seek out and encourage small companies to provide the Agency with needed supplies and services. For more information see the FDA Small Business Program website at <http://www.fda.gov/oc/ofacs/fdasbo/default.html> or contact

*FDA Small Business Program Office Points of Contact:
Mendel D. Hill, Small Business Program Manager
Office of Facilities, Acquisitions and Central Services
Room 2074, HFA230
5600 Fishers Lane, Rockville, MD 20857
PHONE: (301) 827-7211
FAX: (301) 827-7228
e-mail: MHILL1@oc.fda.gov*

Procurement activities include the purchase of scientific and laboratory equipment such as chemicals, glassware, furniture, electronic components, various species of laboratory animals, animal feed, bedding, holding cages, and other related supplies.

The Agency also solicits proposals and awards contracts for research, surveys and studies in the areas of management, construction/renovation, science, and medicine.

The Agency has a Small and Disadvantaged Business Utilization Specialist who is available to assist and counsel small companies in capturing the Agency's procurement and contract dollars. Small companies that are interested in obtaining more information about the Agency's procurement and contract activities may direct their inquiries to:

Small and Disadvantaged Business Utilization Specialist
Food and Drug Administration
Office of Facilities, Acquisitions and Central Services, HFA-505
5630 Fishers Lane, Room 2038
Rockville, MD 20857
301-827-6890

FREQUENTLY CALLED NUMBERS & WEB SITE INDEX

TOLL-FREE 888-INFO-FDA (888-463-6332)

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

CBER contact information at <http://www.fda.gov/cber/pubinquire.htm> or call **Voice Information System** - Direct access to Consumer Safety Officer or Public Affairs Specialist
800-835-4709 or 301-827-1800

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

DIVISION OF SMALL MANUFACTURERS, INTERNATIONAL AND CONSUMER ASSISTANCE (DSMICA)

TOLL-FREE 1-800-638-2041 or 301-443-6597

CDRH FAX-ON-DEMAND (Documents via FAX)

TOLL-FREE 1-800-899-0381 or 301-827-0111

CENTER FOR DRUG EVALUATION AND RESEARCH

DRUG INFORMATION LINE 301-827-4573

Or see CDER small business assistance web site at <http://www.fda.gov/cder/about/smallbiz/default.htm>

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

OUTREACH AND INFORMATION CENTER 1-888-723-3366

5100 Paint Branch Parkway (HFS-555)

College Park, MD 20740

Toll-Free Information Line:

1-888-SAFEFOOD

(1-888-723-3366)

NATIONAL INSTITUTES OF HEALTH GRANTS INFORMATION LINE

(For information about grants involving FDA regulated products) 301-435-0714

SMALL BUSINESS ADMINISTRATION

Small Business Answer Desk

1-800-827-5722

409 3rd Street S.W.

Washington, DC 20416

202-606-4000

SUPERINTENDENT OF DOCUMENTS

New Orders 202-512-1806

Superintendent of Documents

P.O. Box 371954

Pittsburgh, PA 15250-7954

for ordering government publications online 202-512-1530

ACCESS INFORMATION FROM THE INTERNET

World Wide Web (www) FDA Home Page can be reached at the Uniform Resource Locator: <http://www.fda.gov/> (with hypertext links to information about various FDA responsibilities: foods, human drugs, animal drugs, biologics, cosmetics, medical devices and radiological health, toxicology, and FDA news). FDA is placing the documents that the public most frequently requests on the WWW site to give users more immediate access. Web sites Referenced in this document and FDA-related web sites:

CBER - Biologics Standard Operating Policy and Procedures	http://www.fda.gov/cber/regsopp/8403.htm	license forms, instructions, guidance
CBER - Center for Biologics Evaluation and Research	http://www.fda.gov/cber/index.html	blood, biologic products, tissue, in-vitro diagnostics
CBER - Site Map	http://www.fda.gov/cber/sitemap.htm	links to blood, tissue, and biologics information
CDER - ANDA Application Process	http://www.fda.gov/cder/regulatory/applications/ANDA.htm	forms for generic drug submissions, instructions, guidance
CDER - Center for Drug Evaluation & Research	http://www.fda.gov/cder/	prescription human drugs, over-the-counter drugs, medical gases
CDER – Drug Registration / Listing	http://www.fda.gov/cder/drls/default.htm	facility registration and drug listing forms, instructions, guidance
CDER – IND Application Process	http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm	investigational drug forms, instructions, guidance
CDER – NDA Application Process	http://www.fda.gov/cder/regulatory/applications/NDA.htm	forms for new drug submissions, instructions, guidance
CDER – Small Business Assistance	http://www.fda.gov/cder/about/smallbiz/default.htm	assistance for new and small drug businesses
CDRH – Center for Devices & Radiological Health	http://www.fda.gov/cdrh/index.html	human and animal devices, in-vitro diagnostics, radiologicals, lasers
CDRH – Device Advice	http://www.fda.gov/cdrh/devadvice/	device advice, search device databases; 510k / PMA help
CDRH – Device Registration / Listing	http://www.fda.gov/cdrh/devadvice/341.html	forms for facility registration and device listings, instructions, guidance
CDRH / Industry Assistance	http://www.fda.gov/cdrh/industry-asst.html	assistance for small device businesses
CFSAN – Center for Food Safety & Applied Nutrition	http://vm.cfsan.fda.gov/list.html	food [except red meat and poultry], dietary supplements, food additives, cosmetics, dinnerware
CFSAN – LACF / Acidified Food Registration / Process Filing	http://www.cfsan.fda.gov/~comm/lacf-s1.html	forms for facility registration and filing a cooking process [acidified and low acid canned foods only], instructions, and guidance
CFSAN – Starting a Food Business	http://www.cfsan.fda.gov/~comm/foodbiz.html	information, assistance for new food businesses
Compilation of Laws Enforced by Food & Drug Administration	http://www.fda.gov/opacom/laws/	access all FDA regulations

CVM - Center for Veterinary Medicine	http://www.fda.gov/cvm/default.html	animal drugs, animal feed, pet products
CVM - FAQ's	http://www.fda.gov/cvm/faqs/faqs.html	Frequently Asked Questions [and Answers] about veterinary regulations
CVM - NADA / ANADA Application Process	http://www.fda.gov/cvm/index/other/nadaappr.htm	forms for new animal drug submissions, instructions, guidance
FDA - Citizen Petitions	http://www.fda.gov/opacom/morechoices/smallbusiness/citizpet.html	petition requests to add, remove, or change agency regulations
FDA - Ombudsman	http://www.fda.gov/oc/ombudsman/homepage.htm	mediation, resolution of disputes with FDA and help for industry
FDA - Public Docket of Proposed Regulations	http://www.fda.gov/ohrms/dockets/	comment on proposed regulations, view pending regulations
FDA - Public Hearings	http://www.fda.gov/opacom/morechoices/smallbusiness/pubhear.html	how to participate in FDA's rulemaking process
FDA - Recalls	http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html	product recall information, regulations, procedures
FDA FOI - Handbook for Requesting Information and Records	http://www.fda.gov/opacom/backgrounders/foiahand.html	how to submit requests under the Freedom of Information Act
FDA Home Page	http://www.fda.gov/	starting point for all FDA web sites
FDA Modernization Act	http://www.fda.gov/opacom/7modact.html	changes to FDA regulations since 1997
Information for FDA-Regulated Industry	http://www.fda.gov/oc/industry/default.htm	FDA-regulated industry web sites
State Health Agencies	http://www.fda.gov/oca/sthealth.htm	links to state agencies
US Government - Superintendent of Documents	http://www.fda.gov/opacom/morechoices/smallbusiness/supdoc.html	access to all government publications
US Government CFR's Online	http://www.access.gpo.gov/nara/cfr/cfr-table-search.html	access to all government regulations that are online
USDA - Home Web site	http://www.usda.gov/	red meat, poultry regulations, information