



Office of Acquisitions & Grants Services (OAGS)

FDA Small Business Outreach Vendor Fair

February 19, 2014



FDA Mission

FDA is responsible for:

- **Protecting the public health** by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- **Protecting the public** from electronic product radiation
- **Assuring** cosmetics and dietary supplements are safe and properly labeled
- **Regulating** tobacco products
- **Advancing the public health** by helping to speed product innovations
- **Helping the public** get the accurate science-based information they need to use medicines, devices, and foods to improve their health

* FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.

Major Initiatives

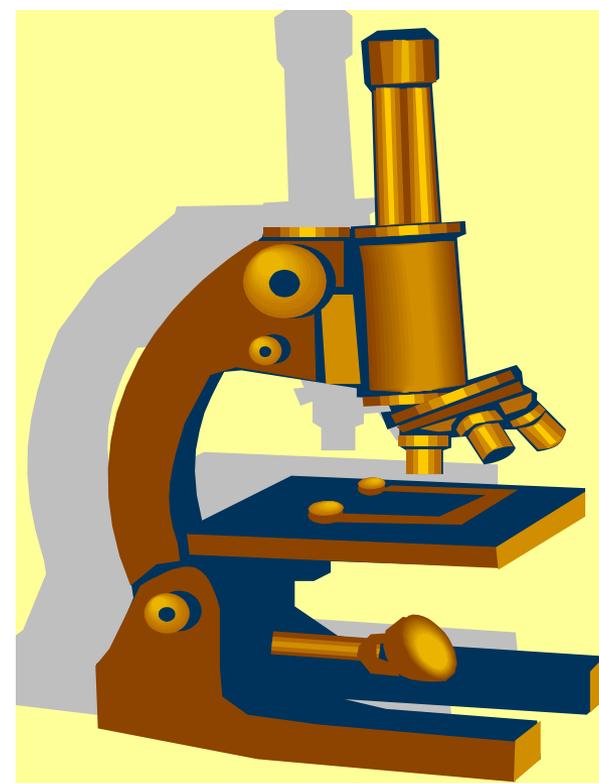
- **Globalization** - FDA works to transform from a predominantly domestically-focused agency operating in a globalized economy to a modern public health regulatory agency fully prepared for a complex globalized regulatory environment.
- **Advancing Regulatory Science** - Building on the achievements of existing agency programs to develop new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.
- **Food Safety** - The Food Safety Modernization Act gives FDA a mandate to develop a science-based food safety system that addresses hazards from farm to table—putting greater emphasis on prevention of foodborne illness.
- **Tobacco** - Passage of the Family Smoking Prevention and Tobacco Control gives FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products to protect public health

Major Initiatives

- **Innovation** - FDA is redoubling efforts to encourage innovations that will promote public health as well as strengthen the American economy.
- **Medical Countermeasures** - FDA plays a critical role in protecting the United States from chemical, biological, radiological, nuclear, and emerging infectious disease threats. FDA's responsibility is to ensure that medical countermeasures (MCMs)—such as drugs, vaccines, and diagnostic tests—to counter these threats are safe, effective, and secure.
- **Transparency** - FDA seeks to make more information available to the public rapidly in a form that is easily accessible and user-friendly and to foster a better understanding of Agency operations and decision-making.

OAGS Mission

Our mission is to provide **high quality support** to FDA programs by managing all contracts, and assistance agreements in a **timely manner** and at a **reasonable cost**.



Centers/Offices OAGS Supports

- ❑ Center for Biologics Evaluation and Research (CBER)
 - ❑ Center for Drug Evaluation and Research (CDER)
 - ❑ Center for Devices and Radiological Health (CDRH)
 - ❑ Center for Food Safety and Applied Nutrition (CFSAN)
 - ❑ Center for Tobacco Products (CTP)
 - ❑ Center for Veterinary Medicine (CVM)
 - ❑ National Center for Toxicological Research (NCTR)
 - ❑ Office of Information Management (OIM)
 - ❑ Office of Regulatory Affairs (ORA)
 - ❑ Office of the Commissioner (OC)
- For more information on each Center/Office and their mission please visit www.fda.gov.



Acquisition Goals and Statistics

SOCIOECONOMIC (as of Jan 17, 2014)

Small Business Award Categories	FY Goal	FY 10	FY 11	FY12	FY13	FY14
Small Businesses*	45%	37.20%	47.46%	55.90%	48.93%	46.94%
Small Disadvantaged Businesses	5.0%	20.85%	28.24%	34.70%	30.69%	22.26%
Women-Owned Small Businesses	5.0%	11.63%	12.05%	16.55%	9.92%	10.28%
HubZone Businesses	3.0%	4.18%	2.96%	3.59%	2.59%	0.53%
Service Disabled Veteran Owned	3.0%	1.96%	3.99%	4.68%	2.14%	7.42%

* The Small Business goal increased from 35% to 45% in FY14



HOW TO DO BUSINESS WITH THE FDA

Commodities and Services Purchased

- Information Technology services, hardware and software.
- Telecommunication products
- A/V Equipment and maintenance
- Scientific software
- Office furniture, equipment, and supplies
- Animal feed
- Bedding and cages
- Chemicals and supplies
- Reagents
- Pharmaceuticals, drugs, and intravenous solutions
- Electronic components and supplies
- X-ray equipment
- Scientific equipment
- Laboratory furniture, equipment, and supplies
- Animals for research (including horses, calves, cats, dogs, guinea pigs, chicks, hens, etc.)

Commodities and Services Purchased

- Research studies
- Investigations, surveys
- Tests and analyses of a scientific or medical nature
- Examinations, surveys, inspections, and reviews
- Professional Services
- Conference support/Events Planning
- Document Management
- Training
- Facility renovation
- Administrative Support/Temporary Services
- Architect/engineering support
- Operation and maintenance of facilities
- Facility support (e.g. custodial, trash, guard services)
- Moving Services

Doing Business with the FDA (1 of 3)

- **Contact Small Business Program Office -**
www.hhs.gov/about/smallbusiness/
- **Review Procurement Forecast for the Products and/or Services that Your Business Sells**
- **Obtain a DUNS number from Dun & Bradstreet and Register in System for Award Management (SAM).** A DUNS number is a business identification number and businesses must have DUNS numbers to do business with the Federal Government. There is no cost to obtain a DUNS number. You must be registered in SAM to do business with the Federal government. www.sam.gov
- **Become Familiar with Federal Contracting Procedures.** Federal agencies must follow certain rules relating to procurement, which can be different than typical business practices. The Federal Acquisition Regulation (FAR) is the primary source of guidance on federal contracting. Most agencies have agency-specific supplements to the FAR.

Doing Business with the FDA (2 of 3)

- **Market Your Business to the Right Contacts and know what FDA buys.**
Do not send information to the highest official that you can find. It is more effective to send information to the contracting office, the Small Business Specialist, or the appropriate program official.
- **Visit FedBizOpps Website at www.fbo.gov**
 - Single point of entry for business opportunities valued in excess of \$25,000
 - Register to receive notifications whenever business opportunities relevant to your industry are posted.
- **Attend Agency Sponsored Vendor Outreach Sessions, Trade Fairs, and Other Business Networking Events.**
 - HHS conducts monthly outreach session
 - Networking and teaming opportunities.
- **Explore Subcontracting Opportunities**

Doing Business with the FDA (3 of 3)

- **Respond to Requests for Information (RFI) / Sources Sought Notices**
 - Submit detail sufficient to determine capabilities
- **Obtain one or more GSA Schedule contracts and/or GWACs.**
 - Being on schedule and/or a GWAC makes good “business sense” and will provide your company with multiple options.
- **Maintain High Standards of Integrity.**
 - Do not attempt to act outside of the boundaries set in the FAR and various agencies supplements.
 - Federal officials involved in the procurement process are limited in what information they can disclose to whom and when. Do not pressure them for additional information and do not attempt to circumvent the boundaries set.

Where to Go for More Information

- Doing Business With FDA - Make Your Connection (<http://www.fda.gov/AboutFDA/business/ucm288023.htm>)
- FedBizOpps (www.fbo.gov) site includes training videos for small business and instructions on registering and monitoring agency requirements.
- HHS Small Business Office (www.hhs.gov/about/smallbusiness) has information on current requirements, forecasts, “Doing Business,” etc.
- The Small Business Administration (www.sba.gov/category/navigation-structure/contracting) has great deal of information with web links for determining size status and resources to research government requirements.
- All grant announcements across the government are available at: <http://www.grants.gov>.



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