Office of Acquisitions & Grants Services (OAGS)

FDA Small Business Outreach Vendor Fair

February 24, 2016





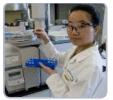
<u>Agenda</u>

- Who we are...
- What we buy...
- Goals and statistics...
- Partnering with OAGS...

































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. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.
- <u>Tobacco</u> 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.
- Sentinel Initiative the Sentinel Initiative, which aims to develop and implement a proactive electronic system that will transform FDA's ability to track the safety of drugs, biologics, and medical devices once they reach the market, is now on the horizon.



OAGS Mission, Vision & Goals

Office of Finance, Budget & Acquisitions

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.



Vision

Our goal is to be an acquisition center of excellence by fostering **strategic collaboration** with our partners and **empowering our workforce** to achieve results that protect and promote the health of all Americans while maintaining the public trust.



Goals

Stewardship and Customer Service

Value and Cost Savings

Performance and Professionalism

- Enhance Center / OAGS Strategic Partnership in the Procurement Process
- Increase Efficiency, Transparency, and Accountability
- Achieve FDA and HHS Contracting Goals
- Achieve Administration Acquisition Reform Goals
- Ensure Compliance with Applicable Laws and Regulations (FAR, HHSAR)

Office of Operations

Centers/Offices OAGS Supports

u	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 and Technology (OIMT)
	Office of Regulatory Affairs (ORA)
	Office of the Commissioner/Office of Operations (OC/OO)

 For more information on each Center/Office and their mission please visit <u>www.fda.gov</u>.



Acquisition Goals and Statistics **SOCIOECONOMIC**

Small Business Award Categories	FY Goal*	FY 10	FY 11	FY12	FY13	FY14	FY15	FY16
Small Businesses	41% (35% until FY14) (43% in FY 14)	37.20%	47.46%	55.90%	48.93%	43.28%	50.10%	98.8%
8(a) Businesses	5.0%	10.12%	19.53%	-	-	-	-	-
Small Disadvantaged Businesses	5.0%	20.85%	28.24%	34.70%	30.69%	25.28%	29.50%	59.7%
Women-Owned Small Businesses	5.0%	11.63%	12.05%	16.55%	9.92%	13.63%	15.90%	21.7%
HubZone Businesses	3.0%	4.18%	2.96%	3.59%	2.59%	3.61%	2.20%	1.0%
Service Disabled Veteran Owned	3.0%	1.96%	3.99%	4.68%	2.14%	2.93%	3.17%	6.3%

Acquisition Goals and Statistics **COMPETITION**

Center	Percent of Eligible Actions Competed	Percent of Eligible Dollars Competed
HHS Goal	65%	75%
FY12	91.0%	96.28%
FY13	91.0%	98.0%
FY14	90.0%	96.0%
FY15	91.0%	95.0%
FY16	91.0%	96.0%

Acquisition Goals and Statistics **AWARDS**

Acquisition Summary	Actions	Dollars (in Millions)
FY10	5,700	\$1,200.0
FY11	6,864	\$1,100.4
FY12	7,757	\$1,178.4
FY13	6,919	\$1,626.2
FY14	6,605	\$1,534.6
FY15	6,906	\$1,551.8
FY16	998	\$131.2

2016 Acquisition Cut-Off Dates (1 of 4)

NOVEMBER 3, 2015

- One-third (1/3) of new Contract actions, including re-competes, valued over \$150,000, identified on the Center AAP must be submitted to OAGS
- One-third (1/3) of Interagency Agreement (IAA) actions identified on the Center AAP must be submitted to OAGS

JANUARY 22, 2016

- Additional 1/3 of new Contract actions, including re-competes, valued over \$150,000, identified on the Center AAP
- Additional 1/3 of IAA actions identified on the Center AAP
- New Competing Grants (New Funding Opportunity Announcements, Sole Sources, Limited Competing Grants and Program Expansion)

FEBRUARY 19, 2016

New contract awards (competitive and non-competitive including competitive 8(a))
 valued over \$150,000 (aggregate total inclusive of options)

2016 Acquisition Cut-Off Dates (2 of 4)

MARCH 11, 2016

- New competitive awards of GSA/GWAC task/delivery orders or BPA calls
 requiring a Statement of Work (SOW) / Performance Work Statement (PWS) /
 Statement of Objectives (SOO) valued over \$150,000 (aggregate total inclusive of options periods)
- IAA's for Assisted Acquisition, i.e., servicing Agency performs acquisition activities on FDA's behalf.

APRIL 27, 2016

- Directed 8(a)s, (i.e., those less than or equal to \$4 million)
- BPA calls under established multiple-award BPAs, including HHS/Federal Strategic Sourcing Initiative (FSSI) BPAs
- Multiple-award Task and Delivery Orders, including orders against FDA contracts and GSA/GWAC/BPA awards <u>NOT</u> requiring a SOW/PWS/SOO
- Multiple-award Task and Delivery Orders, including orders against FDA contracts and GSA/GWAC/BPA awards requiring a SOW/PWS/SOO valued <u>under</u> <u>\$150,000</u> (aggregate total inclusive of options)
- Reimbursable IAAs
- Grants Administrative Supplements

2016 Acquisition Cut-Off Dates (3 of 4)

JUNE 6, 2016

- Task/Delivery Orders and BPA class against Single Award Contracts/vehicles
- BPA calls under established single award BPAs, including HHS/ FSSI BPAs
- Bilateral modifications e.g., new work
- \$25,001 to \$150,000 Simplified Acquisitions (aggregate total inclusive of options)
- Request for full proposal under Broad Agency Announcement (BAA)
- Service IAAs

JULY 6, 2016

- Receipt of full proposal(s) for Broad Agency Announcement (BAA) must be received
- Unilateral modifications (e.g., option exercises or other administrative actions)

JULY 28, 2016

- \$3,500 to \$25, 000 Simplified Actions not subject to OAGS' Higher Purchase Card Limit Program (aggregate total inclusive of options periods)
- All Grants Management documentation to include (Objective Review Documents, Budget Approval Sheets and Programmatic Terms and Conditions)

2016 Acquisition Cut-Off Dates (4 of 4)

AUGUST 15, 2016

Actions < \$3,500 in which vendor DOES NOT accept Purchase Card*

AUGUST 31, 2016

Broad Agency Announcement Funding to allow for FY16 Award

*While there are exceptions, the vast majority of purchases under \$3,500 should be made using the Purchase Card. Accordingly, any requisition received for items or services that are available using the Purchase Card will be returned to the sponsoring office.

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.)	17

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 (HHS Procurement Forecast Data Repository)
- 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. The FDA uses the Health and Human Services Acquisition Regulation (HHSAR).

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 <u>www.fbo.gov</u>
 - 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.

Sources Sought Objectives

- What a Sources Sought actually seeks
 - Evidence of <u>relevant</u> experience and expertise
 - Capacity to provide necessary resources
 - Succinct demonstration of <u>understanding</u> of synopsized requirement
 - Evidence of prior <u>adaptability</u>, e.g., teaming, staffing scalability, obtaining expertise
 - Ability to meet the <u>specific need</u> synopsized
- Most of all, a sources sought seeks a response that addresses the points in the synopsis
- Tailor your response specifically to the sources sought and provide supporting evidence.
- Document your small business category within the NAICS code size standard listed for the proposed acquisition.

Request For Proposal (RFP) Pointers

- Are you capable? Make an intelligent/informed business decision
- Read, read, and re-read Sections C, L & M (statement of work, proposal prep. instructions & evaluation criteria)
- Answer the mail: "How" are you are going to do the job do not parrot back the RFP
- Succinctly demonstrate your understanding of the issue & substantiate your costs
- Pay attention to page limitations
- Be aware of Best Value Lowest cost does not always win
- Always request a debriefing. Learn how to improve

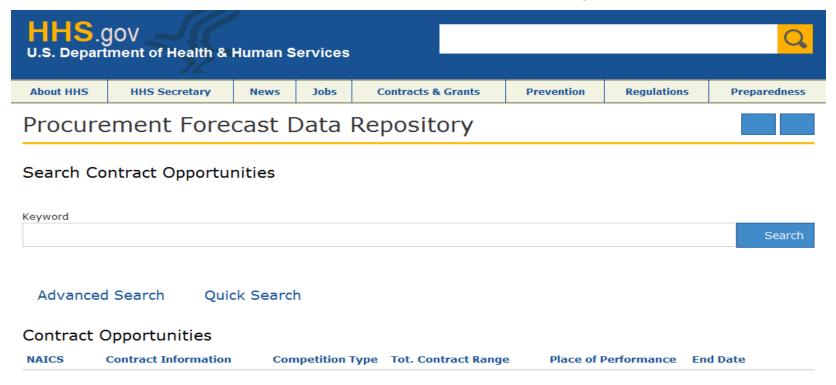
Where to Go for More Information

- Doing Business With FDA Make Your Connection (http://www.fda.gov/AboutFDA/business/ucm288023.htm)
- FedBizOpps (<u>www.fbo.gov</u>) site includes training videos for small business and instructions on registering and monitoring agency requirements.
- HHS Small Business Office (<u>www.hhs.gov/about/smallbusiness</u>) has information on current requirements, forecasts, "Doing Business," etc.
- The Small Business Administration (<u>www.sba.gov/category/navigation-structure/contracting</u>) 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.

Procurement Forecast Data Repository

This forecast is intended to inform vendors - especially small businesses - about HHS's potential procurement opportunities prior to their official solicitation.

http://procurementforecast.hhs.gov/





Desktop Magnetic Resonance Imaging (MRI) System FDA_16-223-SOL-1159880 66 Instruments & laboratory equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation	Feb 19, 2016
Data Support Services 16-223-SOL-00002 R Professional, administrative, and management support services	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation (Modified)	Feb 18, 2016
High Temp Spiking System FDA-1162607 66 Instruments & laboratory equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Jefferson	Sources Sought	Feb 18, 2016
State Egg Inspections FDA-16-EGG H Quality control, testing & inspection services	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Solicitation (Modified)	Feb 18, 2016
Preventative Service Maintenance on four (4) AB Sciex Mass Spectrometer Systems FDASOL1160529 J Maintenance, repair & rebuilding of equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation (Modified)	Feb 18, 2016
PR@ 1800 System FDA-SOL-1160661 66 Instruments & laboratory equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation	Feb 17, 2016

Dry Ice Delivery- FDA CFSAN Laboratories- College Park/Laurel, MD area only Solicitation_1160249 68 Chemicals & chemical products	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation (Modified)	Feb 17, 2016
Service contract for Oxford Instruments Aztec mics-x-stream2-xmx50 Energy Dispersive X-ray Spectrometer FDA-16-1162035-SS J Maintenance, repair & rebuilding of equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Sources Sought	Feb 17, 2016
Locksmith Support Services 116 L Technical representative services	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Sources Sought	Feb 16, 2016
Reagents FDA-1160690 65 Medical, dental & veterinary equipment & supplies	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Philadelphia	Combined Synopsis/Solicitation / Total Small Business	Feb 16, 2016

Laundry Services FDA-SS-1159229 S Utilities and housekeeping services	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Sources Sought	Feb 12, 2016
Operational Qualification of OpenLAB CDS, OpenLAB ECM, and OpenLAB BPM. FDA-SOL-1159951 J Maintenance, repair & rebuilding of equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation (Modified) / Total Small Business	Feb 12, 2016
Waters Technologies UPLC Components Annual Preventive Maintenance Services FDA_16-223-SOL-1161969 J Maintenance, repair & rebuilding of equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Sources Sought / Total Small Business	Feb 12, 2016
RNA Sequencing Services FDA_16-233-1161993 B Special studies and analysis - not R&D	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation) Total Small Business	Feb 11, 2016
Destruction of Pharmaceuticals at International Mail Facilities FDA-SS-1161537 S Utilities and housekeeping services	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Sources Sought (Modified)	Feb 11, 2016
Operation and Maintenance of Facility Services 16-223-SOL-00006 M Operation of Government-owned facilities	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Jefferson	Presolicitation / Total Small Business	Feb 10, 2016

For Vendors - Getting on Schedule

The GSA Schedules program is the premier acquisition vehicle in government, with approximately \$50 billion a year in spending or 10 percent of overall federal procurement spending.

GSA Schedules are fast, easy, and effective contracting vehicles for both customers and vendors. For GSA Schedules, GSA establishes long-term, governmentwide contracts with commercial companies to provide access to millions of commercial products and services at volume discount pricing.

GSA is always looking to update the offerings under the GSA Schedules program and aid vendors in being successful in the government marketplace. Particularly, the GSA Schedules program has a strong record of small business achievement. In Fiscal Year 2011, 35 percent, or approximately \$13 billion in prime contracting, went to small business.

To be successful under the GSA Schedules program, vendors should be prepared to take necessary steps to be productive in a highly competitive marketplace. Having a GSA Schedule contract is a significant investment on the part of the vendor and GSA. Careful analysis, planning, and proactive steps are required to ensure vendors are successful under the GSA Schedules program.

GSA is committed to helping vendors succeed in the government marketplace. To aid you with your decision to get on a GSA Schedule, here is some important information to consider:

- 80% of GSA Multiple Award Schedule (MAS) contractors are small businesses who represent 36% of sales
- More than \$40B flows through GSA MAS contracts every year
- In FY12, approximately 10% of government needs were procured through the GSA MAS contracts
- GSA had over 19,000 MAS contracts in FY12
- Approximately 40% of the 19,000 GSA MAS contracts generate sales

GSA has developed the <u>Vendor Toolbox</u> which is a collection of resources that will ultimately help you decide whether getting a GSA Schedule contract is in your best interests.

Keep current with the latest news about the Multiple Award Schedules (MAS) program on our MAS Group blog. You may want to view this Interact Webinar and GSA Training videos to get a better understanding of the federal market and how GSA Schedules play a role. Many companies follow GSA Schedules on Twitter.

http://www.gsa.gov/





PURCHASING PROGRAMS

- Assisted Acquisition Overview
- GSA SmartPay®

F-TOOLS

- Supply and Procurement e-Tools
- GSA Advantage!®
- eBuv
- GSA eLibrary
- eOffer/eMod
- Vendor Support Center
- Schedule Sales Query

ADDITIONAL RESOURCES ON GSA.GOV

- List of GSA Schedules
- PBS Industry Relations Division

OAGS Contact Information

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Questions

