

Welcome to the 2019 FDA Small Business Fair

White Oak Great Room May 21, 2019



Office of Finance, Budget & Acquisitions



FDA Office of Acquisitions and Grants Services Overview

May 21, 2019





We Enable FDA's Mission



FDA is responsible for:

- Protecting the public health by assuring foods, drugs (human and veterinary), biological products, medical devices, cosmetics, and dietary supplements are safe and properly labeled; and ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.
- Protecting the public from electronic product radiation.
- Regulating tobacco products; including the manufacturing, marketing, and distribution of tobacco products and to reduce tobacco use by minors.
- Advancing the public health by helping to speed product innovations that make medical products more effective and safer.
- Helping the public get accurate science-based information to use medicines, devices, and foods to improve their health.
- Plays a role in the Nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

What FDA's Major Initiatives Mean for OAGS (1 of 2)



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

FDA

What FDA's Major Initiatives Mean for OAGS [FDA (2 of 2)

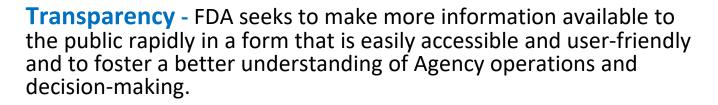


Innovation - FDA is committed to helping deliver innovative, safe, and effective treatments and cures to the patients who need them as quickly as possible. To achieve this goal, we have implemented a variety of expedited review programs and are working to help shorten the development time before a product is even submitted for FDA review.



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.







Sentinel Initiative - the Sentinel Initiative 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



Mission



Our mission is to provide high quality acquisitions and assistance agreements outcomes to FDA.

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

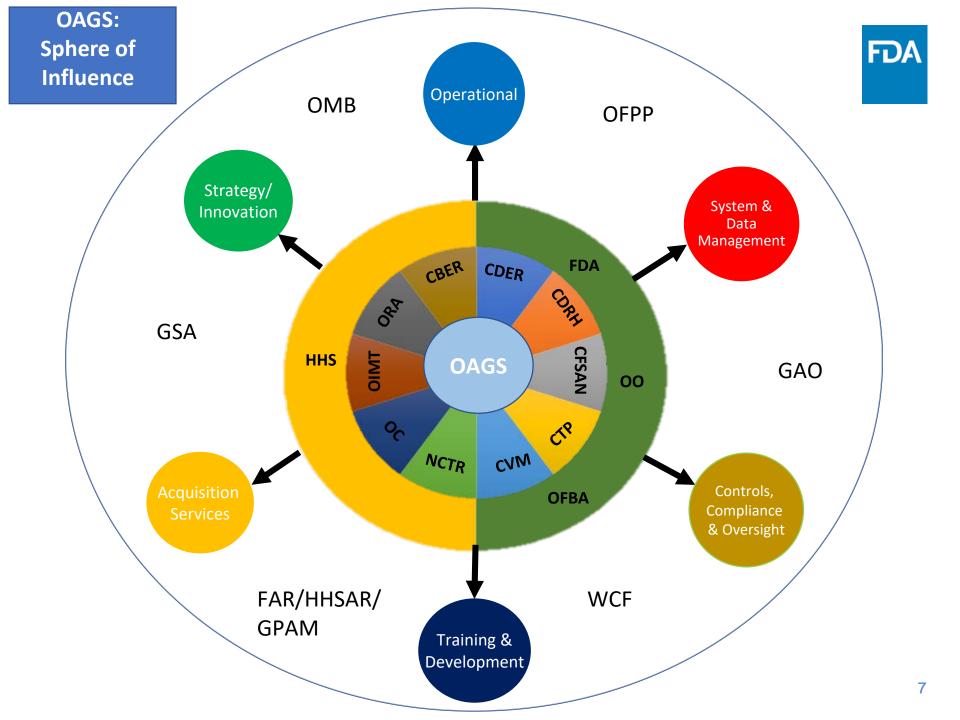
1. Build effective partnerships with our FDA Customers and Stakeholders



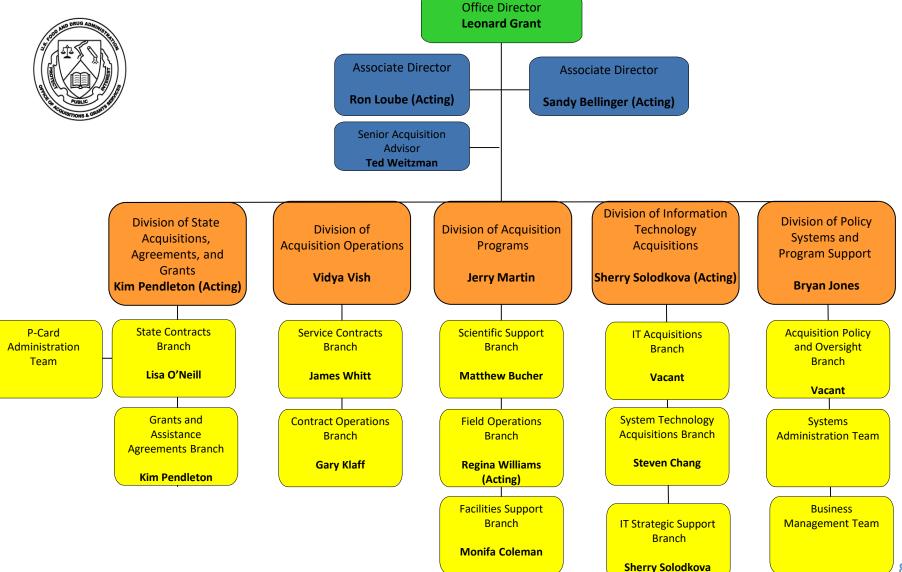
2. Mature our Acquisition Practices

3. Institute a Performance Culture

4. Develop our Organization and our People



OFFICE OF ACQUISITIONS AND GRANTS SERVICES



FDA

How We are Organized









Fiscal Year 2018



Statistics for OAGS

| Purchase Card Data | FY 16 | FY 17 | FY 18 |
|---------------------------------|-----------|-----------|-----------|
| Transaction | \$69.5 M | \$65.8 M | \$66.2 M |
| # of Transactions | 106,162 | 99,260 | 92,225 |
| Cardholder Accounts (Average) | 876 | 847 | 815 |
| Convenience Check Spend | \$180,202 | \$142,315 | \$153,822 |
| Convenience Check Transaction # | 248 | 178 | 146 |
| Rebates Earned | \$1.09 M | \$1.03 M | \$0.94 M |

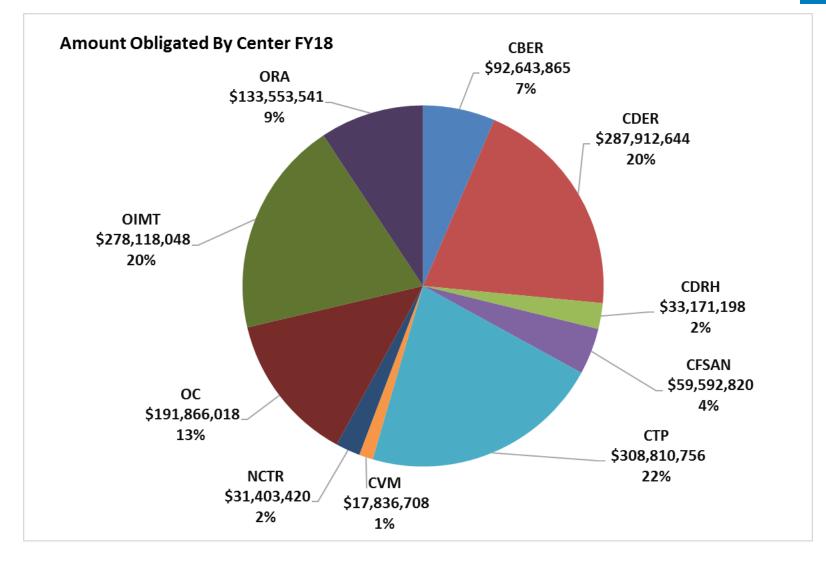
| Fiscal Year Totals* | FY 16 | FY 17 | FY 18 | | | |
|--|----------|----------|----------|--|--|--|
| Actions Awarded | 6,674 | 8,141 | 6,074 | | | |
| Total Obligated | \$1.56 B | \$1.76 B | \$2.00 B | | | |
| *Doesn't include P-Card Data which is obligated external to OAGS nor IAA Reimbursable Dollars which are not considered obligations. | | | | | | |

| Interagency Agreement Data | FY 16 | FY 17 | FY 18 |
|-------------------------------|-----------|-----------|-----------|
| Reimbursable IAAs | 72 | 64 | 55 |
| Reimbursable IAA Dollar Value | | | |
| (Funds-in) | \$27.2 M | \$42.7 M | \$33 M |
| Service IAAs (Funds-out) | 668 | 625 | 601 |
| Service IAAs Total Value | \$227.4 M | \$271.8 M | \$402.7 M |
| Total Awarded | 740 | 689 | 656 |
| Total Obligated | \$277.4 M | \$271.8 M | \$402.7 M |

| Grant Data | FY 16 | FY 17 | FY 18 |
|----------------------------|-----------|-----------|-----------|
| New Competing Grants | 232 | 161 | 165 |
| Non-competing Continuation | | | |
| Grants | 405 | 385 | 389 |
| Total Obligated | \$181.9 M | \$187.2 M | \$199.2 M |

| Contracts (Including PO) Data (DCIS) | FY 16 | FY 17 | FY 18 |
|---|---------|---------|---------|
| Awarded Contracts | 5,297 | 6,906 | 4,864 |
| Total Obligated | \$1.1 B | \$1.3 B | \$1.4 B |

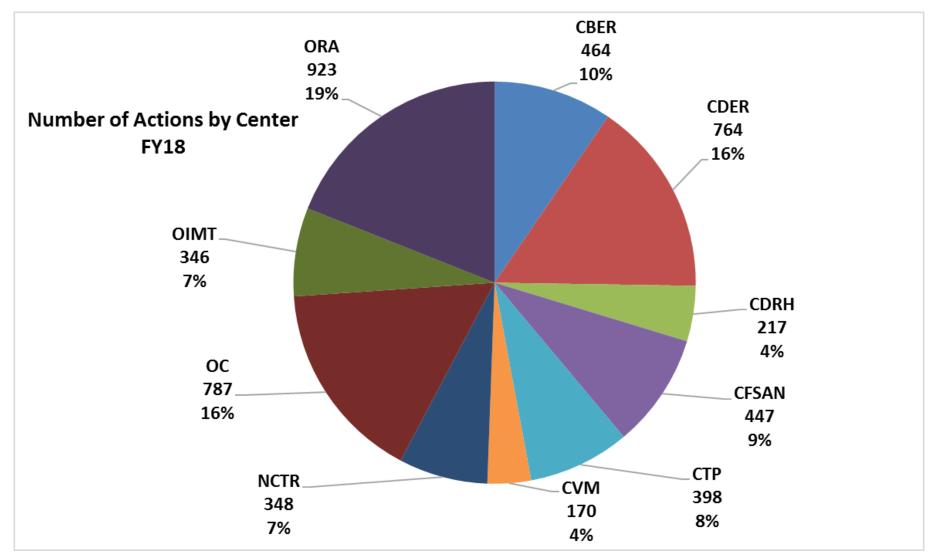
FY18 Statistics for OAGS



Note: This data only represents Contract Awards, not IAAs or Grants

FDA

FY18 Statistics for OAGS



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FDA



FDA SOCIOECONOMIC GOALS

| Small Business Award Categories | FY Goal* | FY12 | FY13 | FY14 | FY15 | FY16 | FY17 | FY18 | FY19 |
|--------------------------------------|--|--------|--------|--------|--------|-------|--------|-------|-------|
| Small Businesses | 40% (35% until FY14) (43% in FY 14) | 55.90% | 48.93% | 43.28% | 50.10% | 48.5% | 39.64% | 36.8% | 70.5% |
| Small Disadvantaged Businesses | 5.0% | 34.70% | 30.69% | 25.28% | 29.50% | 27.9% | 24.31% | 25.0% | 37.0% |
| Women-Owned Small Businesses | 5.0% | 16.55% | 9.92% | 13.63% | 15.90% | 17.8% | 14.22% | 14.1% | 27.3% |
| HubZone Businesses | 3.0% | 3.59% | 2.59% | 3.61% | 2.20% | 2.0% | 1.40% | 1.8% | 5.0% |
| Service Disabled Veteran Owned | 3.0% | 4.68% | 2.14% | 2.93% | 3.17% | 4.9% | 3.42% | 3.4% | 7.9% |

In 2018, FDA awarded more than \$538 Million to Small Businesses.

FDA Competition Data



| Center | Percent of Eligible Actions Competed | Percent of Eligible Dollars Competed |
|----------|---|---|
| HHS Goal | 65% | 75% |
| FY13 | 91.0% | 98.0% |
| FY14 | 90.0% | 96.0% |
| FY15 | 91.0% | 95.0% |
| FY16 | 91.0% | 94.0% |
| FY17 | 90% | 96% |
| FY18 | 89% | 96% |
| FY19 | 88% | 96% |

FY 18 - TOP 20 NAICS BY ACTIONS



| | | Contract | % of Total | Dollars | | % of Dollars |
|---------|--|----------|------------|-----------------|--------------------------|--------------|
| NAICS | Description | Actions | Actions | Obligated | Average | Obligated |
| 334516 | ANALYTICAL LABORATORY INSTRUMENT MANUFACTURING | 551 | 15.2% | \$27,069,562 | \$49,128 | 2.6% |
| 541519 | OTHER COMPUTER RELATED SERVICES | 452 | 12.5% | \$288,670,866 | \$638,652 | 28.0% |
| | ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT | | | | | |
| 541611 | CONSULTING SERVICES | 373 | 10.3% | \$198,295,687 | \$531,624 | 19.3% |
| 541990 | ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES | 341 | 9.4% | \$89,526,344 | \$262,541 | 8.7% |
| 923120 | ADMINISTRATION OF PUBLIC HEALTH PROGRAMS | 319 | 8.8% | \$60,303,002 | \$189,038 | 5.9% |
| | OTHER ELECTRONIC AND PRECISION EQUIPMENT REPAIR AND | | 0.0,0 | +00,000,000 | +=00)000 | |
| 811219 | MAINTENANCE (PT) | 265 | 7.3% | \$9,902,939 | \$37,370 | 1.0% |
| (blank) | n/a - no NAICS | 245 | 6.8% | \$58,473,417 | \$238,667 | 5.7% |
| | RESEARCH AND DEVELOPMENT PHYSICAL, ENGINEERING, LIFE | | | | | |
| 541712 | SCIENCES(EXCEPT BIOTECHNOLOGY) | 121 | 3.3% | \$8,982,565 | \$74,236 | 0.9% |
| | | | | | | |
| 541690 | OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES (PT) | 121 | 3.3% | \$19,952,906 | \$164,900 | 1.9% |
| 541511 | CUSTOM COMPUTER PROGRAMMING SERVICES | 116 | 3.2% | \$90,210,556 | \$777,677 | 8.8% |
| 561210 | FACILITIES SUPPORT SERVICES | 103 | 2.8% | \$15,793,554 | \$153,335 | 1.5% |
| 511210 | SOFTWARE PUBLISHERS | 97 | 2.7% | \$16,500,470 | \$170,108 | 1.6% |
| 541512 | COMPUTER SYSTEMS DESIGN SERVICES (PT) | 82 | 2.3% | \$63,437,834 | \$773,632 | 6.2% |
| 518210 | DATA PROCESSING, HOSTING, AND RELATED SERVICES | 76 | 2.1% | \$56,881,486 | \$748,441 | 5.5% |
| 561320 | TEMPORARY HELP SERVICES | 65 | 1.8% | \$4,476,622 | \$68,871 | 0.4% |
| 541711 | RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY | 64 | 1.8% | \$12,175,457 | \$190,242 | 1.2% |
| | NONUPHOLSTERED WOOD HOUSEHOLD FURNITURE MANUFACTURING | | | | | |
| 337122 | (PT) | 58 | 1.6% | \$206,071 | \$3,553 | 0.0% |
| 922120 | POLICE PROTECTION | 58 | 1.6% | \$80,609 | \$1,390 | 0.0% |
| 511120 | PERIODICAL PUBLISHERS (PT) | 57 | 1.6% | \$5,341,109 | \$93,704 | 0.5% |
| 325414 | BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING | 56 | 1.5% | \$3,359,724 | \$59,995 | 0.3% |
| Grand | | | | , , - | , , - | |
| Total | | 3,620 | 100% | \$1,029,640,781 | \$ <mark>284,43</mark> 1 | 100% |

FY 18 - TOP 20 NAICS BY DOLLARS



| | Description | Dellers Obligated | Contract | % of Dollars |
|------------------|---|-----------------------|-------------|------------------|
| NAICS | | Dollars Obligated | Actions | Obligated |
| 541519 | OTHER COMPUTER RELATED SERVICES | \$288,670,866 | 452 | 28.0% |
| | ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING | | | 10.00/ |
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| 337122 922120 | NONUPHOLSTERED WOOD HOUSEHOLD FURNITURE MANUFACTURING (PT) POLICE PROTECTION | \$206,071 \$80,609 | 58 58 | 0.0% |
| Grand Total | | \$ 1,029,640,781 | 3620 | 100% |



HOW TO DO BUSINESS WITH THE FDA







Federal Acquisition Regulation – primary regulation for use by all Federal Executive agencies in their acquisition of supplies and services





HHSAR -The Department of Health and Human Services (HHS) Acquisition Regulation (HHSAR) establishes uniform HHS acquisition policies and procedures that implement and supplement the FAR. Contains HHS —

- Requirements of law;
- HHS-wide policies;
- Deviations from FAQ requirements

GAO Case Law/Protest Decisions – follow and review

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)
 - https://procurementforecast.hhs.gov/Contract
- 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 a DUNS number to do business with the Federal Government. You must be registered in SAM to do business with the Federal government. <u>www.sam.gov</u>

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 sufficient details to support contractor 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 **DISCRIMATORS**
- Tailor response specifically to the sources sought and provide supporting evidence.
- Document your SB category within NAICS code size standard listed for the proposed acquisition

Effective Capability Statement





- Generally One Page
- Tailor for Specific FDA Center/Program Office
- Core Competencies
- Differentiators
- Team Members/ Subcontractors
- Past Performance
- Visually interesting and appealing

Title this document

CAPABILITY STATEMENT

Show your logo and contact information, with a specific person'sname, phone and email.

This is a CONTENT guide, not a design guide. Add color & graphic elements as appropriate.

Use this section title: Core Competencies

Short introduction statement relating the company's core competencies to the agency's specific needs followed by key-word heavy bullet points

Tips:

- No long paragraphs.
- Use 2-3 short sentences followed by keyword heavy bullet points
- Create a new document for each agency, primeor teaming opportunity
- Tailor each Capability Statement to the agency mission or specific opportunity
- Call this document a Capability Statement
- Preferably, this Capability Statement is one page, one side
- Goto two sides only if absolutely necessary
- Save and distribute as a PDF, not a Word, PowerPoint or other format
- Keep the file format small, definitely under 1MB
- Use the whole page, keep page margins small

Section Title: Past Performance

List past customers for whom you have done similar work. <u>Prioritize</u> by related agency, to all federal to other government to commercial contracts. If the past projects do not relate to the targeted agency's needs, do not list it.

Tip: Ideally, include specific contract details and contact information for immediate references. Include name, title, email, & phone.

Section Title: Differentiators

Identify what makes you different from your competitors and how this benefits the targeted agency

> Tip: Relate your key differentiators to specific needs of the agency, prime or teaming partner.

COMPANY DATA

One very brief company description detailing pertinent data.

Tips: Readers will visityour web site for additional information. Make sure your web site is constantly updated and government-focused. Use graphics if they help tell your story and describe your fit with the target.

List Specific Pertinent Codes and Data:

- DUNS
- CAGE Code
- NAICS (a reasonable number, fewer than 10)
- Socio-economic certifications: 8(a), HUB Zone, SBVOSB, WOSB.
- Accept Credit and Purchase Cards
- GSA Schedule Contract Number(s) and SIN
- Other federal contract vehicles
- BPAs and other federal contract numbers
- Pertinent teaming agreements

Your logo, address, phone numbers (voice, mobile and fax) email, web site and other related contact information.

Request For Proposal (RFP) Pointers



- Are you capable? Make an intelligent/informed business decision
- Read, read, and re-read: SOW/SOO, proposal instructions, and evaluation criteria
- Answer the mail: "How" are you are going to do the job do not parrot back the RFP
- Demonstrate your understanding of the requirement (provide your unique solution) & 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

"Myth-Busting": *Misconceptions about Agency Communications with Industry during Acquisition Process* (OFPP Memorandum – May 7, 2012)



OFPP Myth Busters Campaign

Key theme: There are NOT prohibitions against communicating with vendors one-on-one before a solicitation is released

- FAR 15.201(a) promotes exchanging information "among all interested parties, from the earliest identification of a requirement through receipt of proposals."
- FAR 15.201(f) notes that before a release of a solicitation "general information about agency mission needs and future requirements may be disclosed at any time.'
- Parameter: Prospective contactors must be treated fairly and impartially and that standards of procurement integrity be maintained (FAR 3.104) FAR does not require meetings include all potential offerors, nor does it prohibit one-on-one meetings. However, all potential offerors must be provided any information shared in a meeting that could directly affect the preparation of their proposals.

"Myth-Busting"



MARKETING

Vendors should include only 'business development' and 'marketing staff' in meetings with an agency's technical staff. Subject matter experts are far more helpful than a sales presentation.

FACT

"Myth-Busting"



MARKETING

Best way for vendors to communicate their capabilities is by marketing directly to CO's or signing them up for mailing lists. FACT

CO's and other agency officials are inundated with marketing material that doesn't reach the right people at the right time. Instead, vendors should take advantage of agency events that help connect CO's and program managers with industry.





MYTH

Vendors don't need to tailor their solutions to the specific solicitations at hand, because the agency won't read proposals that closely.

FACT

Vendors should tailor each proposal to the evaluation criteria, proposal instructions, and specific requirements of each solicitation. CO's and evaluation team members read proposals closely for compliance with proposal instructions and must evaluate only against evaluation factors and other award criteria.

BEST PRACTICES

- Develop checklist of solicitation requirements to ensure response/solution is provided for each.
- Respond to all evaluation factors, including past performance information.
- Don't cut and paste from the RFP.
- Don't assume the government will give credit for good performance if it's not documented in the proposal.







Debriefing sessions aren't valuable, because the contracting official will not share any helpful information.



Unsuccessful [and successful] offerors should ask for a debriefing to understand the award decision and improve future proposals.

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.

| HHS U.S. Depar | .GOV rtment of Health & H | uman Se | ervices | l'm look | king for | | Q | |
|--------------------------------------|---|--------------|-------------|--------------------------|---------------|----------------|--------------|--|
| About HHS | HHS Secretary | News | Jobs | Contracts & Grants | Prevention | Regulations | Preparedness | |
| Procurement Forecast Data Repository | | | | | | | | |
| Search Contract Opportunities | | | | | | | | |
| > Advance Keyword keyword | | Quick S | ٩ | Search | earch Results | | | |
| | Opportunities - S | earch l | Results | | | | | |
| Show 50 V | 50 of 186 entries entries Contract Information | â Com | petition Ty | be 🍦 Tot. Contract Range | Place of Pe | < Previous 1 2 | 3 4 Next > | |
| | (COMMS) BPA in support of services-Public EngagementOutreach tra Funding Org: FDA Description: (COMMS) - Pla Professionals Ltd BPA in su | of TBD ck | | > \$25K and < \$150K | , net or t | | 24/2018 | |
| | (RPSM Risk Analytics) Lice for an Oracle tool – OPM Funding Org: FDA Description: (RPSM Risk Analytics) License for an Ora tool – | | | >= \$1M and < \$2M | | 06/ | 30/2018 | |

Key Opportunities below SAT

| Detailed Description | Opportunity Type | Anticipated RFP/RFQ Release | Center |
|--|------------------|-----------------------------------|----------|
| OCE - Identify Tobacco Retailers in Minority/Near Schools | Less than \$250K | 6/1/2019 | СТР |
| OCE - Identifying Tribal Tobacco Retailers | Less than \$250K | 6/1/2019 | СТР |
| OCE - Tribal Retail Inspection RFP | Less than \$250K | 6/1/2019 | СТР |
| Arbitrator Services | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| Cryopreservation Services | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| Expert Witness Services | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| HVAC Air Handler Filters | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| Dry Ice | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| Office Furniture | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| Off-Site Records Storage | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| Printers and Copiers | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| Scientific and Laboratory Equipment (e.g., Ultra-Low Temperature Freezers) | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |
| Transcription Services | Less than \$250K | 3/29/2019 - 6/28/2019 | FDA-Wide |

Key Opportunities above SAT

| OAGS DIVISION | Purchase Request Title | Detailed Description | Opportunity Type | Anticipated RFP/RFQ Release | Center |
|------------------|---|--|------------------------|-----------------------------------|--------|
| DITA | Cellular Services Enhancement (RFI) | Seeking contractor to enhance the signal strength of cellular service at its NCTR campus | Greater than \$250K | 3/1/2019 | NCTR |
| DAP | IVRT, IVPT, in vivo animal model PK and drug distribution studies | Develop and conduct appropriate IVRT, IVPT, in vivo animal model PK and drug distribution studies, and/or in vivo animal model PD studies of locally-acting topical dermal and ophthalmic drug product formulations. | Greater than \$250K | 3/1/2019 | CDER |
| DAO | Communications Support Services recompete CTP- 19-C-0156 | Full-range of regulatory communications activities associated with planning, development, implementation, reporting and analysis of the effectiveness of a robust Federal health communication and education program, including: communications strategy development; research; message and creative development; paid, earned and owned media planning and placement; measurement, analysis and reporting; materials management and dissemination services; web and database support; and exhibit management and support. | Greater than \$250K | 3/15/2019 | CTP |
| DAP | Move and Labor Services | Move and Labor Services, Competitive 8(a) Small Business Set-aside | Greater than \$250K | 4/1/2019 | OFEMS |
| DAO | Records Information Management | The scope of this contract entails operation, management, and support of FDA onsite document, records and information management related activities. Support encompasses records lifecycle activities, quality control, DCC management, storage services, onsite DCC scanning, training, metadata management, and records management. | Greater than \$250K | 4/15/2019 | OHS |
| DITA | DIMES | Acquire professional DevSecOps, Innovation, Modernization, and Engineering Services to modernize FDA's applications and infrastructure | Greater than \$250K | 4/30/2019 | OIMT |

Key Opportunities above SAT (contd)



| OAGS DIVISION | Purchase Request Title | Detailed Description | Opportunity Type | Anticipated RFP/RFQ Release | Center |
|------------------|--|--|------------------------|-----------------------------------|--------|
| DAO | Public Meeting OAO-19-C- 2128 | Conference event planning | Greater than \$250K | 5/1/2019 | CFSAN |
| DAO | A-123 Appendix D Assessment | Technical expertise and advisory services to support FDA's audit readiness, internal control program, fraud risk management, and compliance efforts as set forth by OMB, GAO, and DHHS regulations, policies and guidance | Greater than \$250K | 5/1/2019 | OFBA |
| DAO | Recruitment (a new BPA to cover all types of recruitment from GS13 to SES) | Provide qualified Executive, Senior, and Mid-Level Clinical and Non- Clinical candidates for any CDRH staffing requirements. This support may also be related to new positions tied to a strategic focus – not something tied to attrition. | Greater than \$250K | 5/1/2019 | CDRH |
| DSAAG | Northern Mariana Island Enforcement Contract via retailer inspections | Northern Mariana Island : Northern Mariana Island Enforcement Contract via retailer inspections | Greater than \$250K | 5/1/2019 | СТР |
| DSAAG | Puerto Rico Enforcement Contract via retailer inspections. Puerto Rico : Puerto Rico Enforcement Contract via retailer inspections. | | Greater than \$250K | 5/1/2019 | СТР |
| DSAAG | G OCE - State Contract Evaluation and Site Visit Coordination | | Greater than \$250K | 5/1/2019 | СТР |

Key Opportunities above SAT (contd)



| OAGS DIVISION | Purchase Request Title | Detailed Description | Opportunity Type | Anticipated RFP/RFQ Release | Center |
|------------------|--|--|------------------------|-----------------------------------|--------|
| DAO | Information Technology Program and Project Management | IT program and project management support services to facilitate all phases of the IT Enterprise Performance Life Cycle (EPLC). FDA-IPS support includes: strategic planning, concept development and project initiation, configuration design and functional area analysis, program and systems analysis and modeling, quality assurance, service-oriented architecture, audit activities as well as mentoring and program and project coordination support, senior and junior level assistance with the daily management of their projects including administrative assistive and process tools, documentation, and privacy implementation. | Greater than \$250K | 6/1/2019 | OIMT |
| DAP | Pathology Services at the FDA's National Center for Toxicological Research | Pathology support, ranging from necropsy of a few animals and collection of a few tissues to complete necropsy of over a thousand animals requiring special handling of tissues, histopathology, special staining or other techniques (immunohistochemistry, digital imaging, etc.), hematology, urinalysis, and/or clinical chemistry. Other required techniques include, but are not limited to, teratology techniques, reproductive and developmental toxicology techniques, respiratory pathology techniques (inhalation toxicology studies), sperm morphology and motility analysis, vaginal cytology, vaginal smears for sperm evaluations, and mammary whole mounts. | Greater than \$250K | 9/1/2019 | NCTR |
| DAP | Operation & Maintenance of Facilities Jefferson Laboratories Complex | Services include, but are not limited to, operation and maintenance of all campus utility systems; craft shop support services; operation and maintenance of utility plants and equipment; maintenance of all process and non-process equipment; maintenance, alteration and repair of buildings and structures; pest control and grounds maintenance; janitorial and housekeeping services; and cafeteria food service operations at the FDA's Jefferson Laboratories Complex located in Jefferson, Arkansas. | Greater than \$250K | 11/1/2019 | NCTR |

Potential Subcontracting Opportunities

| OAGS DIVISION | Purchase Request Title | Detailed Description | Opportunity Type | Anticipated RFP/RFQ Release | Center |
|------------------|---|--|--|-----------------------------------|--------|
| DAP | CTP - Consumer Reactions and interpretations | Provide data on reactions and interpretations of consumers and other individuals regarding questions of immediate concern through formative, qualitative, and/or quantitative research methodologies to support enforcement of matters relating to tobacco products' labeling, marketing, advertising, and promotion and/or to support rulemaking efforts, policy decisions, and guidance development. | Subcontracting Possibility | 3/21/2019 | СТР |
| DAP | CTP - in vivo and in vitro toxicological analyses of tobacco and related products | Support the FDA's implementation of the Tobacco Control Act through in vivo and in vitro toxicological analyses of tobacco and related products. | , and the second s | 4/1/2019 | СТР |
| DAP | Phase I Clinical trials | Provision of a Phase I clinical research unit, the conduct of Phase I clinical trials and the provision of a full range of services to support the clinical trials and result reporting. | Subcontracting Possibility | 4/1/2019 | CDER |
| DAP | Sentinel Initiative FY 2019 | This requirement seeks to strengthen the core capabilities of Sentinel and direct the program to meet the challenges during the period of performance. Specifically, the objectives are to maintain current production-level analytic capabilities and Build enhanced capabilities and improve the data infrastructure | Subcontracting Possibility | 4/1/2019 | CDER |
| DITA | DevSecOps, Innovation, Modernization, and Engineering Services (DIMES) | Infrastructure Modernization, Mobility, Cloud, Technology Innovation, Data Governance - Single Award BPA or IDIQ | Subcontracting Possibility | 4/1/2019 | OIMT |
| DITA | Voice, Data, & Network Services | Telecommunications - Migration of FDA Voice, Data, and Network Services - Via GSA's EIS GWAC | Subcontracting Possibility | 4/1/2019 | ΟΙΜΤ |
| DITA | CTP - IT Systems Support BPA | O&M and development of many IT systems for the Center for Tobacco Products - Multiple Award BPA | Subcontracting Possibility | 5/1/2019 | ΟΙΜΤ |

| ★ FedB | JIZOPPS.G | Federal Business Opportunitie | s | E. | GOV USA.gov |
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| Home | Getting Started | General Info | Opportunities | Agencies | Privacy |
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FDA

FedBiz Opportunities FDA



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|--|---|---|--------------|
| Opportunity | Agency/Office/Location 🔻 | Type ▼ / Set-aside ▼ | Posted On 🔺 |
| HIV Risk Questionnaire (HRQ) Study / Assessment of the Predictive Value of a Panel of Questions for Recent Infection with HIV FDA_1209847 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 | Sources Sought / Total Small Business | Mar 15, 2019 |
| FDA IT Lifecycle Support Services FDA_RFTOP_1210222 D Information technology services, including telecommunications services | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Fair Opportunity / Limited Sources Justification | Mar 15, 2019 |
| BioSpot Bioaerosol Sampler FDA-1207922 66 Instruments & laboratory equipment | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Jefferson | Award / Total Small Business | Mar 15, 2019 |
| RFP for Investigation into Waterpipe Physical Design Parameters Effects on HPHC Yields in Smoke and Charcoal Emissions FDA-19-RFP-1209909 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 (Modified) | Mar 14, 2019 |
| (3) Genetic Analyzer Systems, Thermocyclers, UV Gel Imagers, FDA-19-SOL-1210123 66 Instruments & laboratory equipment | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Combined Synopsis/Solicitation | Mar 13, 2019 |
| Multi-Method Consumer Perception Investigations FDA-RFP-19-1201023 A Research & Development | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Presolicitation (Modified) | Mar 13, 2019 |
| Preventive Maintenance Agreement for Zeiss Microscopes FDA_19-223-SOL-1211358 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 | Mar 13, 2019 |
| Sentinel Initiative FDA-19-RFP-1209951 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 | Presolicitation (Modified) | Mar 13, 2019 |
| Texture Analyzer FDASOL1211700 66 Instruments & laboratory equipment | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Combined Synopsis/Solicitation / Total Small Business | Mar 12, 2019 |

FedBiz Opportunities (cont'd)

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| 24 age-matched baboons (6-9 months of age) Bordetella Free Weanling Baboons FDA_SOL_1210087 88 Live animals | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Jefferson | Combined Synopsis/Solicitation (Modified) | Mar 12, 2019 |
|--|---|---|--------------|
| Protein Detection System FDASOL1210215 66 Instruments & laboratory equipment | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Combined Synopsis/Solicitation / Total Small Business | Mar 11, 2019 |
| Egg Baseline Study FDA-SourceSought-1210539 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 | Sources Sought | Mar 11, 2019 |
| Postmortem Toxicology FDA-SSN-1210605 Q Medical services | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Sources Sought | Mar 08, 2019 |
| RFI - Fully Integrated Records Facility FDA-19-RFI-FIRF R - Professional, administrative, and management support services | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Sources Sought (Modified) | Mar 08, 2019 |
| High Throughput Next-Generation Sequencing (NGS) System FDA_19-233-1210758 66 Instruments & laboratory equipment | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Combined Synopsis/Solicitation | Mar 08, 2019 |
| Service contract CytoPatch Automated Patch Clamp System FDA-19-NOI-1211007 66 Instruments & laboratory equipment | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Presolicitation | Mar 08, 2019 |
| <u>Compact High-performance Ion Mobility Mass</u> <u>Spectrometry System</u> FDA-19-RFQ-1211325 66 Instruments & laboratory equipment | Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville | Combined Synopsis/Solicitation / Total Small Business | Mar 07, 2019 |

In Summary.... What Really Works?



- Review HHS Small Business website /Attend Outreach
- Know agency mission (which agencies procures your products/services)
- Understand federal acquisition process (FAR and agency rules)
- Obtain GSA Schedule
- Procurement Forecast
- FedBizOpps
- Past Performance
- Subcontracting Opportunities

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Questions