

# Welcome to the 2019 FDA Small Business Fair

White Oak Great Room March 18, 2019



Office of Finance, Budget & Acquisitions



# **Opening Remarks**

### Jay Tyler Chief Financial Officer



Office of Finance, Budget & Acquisitions



### FDA Office of Acquisitions and Grants Services Overview

March 18, 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.



**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 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

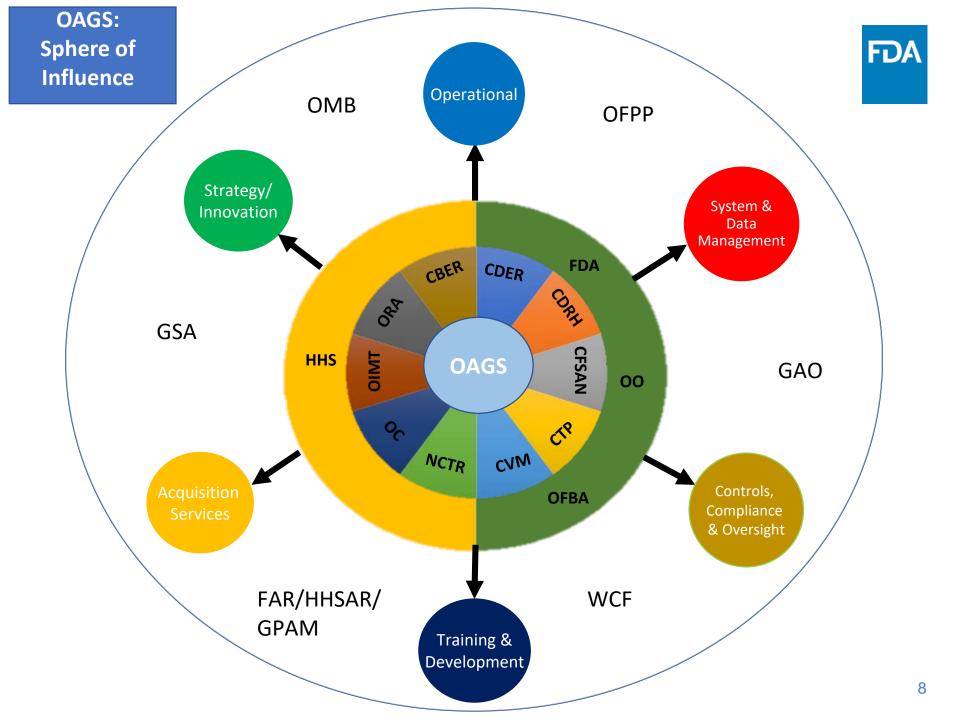
**1.** Build effective partnerships with our FDA Customers and Stakeholders



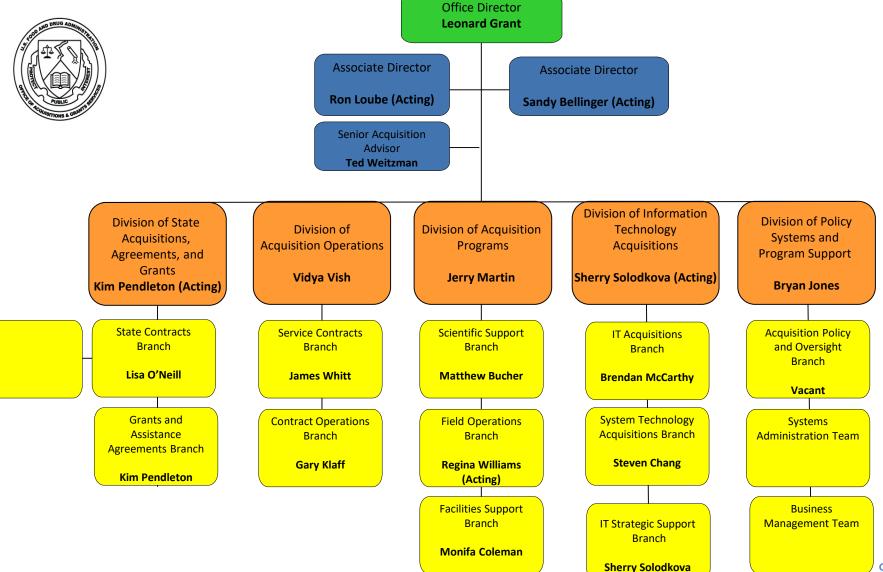
2. Mature our Acquisition Practices

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

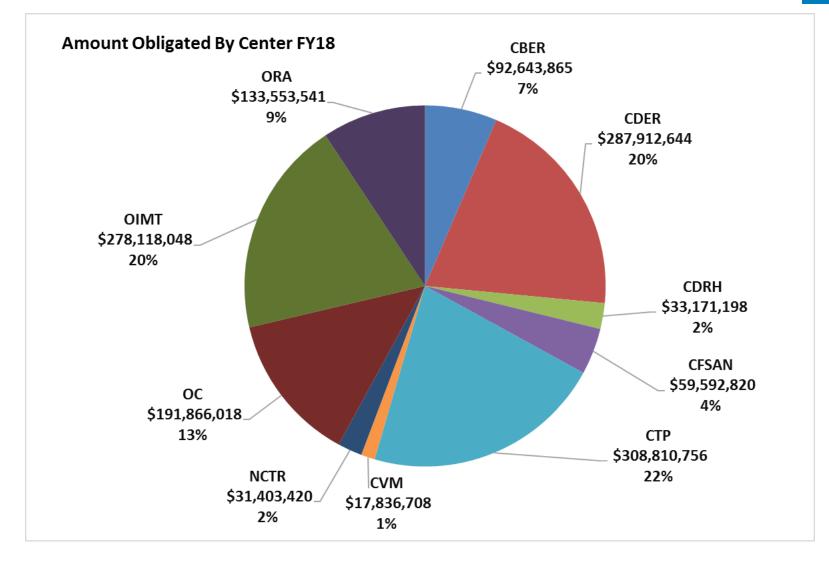
Fiscal Year Totals*	FY 16	FY 17	FY 18				
Actions Awarded	6,674	8,141	6,074				
Total Obligated	\$1.56 B	\$1.76 B	\$2.00 B				
*Doesn't include P-Card Data which is obligated external to OAGS nor IAA Reimbursable Dollars which are not considered obligations.							

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

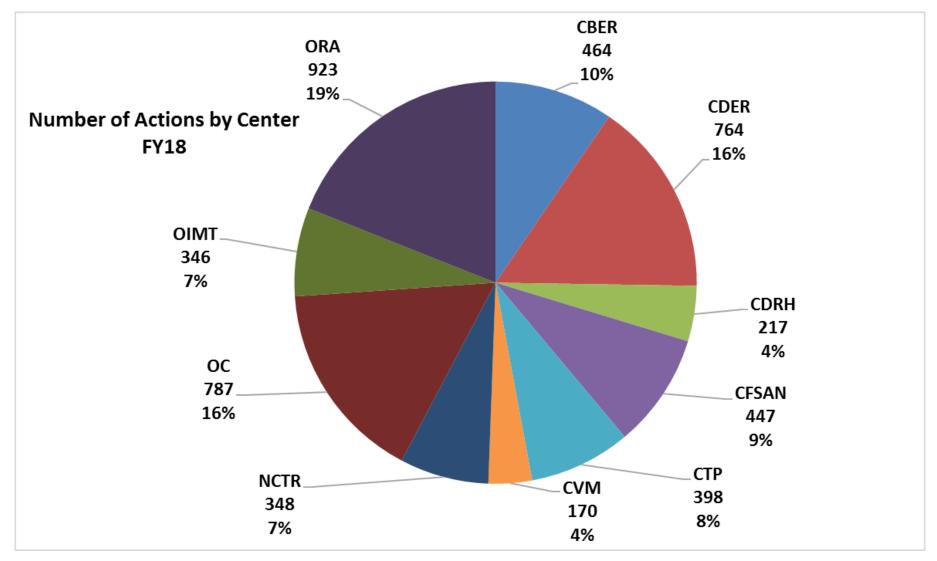
### **FY18 Statistics for OAGS**



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

FDA

### **FY18 Statistics for OAGS**



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

FDA



### FDA SOCIOECONOMIC GOALS

FY Goal*	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19
<b>40%</b> (35% until FY14) (43% in FY 14)	55.90%	48.93%	43.28%	50.10%	48.5%	39.64%	36.8%	70.5%
5.0%	34.70%	30.69%	25.28%	29.50%	27.9%	24.31%	25.0%	37.0%
5.0%	16.55%	9.92%	13.63%	15.90%	17.8%	14.22%	14.1%	27.3%
3.0%	3.59%	2.59%	3.61%	2.20%	2.0%	1.40%	1.8%	5.0%
2.0%	4 69%	2.4.4%	2.02%	2 47%	4.0%	2 42%	2 49/	7.9%
	Goal* 40% (35% until FY14) (43% in FY 14) 5.0%	Goal*         FY12           40%	Goal*         FY12         FY13           40% (35% until FY14) (43% in FY 14)         55.90%         48.93%           5.0%         34.70%         30.69%           5.0%         16.55%         9.92%           3.0%         3.59%         2.59%	Goal*         FY12         FY13         FY14           40%	Goal*         FY12         FY13         FY14         FY15           40% (35% until FY14) (43% in FY 14)         55.90%         48.93%         43.28%         50.10%           5.0%         34.70%         30.69%         25.28%         29.50%           5.0%         16.55%         9.92%         13.63%         15.90%           3.0%         3.59%         2.59%         3.61%         2.20%	Goal*FY12FY13FY14FY15FY1640% (35% until FY14) (43% in FY 14)55.00%48.93%43.28%50.10%48.5%5.0%34.70%30.69%25.28%29.50%27.9%5.0%16.55%9.92%13.63%15.90%17.8%3.0%3.59%2.59%3.61%2.20%2.0%	Goal*FY12FY13FY14FY15FY16FY17 $40\%_{(35\% until FY14)}_{(43\% in FY 14)}$ 55.90% $48.93\%$ $43.28\%$ $50.10\%$ $48.5\%$ $39.64\%$ 5.0%34.70%30.69%25.28%29.50%27.9%24.31%5.0%16.55%9.92%13.63%15.90%17.8%14.22%3.0%3.59%2.59%3.61%2.20%2.0%1.40%	Goal*         FY12         FY13         FY14         FY15         FY16         FY17         FY18           40% (35% until FY14) (43% in FY 14)         355.90%         48.93%         43.28%         50.10%         48.5%         39.64%         36.8%           5.0%         34.70%         30.69%         25.28%         29.50%         27.9%         24.31%         25.0%           5.0%         16.55%         9.92%         13.63%         15.90%         17.8%         14.22%         14.1%           3.0%         3.59%         2.59%         3.61%         2.20%         2.0%         1.40%         1.8%

#### 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			, , ,	. ,	
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%
					4	
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 <i>,</i> 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	\$284,431	100%

# FY 18 - TOP 20 NAICS BY DOLLARS



			Contract	% of Dollars
NAICS	Description	Dollars Obligated	Actions	Obligated
541519	OTHER COMPUTER RELATED SERVICES	\$288,670,866	452	28.0%
	ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING			
541611	SERVICES	\$198,295,687	373	19.3%
541511	CUSTOM COMPUTER PROGRAMMING SERVICES	\$90,210,556	116	8.8%
541990	ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES	\$89,526,344	341	8.7%
541512	COMPUTER SYSTEMS DESIGN SERVICES (PT)	\$63,437,834	82	6.2%
923120	ADMINISTRATION OF PUBLIC HEALTH PROGRAMS	\$60,303,002	319	5.9%
(blank)	n/a - no NAICS	\$58,473,417	245	5.7%
518210	DATA PROCESSING, HOSTING, AND RELATED SERVICES	\$56,881,486	76	5.5%
334516	ANALYTICAL LABORATORY INSTRUMENT MANUFACTURING	\$27,069,562	551	2.6%
541690	OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES (PT)	\$19,952,906	121	1.9%
511210	SOFTWARE PUBLISHERS	\$16,500,470	97	1.6%
561210	FACILITIES SUPPORT SERVICES	\$15,793,554	103	1.5%
541711	RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY	\$12,175,457	64	1.2%
811219	OTHER ELECTRONIC AND PRECISION EQUIPMENT REPAIR AND MAINTENANCE (PT)	\$9,902,939	265	1.0%
541712	RESEARCH AND DEVELOPMENT PHYSICAL, ENGINEERING, LIFE SCIENCES (EXCEPT BIOTECHNOLOGY)	\$8,982,565	121	0.9%
511120	PERIODICAL PUBLISHERS (PT)	\$5,341,109	57	0.5%
561320	TEMPORARY HELP SERVICES	\$4,476,622	65	0.4%
325414	BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING	\$3,359,724	56	0.3%
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**

FDA



- 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:

- Nolong paragraphs.
- Lise 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), HUBZone, 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 logs, 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								
Keyword keyword								
	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	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.		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	ΟΙΜΤ
DITA	Voice, Data, & Network Services	Telecommunications - Migration of FDA Voice, Data, and Network Services - Via GSA's EIS GWAC	Subcontracting Possibility	4/1/2019	OIMT
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	28	E-	E-GOV USA.gov		
	Home	Getting Started	General Info	Opportunities	Agencies	Privacy		
9	Posted Date: Last 90 E	Any Any Any State or Territory	Type: Any Agency: D	Inities.	Locate acti Recover SEARCH I SEARCH SEARCH SEARCH SEARCH Click h Click h Click h Click h	RECOVERY ons funded by the American y and Reinvestment Act. RECOVERY OPPORTUNITIES CH RECOVERY AWARDS COVERY REPORTS ere for Opportunities ere for Opportunities ere for Awards to learn more.		
	ATTENTION: Agency users are responsible for properly uploading controlled, unclassified materials to FBO using the access control procedures for document packages and attachments detailed in the <u>FBO Buyers Guide</u> . Do not upload ANY classified materials to FBO.					BUSINESS EVENTS about the Small Business ent Listing or <u>search now</u> for ISMALL BUSINESS EVENTS		
	Buyers / Eng Government users may opportunities. Username Password	ineers post, manage, and award View Opportunities No login is required to vi opportunities. Register Now Password Reminder Recovery FAQs	<u>Vendors</u> and citi opportunities. Username	/ Citizens izens may search, monitor, au > <u>Find Opportun</u> No login is requ opportunities. > <u>Reqister Now</u> > <u>Password Rer</u> > <u>Recovery FAQ</u>	nd retrieve FBO now or Collaboratio more or sea uired to view VEN minder 2 User ( b S Uver Vendor Engineer	DOR COLLABORATION		

FDA

### FedBiz Opportunities FDA



		• •	
Opportunity	Agency/Office/Location 🔻	Type ▼ / Set-aside ▼	Posted On 🔺
<ul> <li>HIV Risk Questionnaire (HRQ) Study / Assessment of the Predictive Value of a Panel of Questions for Recent Infection with HIV FDA_1209847</li> <li>B - Special studies and analysis - not R&amp;D</li> </ul>	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
<ul> <li>RFP for Investigation into Waterpipe Physical Design Parameters Effects on HPHC Yields in Smoke and Charcoal Emissions</li> <li>FDA-19-RFP-1209909</li> <li>B – Special studies and analysis - not R&amp;D</li> </ul>	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation (Modified)	Mar 14, 2019
<ul> <li>(3) Genetic Analyzer Systems, Thermocyclers, UV Gel Imagers,</li> <li>FDA-19-SOL-1210123</li> <li>66 Instruments &amp; laboratory equipment</li> </ul>	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
<ul> <li>Preventive Maintenance Agreement for Zeiss Microscopes</li> <li>FDA_19-223-SOL-1211358</li> <li>J Maintenance, repair &amp; rebuilding of equipment</li> </ul>	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)

DA

<ul> <li>24 age-matched baboons (6-9 months of age) Bordetella</li> <li>Free Weanling Baboons</li> <li>FDA_SOL_1210087</li> <li>88 Live animals</li> </ul>	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
<ul> <li>Egg Baseline Study</li> <li>FDA-SourceSought-1210539</li> <li>B Special studies and analysis - not R&amp;D</li> </ul>	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
Compact High-performance Ion Mobility Mass     Spectrometry System     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

### **OAGS Contact Information**



Ron Loube, Acting Associate Director, 240-402-7539 / ronald.loube@fda.hhs.gov

Sandy Bellinger, Acting Associate Director, 240-402-7524 / sandra.bellinger@fda.hhs.gov

Ted Weitzman, Senior Acquisition Advisor, 240-402-7626 / theodore.Weitzman@fda.hhs.gov

Sherry Solodkova, Acting Director, Division of Information Technology Acquisitions (DITA) 240-402-7554 / sherry.solodkova@fda.hhs.gov

Jerry Martin, Director, Division of Acquisition Programs (DAP) 240-402-7608 / jerry.martin@fda.hhs.gov

Kim Pendleton, Acting Division of State Acquisition, Agreements, and Grants (DSAAG) 240-402-7539 / kimberly.pendleton@fda.hhs.gov

Vidya Vish, Director, Division of Acquisition Operations (DAO) 240-402-7576 / <u>vidya.vish@fda.hhs.gov</u>

Bryan Jones, Director, Division of Systems, Policy, and Program Support (DPSPS) 240.402.7571 / <u>bryan.jones@fda.hhs.gov</u>

<sup>7</sup> Anita Allen, Small Business Specialist, anita.allen1@cms.hhs.gov





# Questions