

FDA Office of Acquisitions and Grants Services Hub-Zone Small Business Vendor Outreach Event

June 25, 2018





Agenda FDA



- Who We Are
- What We Do
- How We Are Organized
- Our Focus
- Working with OAGS

We Enable FDA's 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 US territories and possessions.

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.

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





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 - Sentinel is the FDA's national electronic system which enhances researchers' ability to proactively monitor the safety of medical products after they have reached the market and complements the Agency's existing Adverse Event Reporting System.

Centers/Offices that OAGS Supports





Center for Biologics Evaluation and Research (CBER)

Center for Drug Evaluation and Research (CDER)

Center for Devices and Radiological Health (CDRH)

Center for Food Safety and Applied Nutrition (CFSAN)

Center for Tobacco Products (CTP)

Center for Veterinary Medicine (CVM)

National Center for Toxicological Research (NCTR)

Office of Information Management 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 its mission please visit www.fda.gov.

OAGS Mission, Vision & Goals



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

- 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

How We are Organized



Grants and Assistance Agreements Branch

Negotiate, award and monitor federal funds awarded through various grant mechanisms. Award ad administer Inter-Agency Agreements (IAGs)

State Contracts Branch

Contracts to support the Mammography Standards Quality Act, Food, Tissue and Feed Programs. These contracts commission the states to conduct inspections to ensure the quality and safety of the nations' food, animal feed and medical devices

Facilities Support Branch

Provides facility support, furniture, construction and renovation, architect/engineering services contracts and simplified acquisitions for all headquarter locations, Irvine, San Juan, and Dauphin Island

Business Management Team (BMT) Facilitates collaboration between OAGS and the FDA Center/Offices to provide early acquisition support and multidisciplinary technical expertise in

Services Branch

Service contracts and simplified acquisitions, including but not limited to, document control/records management, events management, management support services, guard services, moving, library support, custodial, etc.

Contract Operations Branch

Service contracts and simplified acquisitions, including but not limited to, studies chemicals/drugs/reagents, animals, lab equipment, etc.

Field Operations Branch

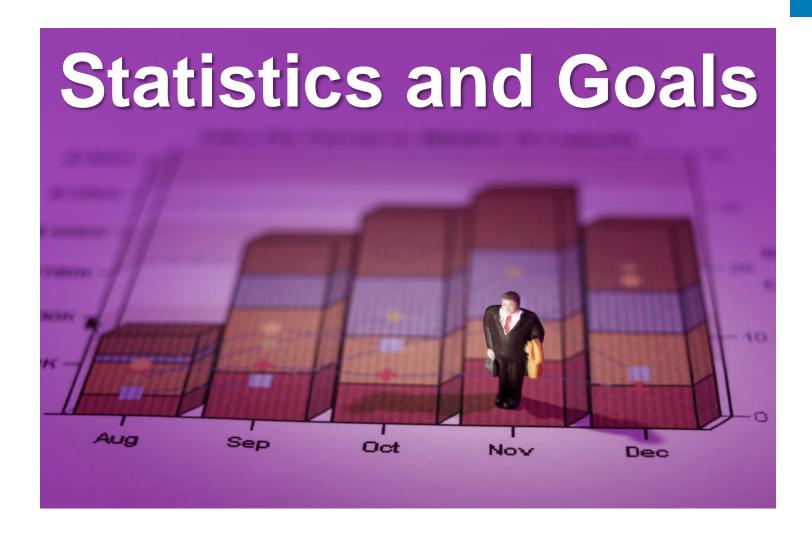
Provides support for National Center for Toxicological Research (NCTR) (Jefferson, AR) related work as well as lab supplies and lab equipment as designated

order to make the acquisition

Scientific Support Branch

Mission specific contracts and simplified acquisitions, including research and development requirements and lab supply and equipment requirements





Fiscal Year 2017

Statistics for OAGS

Purchase Card Data	FY 16	FY 17
Transaction	\$69.5M	\$65.8M
# of Transactions	106,162	99,260
Cardholder Accounts (Average)	876	847
Convenience Check Spend	\$180,202	\$142,315
Convenience Check Transaction #	248	178
Rebates Earned	\$1.09M	\$1.03M

Grant Data	FY 16	FY 17
Awarded Grants	637	542
Post Award Grant Actions	452	731
Total Obligated	\$182.1 M	\$187.2 M



Fiscal Year Totals*	FY 16	FY 17	
Actions Awarded	7,126	8,185	
Total Obligated	\$1.56 B	\$1.76 B	
*Doesn't include P-Card Data which is obligated external to OAGS			

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

Contracts (Including PO) Data	FY 16	FY 17
Awarded Cotnracts	5,297	6,223
Total Obligated	\$1.1 B	\$1.3 B

FDA Socioeconomic Goals FDA



Small Business Award Categories	FY Goal*	FY12	FY13	FY14	FY15	FY16	FY17	FY18 (YTD as of 6/20/18)
Small Businesses	41% (35% until FY14) (43% in FY 14)	55.90%	48.93%	43.28%	50.10%	48.5%	39.64%	37.67%
Small Disadvantaged Businesses	5.0%	34.70%	30.69%	25.28%	29.50%	27.9%	24.31%	25.38%
Women-Owned Small Businesses	5.0%	16.55%	9.92%	13.63%	15.90%	17.8%	14.22%	15.28%
HubZone Businesses	3.0%	3.59%	2.59%	3.61%	2.20%	2.0%	1.40%	1.04%
Service Disabled Veteran Owned	3.0%	4.68%	2.14%	2.93%	3.17%	4.9%	3.42%	3.85%

In 2017 more than \$514 Million Awarded to Small Businesses!!!

FDA Competition Data FDA



	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 (YTD as of 05/01/2018)	88%	96%

Awarded Actions and Volume FDA



Fiscal Year	Actions	Dollars (in Millions)
FY13	6,919	\$1,626.2
FY14	6,605	\$1,534.6
FY15	6,906	\$1,551.8
FY16	7,126	\$1,540.9
FY17	8,185	\$1,760.0
FY18 (YTD as of 5/18/18)	3,153	\$963.6

FY 17 - TOP 20 NAICS BY ACTIONS



					1	
					% to total	% to total
NACIS Code <u></u>	Description	Dollars Obligated	Count 🛂	Average	count	dollars
334516	Computer and Electronic Product Manufacturing	\$32,319,233	883	\$36,602	18.01%	3.76%
541519	Professional, Scientific, and Technical Services	\$272,180,541	657	\$414,278	13.40%	31.63%
923120	Administration of Human Resource Programs	\$53,718,732	486	\$110,532	9.91%	6.24%
541611	Professional, Scientific, and Technical Services	\$101,892,998	429	\$237,513	8.75%	11.84%
541990	Professional, Scientific, and Technical Services	\$79,401,641	368	\$215,765	7.50%	9.23%
811219	Repair and Maintenance	\$9,997,558	325	\$30,762	6.63%	1.16%
541712	Professional, Scientific, and Technical Services	\$28,152,675	227	\$124,021	4.63%	3.27%
561210	Administrative and Support Services	\$20,658,473	183	\$112,888	3.73%	2.40%
561320	Administrative and Support Services	\$12,761,220	172	\$74,193	3.51%	1.48%
541512	Professional, Scientific, and Technical Services	\$77,101,868	159	\$484,917	3.24%	8.96%
541511	Professional, Scientific, and Technical Services	\$72,635,741	158	\$459,720	3.22%	8.44%
541690	Professional, Scientific, and Technical Services	\$22,411,183	146	\$153,501	2.98%	2.60%
511210	Publishing Industries (except Internet)	\$16,692,619	123	\$135,712	2.51%	1.94%
541711	Professional, Scientific, and Technical Services	\$16,292,801	113	\$144,184	2.30%	1.89%
	Internet Service Providers, Web Search Portals,					
518210	and Data Processing Services	\$28,384,284	109	\$260,406	2.22%	3.30%
333315	Machinery Manufacturing	\$321,896	90	\$3,577	1.84%	0.04%
511120	Publishing Industries (except Internet)	\$5,263,010	77	\$68,351	1.57%	0.61%
337122	Furniture and Related Product Manufacturing	\$3,813,167	68	\$56,076	1.39%	0.44%
541380	Professional, Scientific, and Technical Services	\$6,320,210	68	\$92,944	1.39%	0.73%
922120	Justice, Public Order, and Safety Activities	\$65,598	63	\$1,041	1.28%	0.01%

FY 17 - TOP 20 NAICS BY DOLLARS



NAICS Code <u></u>	Description	Dollars Obligated 🛂	Count
541519	Professional, Scientific, and Technical Services	\$272,180,541	657
541810	Professional, Scientific, and Technical Services	\$125,538,784	18
541611	Professional, Scientific, and Technical Services	\$101,892,998	429
541820	Professional, Scientific, and Technical Services	\$93,071,147	44
541990	Professional, Scientific, and Technical Services	\$79,401,641	368
541512	Professional, Scientific, and Technical Services	\$77,101,868	159
541511	Professional, Scientific, and Technical Services	\$72,635,741	158
923120	Administration of Human Resource Programs	\$53,718,732	486
541513	Professional, Scientific, and Technical Services	\$37,018,410	17
334516	Computer and Electronic Product Manufacturing	\$32,319,233	883
518210	Internet Service Providers, Web Search Portals, and Data Processing Services	\$28,384,284	109
541712	Professional, Scientific, and Technical Services	\$28,152,675	227
541690	Professional, Scientific, and Technical Services	\$22,411,183	146
561210	Administrative and Support Services	\$20,658,473	183
334111	Computer and Electronic Product Manufacturing	\$20,052,759	58
511210	Publishing Industries (except Internet)	\$16,692,619	123
541711	Professional, Scientific, and Technical Services	\$16,292,801	113
561320	Administrative and Support Services	\$12,761,220	172
811219	Repair and Maintenance	\$9,997,558	325
541910	Professional, Scientific, and Technical Services	\$9,723,781	39



HOW TO DO BUSINESS WITH THE FDA



Commodities and Services Purchased (1 of 2)

- Information Technology Services, Hardware and Software
- Telecommunication Products
- A/V Equipment and Maintenance
- Scientific Software
- Office Furniture, Equipment, and Supplies
- Animal Feed
- Bedding and Cages
- Chemicals and Supplies
- Reagents
- Pharmaceuticals, Drugs, and Intravenous Solutions
- Electronic components and Supplies
- X-ray Equipment
- Scientific Equipment
- Laboratory Furniture, Equipment, and Supplies
- Animals for Research (including horses, calves, cats, dogs, guinea pigs, chicks, hens, etc.)

Commodities and Services Purchased (2 of 2)



- Research Studies
- Investigations and 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)
 - 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. 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 <u>Federal Acquisition Regulation</u> (<u>FAR</u>) 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 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.

Where to Go for More Information

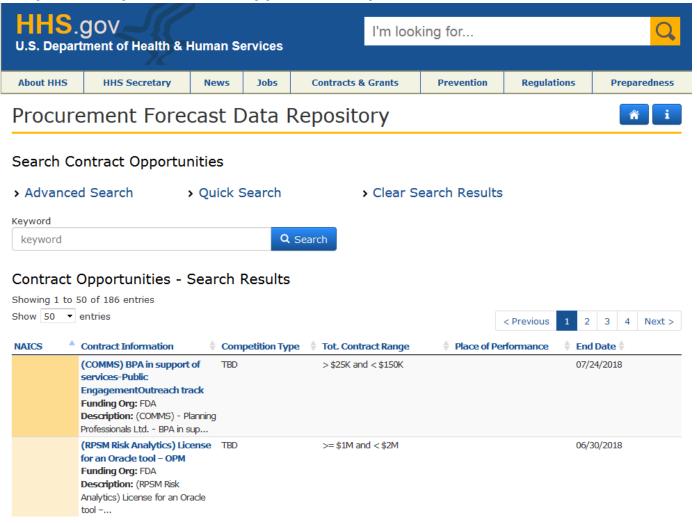


- Doing Business With FDA Make Your Connection (http://www.fda.gov/AboutFDA/business/default.htm)
- FedBizOpps (<u>www.fbo.gov</u>) site includes training videos for small business and instructions on registering and monitoring agency requirements.
- HHS Small Business Office (<u>www.hhs.gov/about/smallbusiness</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.



Procurement Forecast Data Repository (Continued)

FDA

TBD

Funding Organization

Competition Type

Reference IDV

Incumbent Contractor Name

Contract Opportunity Details

Back To List | Email Contract Opportunity

Contract Information

Project Title

Cisco Maintenance_FY17

Contract Type

TBD

Requirement Type

New Requirement

Transaction Number

Contract Vehicle

Contract Description

The procurement of CISCO SmartNet maintenance support for FDA CISCO hardware and Enterprise License Agreement (ELA). Maintenance support will be for a 12-month period. POC: MOYE, ALBERT 301-796-4492

Point of Contact Information

Name

Albert Moye

Title

Agency

CTP

Email

Albert.Moye@fda.hhs.gov

Phone

301-796-4492

Estimated Dates

Solicitation Quarter

2

Award Date

07/01/2017

Period Of Performance Start

07/01/2017

Period Of Performance End

06/30/2018

FedBizOpps Website FDA



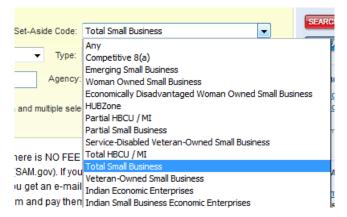
Federal Business Opportunities

https://www.fbo.gov/



FedBizOpps Website





Search by set aside type.



Search by action type.

Sources Sought for MerMade 8 DNA/RNA Synthesize System FDA-SS-17-1182443 65 — Medical, dental & veterinary equipment & supplies	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Sources Sought / Total Small Business	Apr 21, 2017	
Toter FDA-17-SOL-1181127 81 Containers, packaging, & packing supplies	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville	Combined Synopsis/Solicitation / Total Small Business	Apr 21, 2017	

See the opportunities!

Preventive maintenance for AB Sciex Voyager mass spectrometer FDA_SOL_1198582 J Maintenance, repair & rebuilding of equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Jefferson Combined Synopsis/Solicitation (Modified) / Total Small Business
Training and Pilot Processing Laboratory Facility Services for Processing Technology Courses 1195225 U Education & training services	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville Jun 18, 2018
Portable Digital X-Ray FDA-SOL-1201715 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 Jun 18, 2018
FDA White Oak Building 51 Office Furniture FDA-SS-1197854 71 — Furniture	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville Special Notice / Total Small Business Jun 18, 2018
Replacement Detectors for Leco Pegasus Mass Spectrometer FDA_SOL_1197677 66 Instruments & laboratory equipment	Department of Health and Human Services Food and Drug Administration Combined Synopsis/Solicitation Jun 15, 2018 Office of Acquisitions and Grants Services - Jefferson
Autosampler FDA_SOL_1199552 66 Instruments & laboratory equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Jefferson Combined Synopsis/Solicitation / Total Small Business Jun 15, 2018
Advanced Evaporator System FDA-18-223-SOL-1199437 66 – Instruments & laboratory equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Jefferson Combined Synopsis/Solicitation (Modified) / Total Small Business
Immunoassay Analyzer Systems FDA-18-RFQ-1199468 66 Instruments & laboratory equipment	Department of Health and Human Services Food and Drug Administration Office of Acquisitions and Grants Services - Rockville Combined Synopsis/Solicitation Jun 14, 2018



GSA- Schedules FDA

INDUSTRY PARTNERS

Overview

Getting Started With GSA Schedules

Responding to a Solicitation

Managing a Schedules Contract

Resources, Training, and Tools

GSA Schedule Solicitations

Welcome Package

For Industry Partners - 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 (10%) of overall federal procurement spending.

GSA Schedules are fast, easy, and effective contracting vehicles for both customers and industry partners. 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 continually updates the offerings under the GSA Schedules program, and aids industry partners in being successful in the government marketplace. Particularly, the GSA Schedules program has a strong record of small business achievement.

To be successful under the GSA Schedules program, industry partners 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 industry partner and GSA. Careful analysis, planning, and proactive steps are required to ensure industry partners are successful under the GSA Schedules program.

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

- Eighty percent (80%) of GSA Multiple Award Schedule (MAS) contractors are small businesses who represent 36 percent (36%) of sales;
- More than \$40B flows through GSA MAS contracts every year;
- In Fiscal Year 2012, approximately 10 percent of government needs were procured through the GSA MAS contracts;
- · GSA had over 19,000 MAS contracts in Fiscal Year 2012; and
- Approximately 40 percent (40%) of the 19,000 GSA MAS contracts generate sales.

CONTACTS

National Customer Service Center (800) 488-3111

View Contact Details

Vendor Support Center (877) 495-4849

View Contact Details



Register for a live webinar or 24/7 online training: www.gsa.gov/masnews

gsaschedules@gsa.gov

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PURCHASING PROGRAMS

OAGS Contact Information



Ted Weitzman, Senior Acquisition Advisor, 240.402.7626 / theodore.weitzman@fda.hhs.gov

Sandy Bellinger, Director, Division of Information Technology Acquisitions (DITA) **240.402.7524 / sandra.bellinger@fda.hhs.gov**

Jerry Martin, Acting Director, Division of Acquisition Programs (DAP) 870-543-7040 / jerry.martin@fda.hhs.gov

Ronald Loube, Director, Division of State Acquisition, Agreements, and Grants (DSAAG) **240.402.7539 / ronald.loube@fda.hhs.gov**

Vidya Vish, Director, Division of Acquisition Operations (DAO) **240.402.7576 / vidya.vish@fda.hhs.gov**

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



Jonathan Ferguson, Small Business Specialist, 301.496.9639 or jonathan.ferguson@hhs.gov



QUESTIONS



