

Welcome to the 2018 FDA Small Business Outreach Fair

White Oak Great Room
February 20, 2018



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

Jacob O'Hatnick

Contract Specialist, Division of IT Acquisitions, OAGS





- Who We Are
- What We Do
- How We Are Organized
- Our Focus
- Working in 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 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.

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 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

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

Goals and Statistics



Fiscal Year 2017 Statistics for OAGS

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

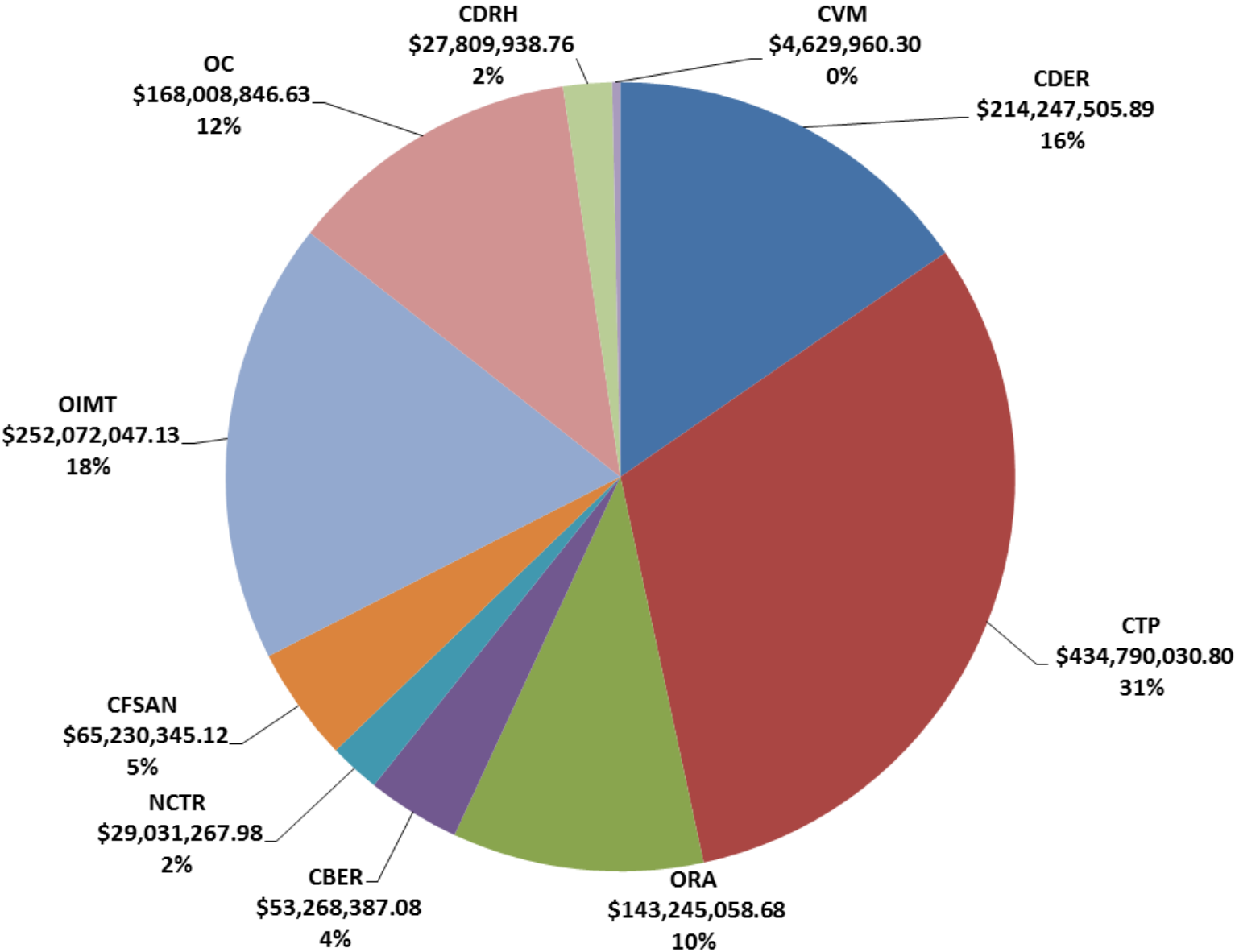
Contracts (Including PO)	FY 16	FY 17
Awarded Contracts	5,297	6,223
Total Obligated	\$1.1 B	\$1.3 B

Grant Data	FY 16	FY 17
Awarded Grants	637	542
Post Award Grant Actions	452	731
Total Obligated	\$182M	\$187M

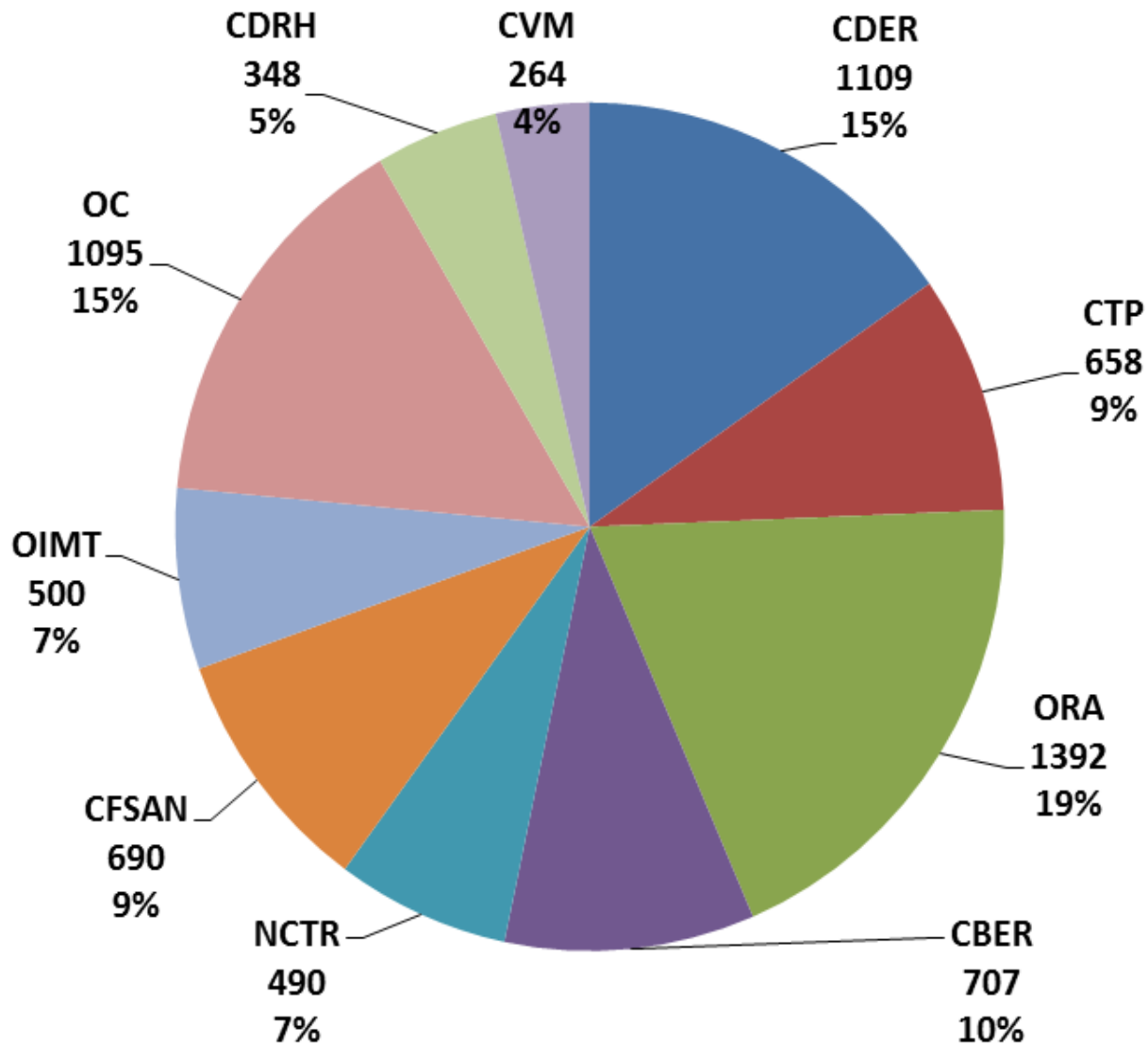
Purchase Cards	FY 16	FY 17
Transaction	\$69.5M	\$65.8M
# of Transactions	106,162	99,260
Cardholder Accounts	876	847
Convenience Check Spend	\$180K	\$142K
Convenience Check Transaction #	248	178
Rebates Earned	\$1.09M	\$1.03M

Interagency Agreement	FY 16	FY 17
Reimbursable IAAs	72	64
Reimbursable IAA Dollar Value (Funds-in)	\$27M	\$42M
Service IAAs (Funds-out)	668	625
Service IAAs Total Value	\$277M	\$271M
Total Awarded	740	689
Total Obligated	\$277M	\$271M

FY17 Obligations by Center



FY17 Count by Center



FDA SOCIOECONOMIC GOALS



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

Small Business Award Categories	FY Goal*	FY14	FY15	FY16	FY17	FY18 (YTD)
Small Businesses	40% <small>(35% until FY14) (43% in FY 14)</small>	43%	50%	49%	40%	59%
Small Disadvantaged Businesses	5.0%	25%	30%	28%	24%	44%
Women-Owned Small Businesses	5.0%	14%	16%	18%	14%	26%
HubZone Businesses	3.0%	4%	2%	2%	1%	2%
Service Disabled Veteran Owned	3.0%	3%	3%	5%	3%	2%

FDA Competition Goals



Eligible Actions Competed	HHS Goal	FY14	FY15	FY16	FY17	FY18 YTD
Percent (%)	65%	90%	91%	91%	90%	84%
Dollars (\$)	75%	96%	95%	94%	96%	92%

Awarded Actions and Volume



Acquisition Summary	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)	970	399.0

How to do Business with the FDA



Office of Finance, Budget & Acquisitions



Top Product Service Codes FY17



PSC Description

- R426 Support- Professional: Communications
- D324 It And Telecom- Business Continuity
- D306 It And Telecom- Systems Analysis
- R499 Support- Professional: Other
- D399 It And Telecom- Other It And Telecommunications
- H199 Quality Control- Miscellaneous
- R408 Support- Professional: Program Management/Support
- 6640 Laboratory Equipment And Supplies
- 7030 Information Technology Software
- B529 Special Studies/Analysis- Scientific Data
- D318 It And Telecom- Integrated Hardware/Software/Services Solutions, Predominantly Services
- D302 It And Telecom- Systems Development
- D319 It And Telecom- Annual Software Maintenance Service Plans

Top NAICS Codes FY17

NAICS	Description
541519	Other Computer Related Services
541810	Advertising Agencies
541820	Public Relations Agencies
541512	Computer Systems Design Services
541611	Administrative Management And General Management Consulting Services
541990	All Other Professional, Scientific, And Technical Services
541511	Custom Computer Programming Services
923120	Administration Of Public Health Programs
334516	Analytical Laboratory Instrument Manufacturing
541712	Research And Development In The Physical, Engineering, And Life Sciences (Except Biotechnology)
334111	Electronic Computer Manufacturing
541711	Research And Development In Biotechnology
541690	Other Scientific And Technical Consulting Services

Doing Business with the FDA (1 of 3)



- **Contact Small Business Program Office**
www.hhs.gov/about/smallbusiness/
- **Review Procurement Forecast for the Products and/or Services that Your Business Sells (HHS Procurement Forecast Data Repository)**
- **Obtain a DUNS number from Dun & Bradstreet and Register in System for Award Management (SAM).**
 - A DUNS number is a no-cost business identification number businesses must to do business with the Federal Government. 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 FAR is the primary source of guidance on federal contracting. Most agencies have agency-specific supplements to the FAR. The FDA uses the Health and Human Services Acquisition Regulation (HHSAR).

Doing Business with the FDA (2 of 3)



- **Market Your Business to the Right Contacts and know what FDA buys.**
 - Do not send information to the highest official that you can find. It is more effective to send information to the contracting office, the Small Business Specialist, or the appropriate program official.

- **Visit FedBizOpps Website at www.fbo.gov**
 - Single point of entry for business opportunities valued in excess of \$25,000
 - Register to receive notifications whenever business opportunities relevant to your industry are posted.

- **Attend Agency Sponsored Vendor Outreach Sessions, Trade Fairs, and Other Business Networking Events.**
 - HHS conducts monthly outreach session
 - Networking and teaming opportunities.

- **Explore Subcontracting Opportunities**

Doing Business with the FDA (3 of 3)



- **Respond to Requests for Information (RFI) / Sources Sought Notices**
 - Submit detail sufficient to determine capabilities

- **Obtain one or more GSA Schedule contracts and/or GWACs.**
 - Being on schedule and/or a GWAC makes good “business sense” and will provide your company with multiple options.

- **Maintain High Standards of Integrity.**
 - Do not attempt to act outside of the boundaries set in the FAR and various agencies supplements.
 - Federal officials involved in the procurement process are limited in what information they can disclose to whom and when. Do not pressure them for additional information and do not attempt to circumvent the boundaries set.

Where to Go for More Information



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

<http://procurementforecast.hhs.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.

HHS.gov
U.S. Department of Health & Human Services

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Procurement Forecast Data Repository

Search Contract Opportunities

[Advanced Search](#) [Quick Search](#)

Keyword

Contract Opportunities

Showing 1 to 50 of 868 entries

Show entries

[< Previous](#) | **1** | [2](#) | [3](#) | [4](#) | [5](#) | [Next >](#)

NAICS	Contract Information	Competition Type	Tot. Contract Range	Place of Performance	End Date
541711 - Research and Development in Biotechnology	Basic Food and Drug Law Course to be presented to FDA employees Funding Org: FDA Description: Basic Food and Drug	Reserved for Small Business	> \$25K and < \$150K		

Search more than **24,100*** active federal opportunities.

Posted Date: Set-Aside Code:

Place of Performance: Type:

Keyword / Solicitation #: Agency:

Additional criteria and multiple selections are available on the [advanced search form](#).
** Notices posted within the last 90 days.*

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 [FBO Buyers Guide](#). Do not upload ANY classified materials to FBO.

Buyers / Engineers

Government users may post, manage, and award opportunities.

Username

Password

- [View Opportunities](#)
No login is required to view opportunities.
- [Register Now](#)
- [Password Reminder](#)
- [Recovery FAQs](#)

Vendors / Citizens

Vendors and citizens may search, monitor, and retrieve opportunities.

Username

Password

- [Find Opportunities](#)
No login is required to view opportunities.
- [Register Now](#)
- [Password Reminder](#)
- [Recovery FAQs](#)

RECOVERY

Locate actions funded by the American Recovery and Reinvestment Act.

FBO RECOVERY REPORTS

- [Click here for Opportunities](#)
- [Click here for Awards](#)

Click [here](#) to learn more.

SMALL BUSINESS EVENTS

[Learn more](#) about the Small Business Central Event Listing or [search now](#) for events.

VENDOR COLLABORATION

FBO now contains the Vendor Collaboration Central Event Listing. [Learn more](#) or [search](#).

USER GUIDES

- [Buyer](#)
- [Vendor](#)
- [Engineer](#)
- [Location / Agency Admin](#)



INDUSTRY PARTNERS

Overview

Guide to Preparing a MAS Offer

Managing a Schedules Contract

Resources, Training, and Tools

GSA Schedule Solicitations

Now You Have Your Schedule

For Industry Partners - Getting on Schedule

The GSA Schedules program is the premier acquisition vehicle in government, with approximately \$40 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

CONTACTS

National Customer Service Center
mashelpdesk@gsa.gov
(800) 488-3111

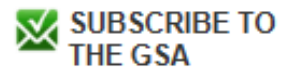
- [View Contact Details](#)

Vendor Support Center
vendor.support@gsa.gov
(877) 495-4849

- [View Contact Details](#)



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



Where to Go for More Information



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Sandy Bellinger, Director, Division of Information Technology Acquisitions

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Jerry Martin, Acting Director, Division of Acquisition Programs

870.543.7040

Ronald Loube, Director, Division of State Acquisition, Agreements, and Grants

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Vidya Vish, Director, Division of Acquisition Operations

240.402.7576

Bryan Jones, Director, Division of Systems, Policy, and Program Support

240.402.7571

Jonathan Ferguson, Small Business Specialist,

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QUESTIONS

