

FDA Office of Acquisitions and Grants Services Overview

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Office of Finance, Budget & Acquisitions





- 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 redoubling efforts to encourage innovations that will promote public health as well as strengthen the American economy.



Medical Countermeasures - FDA plays a critical role in protecting the United States from chemical, biological, radiological, nuclear, and emerging infectious disease threats. FDA's responsibility is to ensure that medical countermeasures (MCMs)—such as drugs, vaccines, and diagnostic tests—to counter these threats are safe, effective, and secure.



Transparency - FDA seeks to make more information available to the public rapidly in a form that is easily accessible and user-friendly and to foster a better understanding of Agency operations and decision-making.



Sentinel Initiative - the Sentinel Initiative 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 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

Goals and Statistics



FY16 Statistics for OAGS



Fiscal Year Totals*	FY 15	FY 16
Actions Awarded**	6,104	7,126
Total Obligated	\$1.67 B	\$1.54 B
*Doesn't include P-Card Data which is obligated external to OAGS		
**Doesn't include Post Award Grant Actions for FY15		

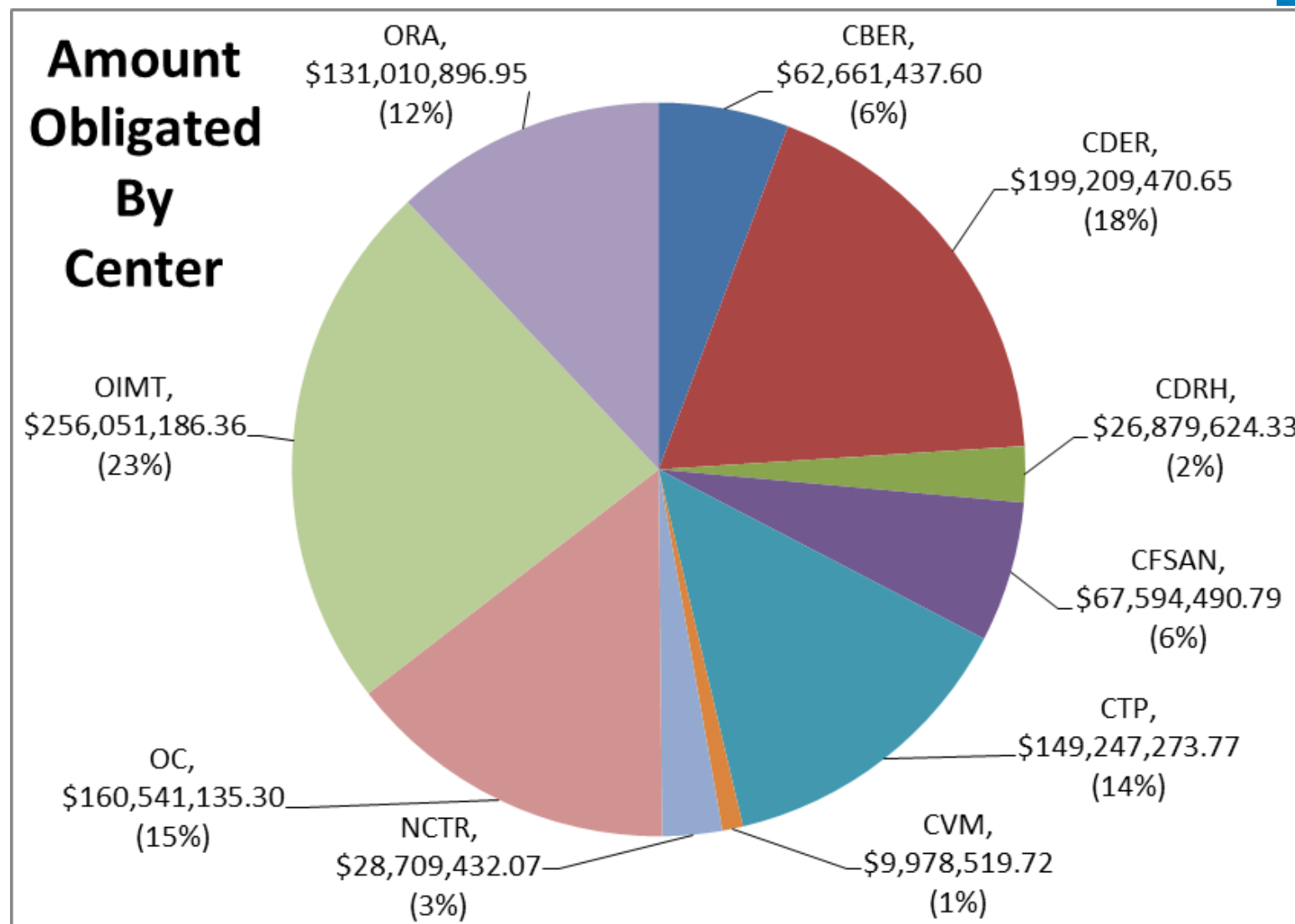
Grant Data	FY 15	FY 16
Awarded Grants	575	637
Post Award Grant Actions	Not Recorded	452
Total Obligated	\$161.03 M	\$182.1 M

Purchase Card Data	FY 15	FY 16
Transaction	\$67.9 M	\$69.5 M
# of Transactions	107,573	106,162
Cardholder Accounts (Average)	877	876
Convenience Check Spend	\$176,477	\$180,202
Convenience Check Transaction #	247	248
Rebates Earned	\$.987 M	\$1.09 M

Contracts (including PO) Data	FY 15	FY 16
Awarded Contracts	5,042	5,297
Total Obligated	\$1.2 B	\$1.1 B

Interagency Agreement Data	FY 15	FY 16
Reimbursable IAAs	45	72
Reimbursable IAA Dollar Value (Funds-in)	\$81.2 M	\$27.2 M
Service IAAs (Funds-out)	442	668
Service IAAs Total Value	\$225.9 M	\$277.4 M
Total Awarded	487	740
Total Obligated	\$307.1 M	\$277.4 M

FY16 Statistics for OAGS



Note: This data only represents Contract Awards, not IAAs nor Grants

FDA SOCIOECONOMIC GOALS



Small Business Award Categories	FY Goal*	FY 11	FY12	FY13	FY14	FY15	FY16	FY17 (YTD)
Small Businesses	41% (35% until FY14) (43% in FY 14)	47.46%	55.90%	48.93%	43.28%	50.10%	48.5%	35.5%
8(a) Businesses	5.0%	19.53%	-	-	-	-	-	-
Small Disadvantaged Businesses	5.0%	28.24%	34.70%	30.69%	25.28%	29.50%	27.9%	24.8%
Women-Owned Small Businesses	5.0%	12.05%	16.55%	9.92%	13.63%	15.90%	17.8%	9.5%
HubZone Businesses	3.0%	2.96%	3.59%	2.59%	3.61%	2.20%	2.0%	1.2%
Service Disabled Veteran Owned	3.0%	3.99%	4.68%	2.14%	2.93%	3.17%	4.9%	1.2%

In 2016 more than \$507 Million Awarded to Small Businesses!!!

FDA Competition Data



Center	Percent of Eligible Actions Completed	Percent of Eligible Dollars Completed
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 (YTD)	91%	98%

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 (YTD)	1,893	\$315.7

In 2016, more than \$507 Million Awarded to Small Businesses!

Totals include Contract Actions, Grants, and IAAs.

HOW TO DO BUSINESS WITH THE FDA

Commodities and Services Purchased

- ☐ Information Technology services, hardware and software
- ☐ Telecommunication products
- ☐ A/V Equipment and maintenance
- ☐ Scientific software
- ☐ Office furniture, equipment, and supplies
- ☐ Animal feed
- ☐ Bedding and cages
- ☐ Chemicals and supplies
- ☐ Reagents
- ☐ Pharmaceuticals, drugs, and intravenous solutions
- ☐ Electronic components and supplies
- ☐ X-ray equipment
- ☐ Scientific equipment
- ☐ Laboratory furniture, equipment, and supplies
- ☐ Animals for research (including horses, calves, cats, dogs, guinea pigs, chicks, hens, etc.)

Commodities and Services Purchased

- ☐ Research studies
- ☐ Investigations, surveys
- ☐ Tests and analyses of a scientific or medical nature
- ☐ Examinations, surveys, inspections, and reviews
- ☐ Professional Services
- ☐ Conference support/Events Planning
- ☐ Document Management
- ☐ Training
- ☐ Facility renovation
- ☐ Administrative Support/Temporary Services
- ☐ Architect/engineering support
- ☐ Operation and maintenance of facilities
- ☐ Facility support (e.g. custodial, trash, guard services)
- ☐ Moving Services

Doing Business with the FDA (1 of 3)

- **Contact Small Business Program Office - www.hhs.gov/about/smallbusiness/**
- **Review Procurement Forecast for the Products and/or Services that Your Business Sells (HHS Procurement Forecast Data Repository)**
 - <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 DUNS numbers to do business with the Federal Government. There is no cost to obtain a DUNS number. You must be registered in SAM to do business with the Federal government. www.sam.gov
- **Become Familiar with Federal Contracting Procedures.**
 - Federal agencies must follow certain rules relating to procurement, which can be different than typical business practices. The Federal Acquisition Regulation (FAR) is the primary source of guidance on federal contracting. Most agencies have agency-specific supplements to the FAR. The FDA uses the Health and Human Services Acquisition Regulation (HHSAR).

Doing Business with the FDA (2 of 3)

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

Procurement Forecast Data Repository



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

<http://procurementforecast.hhs.gov/>



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50

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3

4

5

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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		

FedBizOpps Website

FDA



Federal
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Home

Getting Started

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

Posted Date:

Last 90 Days

Set-Aside Code:

Any

Place of Performance:

Any State or Territory

Type:

Any

Keyword / Solicitation #:

Agency:

Search

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.

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VENDOR COLLABORATION



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[Engineer](#)

[Location / Agency Admin](#)

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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](#)



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**PURCHASING
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QUESTIONS

