



FDA FY2025 Small Business Fair

A large, stylized DNA double helix structure is positioned on the left side of the slide, extending from the top to the bottom. The helix is rendered in various shades of blue, with some segments appearing as solid lines and others as semi-transparent outlines. In the background, there are faint, light blue molecular structures and hexagonal patterns, suggesting a scientific or pharmaceutical theme.

Welcome to the FDA FISCAL YEAR 2025 SMALL BUSINESS FAIR

November 14, 2024

Welcome & Opening Remarks

Leonard Grant
Head of Contracting Activity
Food & Drug Administration



- ❑ **The Food and Drug Administration (FDA) recognizes that Small Businesses are the backbone of the US Economy**
 - America's 32 million small business owners are the engine of job creation and economic growth in this country
 - Understand the need for greater support (education, information, access) for Small Businesses to advance equity
 - Need Small Businesses to thrive not just survive
- ❑ **It is important to the FDA to partner with the Small Business Community**
 - FDA historically meets or exceeds its annual Small Business Goals; FY24 FDA met ALL SB goals
 - FDA hosted 2 Small Business Vendor Fairs in FY24
 - FDA's FY25 Q1 Procurement Forecast is released in HHS' Small Business Customer Experience (SBCX) portal
 - Looking to increase Small Business "Meet and Greets" throughout the year
- ❑ **OAGS staff works closely with the SBA, HHS Office of Small and Disadvantaged Business Utilization (OSDBU), and our Small Business Specialist (Cindy Anderson) to support access to federal contracting opportunities within the FDA**
 - HHS OSDBU Small Business Customer Experience (SBCX) - <https://mysbcx.hhs.gov>
 - Actions go through our Small Business Specialist, and if necessary, SBA PCR for review and concurrence
- ❑ **Take advantage of this informative event and the opportunities provided to understand our mission, meet, and network with the attending FDA staff (to include Contracting, Program), Large Business Partners, and GSA Customer Service Managers**

OAGS Contact Information



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- **Cynthia Anderson, FDA Small Business Specialist** Cynthia.Anderson@hhs.gov



Office of Acquisitions and Grant Services Overview

Kofo Adenola



- FDA Mission
- OAGS Mission, Vision, & Goals
- Organizational Structure
- Small Business Goals & Statistics
- How to Do Business with FDA
- Key Contacts



- The Food and Drug Administration is responsible for **protecting the public health** by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.



- FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to **protect the public health and to reduce tobacco use by minors**.



- FDA is responsible for advancing the public health by **helping to speed innovations** that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.



- FDA also plays a significant role in the Nation's **counterterrorism capability**. FDA fulfills this responsibility 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.

OAGS Mission, Vision, & Goals



Mission



To provide high quality acquisitions and assistance agreements outcomes to FDA.

Vision



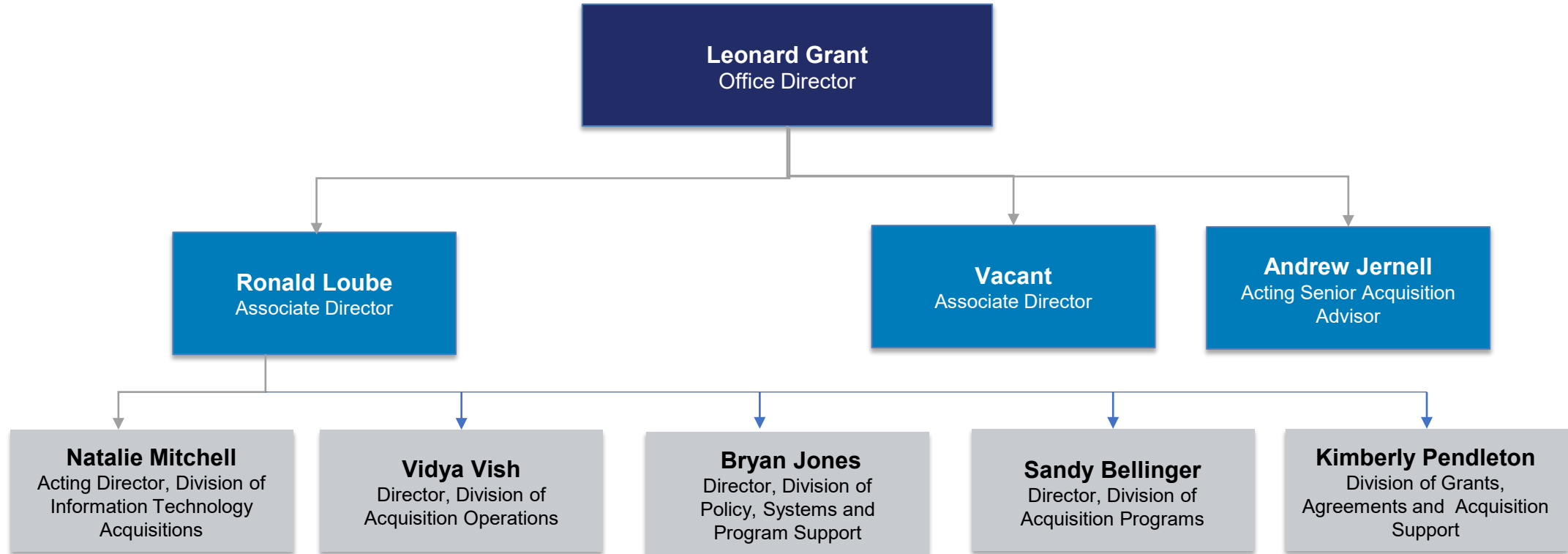
To be an acquisition center of excellence by **fostering strategic collaboration** with our partners and **empowering our workforce** to achieve results that protect and promote the health of all Americans while maintaining the public trust.

Goals



- Build effective **partnerships** with our FDA Customers and Stakeholders
- **Mature** our Acquisition Practices
- Institute a **Performance Culture**
- **Develop** our Organization and our People

Organizational Structure

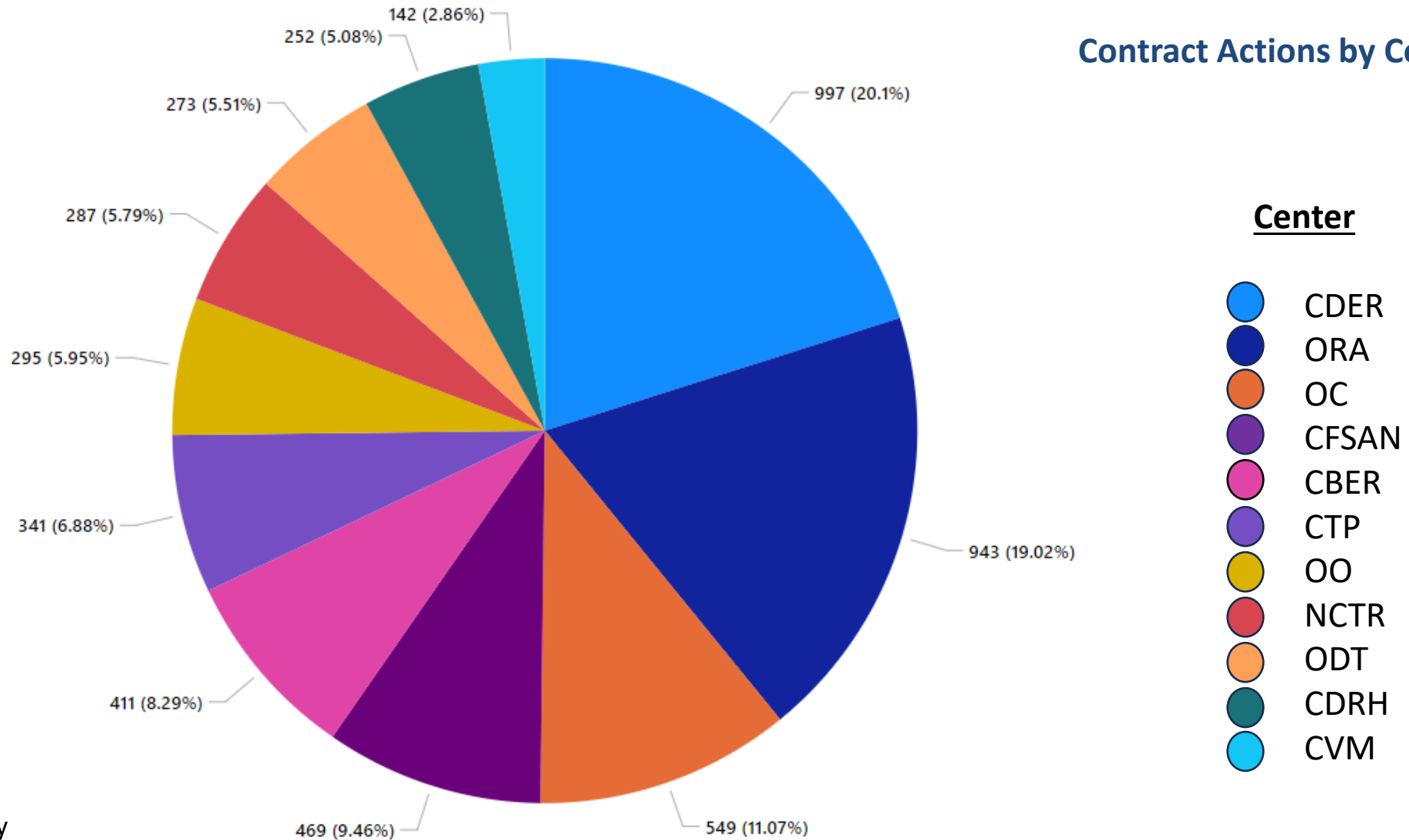


Our staff provides the required depth of knowledge and experience to award and manage billions of dollars in contracts and grants to improve mission outcomes across the FDA

FY24 Statistics for OAGS



Contract Actions by Center

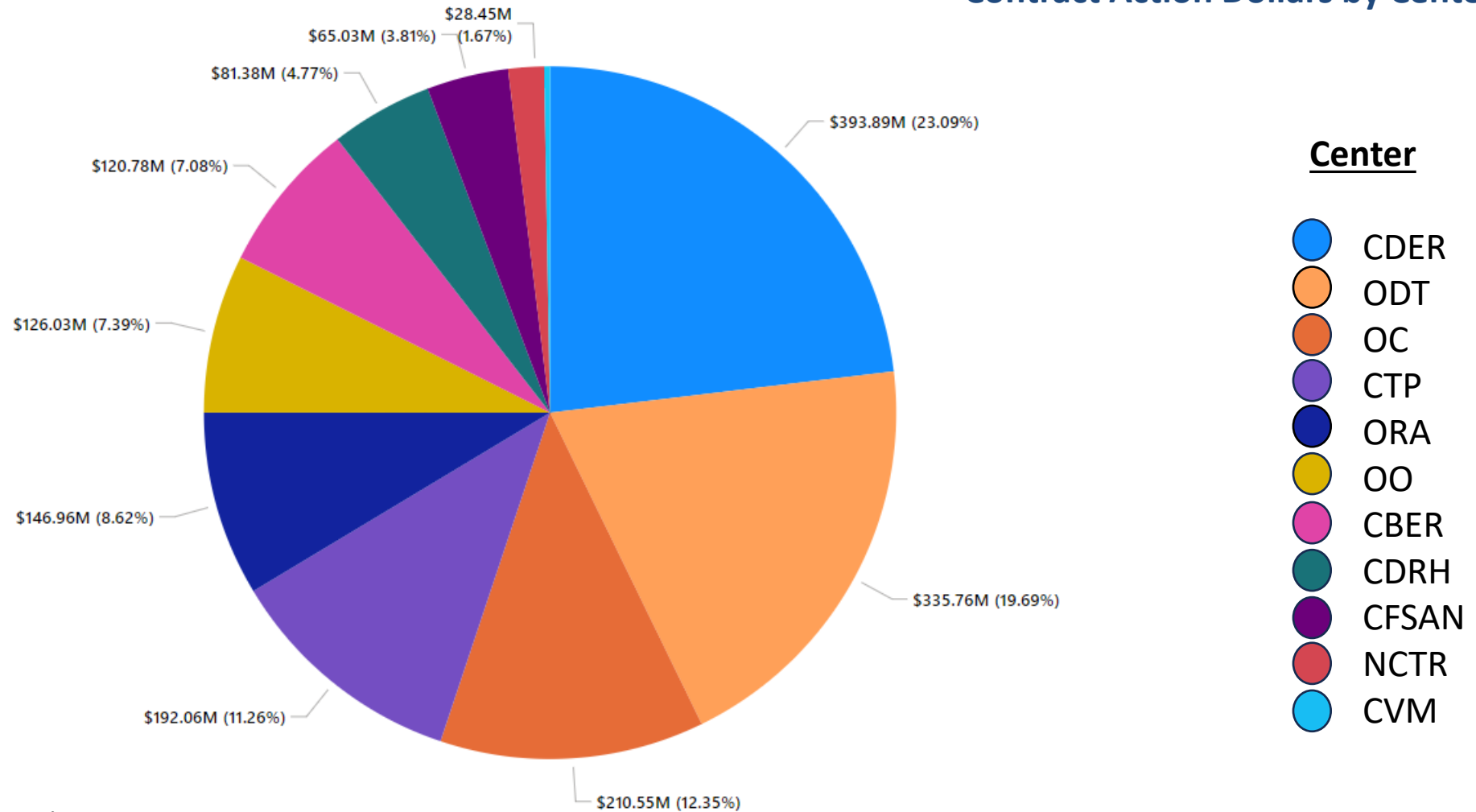


Note: This data only represents Contract Awards, not IAAs or Grants

FY24 Statistics for OAGS



Contract Action Dollars by Center



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

FDA Socioeconomic Goals



Small Business Award Categories	FY Goal (FY15-21)	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23	FY Goals	FY 24 (Draft)
Small Businesses	38%	48.50%	39.64%	36.80%	39.06%	40.09%	34.33%	33.49%	38.02%	33.06%	44.35%
Small Disadvantaged Businesses	5.00%	27.90%	24.31%	25.00%	27.14%	26.96%	23.84%	23.96%	25.84%	26.50%	30%
Women-Owned Small Businesses	5.00%	17.80%	14.22%	14.10%	14.13%	12.68%	10.33%	11.01%	11.58%	9%	12.12%
HubZone Businesses	3.00%	2.00%	1.40%	1.80%	2.75%	4.09%	3.81%	4.48%	4.37%	4.34%	6.35%
Service-Disabled Veteran Owned	3.00%	4.90%	3.42%	3.40%	2.81%	3.91%	2.29%	3.22%	3.79%	4.41%	5.43%

In 2024, FDA awarded more than \$769.16 Million to Small Businesses!

Top 10 Contract Expenditure Categories for FY 2024



Top 10 Vendors

Vendor Name	Sum of Dollars Obligated
DELOITTE CONSULTING LLP	\$ 147,881,571.00
TRUE NORTH COMMUNICATIONS INC	\$ 77,060,488.00
BOOZ ALLEN HAMILTON INC	\$ 68,261,517.03
REI SYSTEMS INC	\$ 42,407,961.97
HP ENTERPRISE SERVICES LLC	\$ 41,326,555.23
HARVARD PILGRIM HEALTH CARE INC	\$ 35,805,908.27
MPF-ZAI SOLUTIONS LLC	\$ 32,016,257.76
INTERNATIONAL BUSINESS MACHINE COPORATION	\$ 31,567,180.95
EAGLE HILL CONSULTING LLC	\$ 31,412,119.88
IDERA INC.	\$ 31,070,360.21
Grand Total	\$ 538,809,920.30

Top 10 NAICS

Top 10 NAICS by Expenditures	Sum of Dollars Obligated
CUSTOM COMPUTER PROGRAMMING SERVICES – 541511	\$ 299,832,202.89
ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES – 541611	\$ 267,879,063.23
COMPUTER SYSTEMS DESIGN SERVICES - 541512	\$ 266,626,999.76
OTHER COMPUTER RELATED SERVICES - 541519	\$ 203,476,980.63
ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES – 541990	\$ 144,452,853.99
ADVERTISING AGENCIES – 541810	\$ 97,676,040.32
COMPUTING INFRASTRUCTURE PROVIDERS, DATA PROCESSING, WEB HOSTING, AND RELATED SERVICES – 518210	\$ 91,118,793.55
RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY (EXCEPT NANOBIO TECHNOLOGY) – 541714	\$ 79,906,499.25
ADMINISTRATION OF PUBLIC HEALTH PROGRAMS – 923120	\$ 57,584,222.32
COMMERCIAL AND INSTITUTIONAL BUILDING CONSTRUCTION – 236220	\$ 52,698,622.00
Grand Total	\$ 1,561,252,277.94

Top 10 Small Business Contract Expenditure Categories for FY 2024



Top 10 Small Business Vendors

Top 10 SB Contract Expenditures	Sum of Dollars Obligated
MPF-ZAI SOLUTIONS, LLC	\$ 32,016,257.76
PRECISE SOFTWARE SOLUTIONS, INC.	\$ 31,070,360.21
MCP COMPUTER PRODUCTS INC.	\$ 25,938,800.76
SPATIAL FRONT INCORPORATED	\$ 19,536,930.88
KAIVA STRATEGIES, LLC	\$ 18,039,008.14
BIRDI SYSTEMS, INC.	\$ 17,229,131.47
VETS SYNERGETIC GROUP LLC	\$ 15,064,787.55
PN-HEITECH, LLC	\$ 13,946,459.61
SUNTIVA, LLC	\$ 13,138,753.93
SOFTWARE INFORMATION RESOURCE CORP.	\$ 12,695,833.90
Grand Total	\$ 198,676,324.21

Top 10 NAICS (SB)

Top 10 NAICS (Small Business Contracts)	Sum of Dollars Obligated
OTHER COMPUTER RELATED SERVICES – 541519	\$ 101,892,863.46
ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES – 541611	\$ 88,976,853.00
ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES – 541990	\$ 76,590,840.08
CUSTOM COMPUTER PROGRAMMING SERVICES – 541511	\$ 70,902,050.95
COMPUTER SYSTEMS DESIGN SERVICES – 541512	\$ 51,943,178.71
ELECTRONIC COMPUTER MANUFACTURING – 334111	\$ 26,420,879.35
SECURITY SYSTEMS SERVICES (EXCEPT LOCKSMITHS) – 561621	\$ 19,329,090.68
FACILITIES SUPPORT SERVICES – 561210	\$ 18,970,703.37
COMPUTER FACILITIES MANAGEMENT SERVICES – 541513	\$ 18,734,017.13
OTHER SCIENTIFIC AND TECHNICAL CONSULTING SERVICES – 541690	\$ 11,760,853.61
Grand Total	\$ 485,521,330.34

FDA FY24 Competition Data



Category	Actions Completed			Dollars Completed		
	Total Available for Competition	Competed	Competition Percentage	Total Available for Competition	Competed	Competition Percentage
Total FDA	4,964	3,245	65.37%	\$1,705,489,191.22	\$1,203,947,773.51	70.6%
HHS Target			65%			75%

Note: FDA's State Inspection Programs is not available for Competition via Statutory Authority.

Target your Engagement

- Focus on Primary NAICS codes and consider teaming/partnering
- Learn about FDA market and the goods and services it procures
- Read OFPP “Myth-Busting” [Memorandums](#) to improve engagement

Develop Allies

- Engage with [FDA SB Specialist](#)
- Participate in FDA and HHS [outreach events](#)

Own Your Future

- Review FDA [Forecast of Opportunities](#)
- Register with [HHS Small Business Customer Experience \(SBCX\) system](#)
- Understand how to write a [capability statement](#)
- Know the Rules ([FAR](#) and [GAO Case Law-Protest Decisions](#))

- [Doing Business With FDA | FDA](#)
- [FDA eBid Board](#): The FDA eBidBoard is provided as an electronic mechanism designed to promote awareness of and competition in business opportunities for contract actions with an anticipated value between \$15,001 - \$25,000.
- [Small Business Outreach Vendor Fairs | FDA](#): All slides and recordings from FDA Small Business Fairs since 2014

OAGS Contracting Officer Panel

Panel Introductions

Moderator: Jay O’Keefe, OD-Training

Kim Davis, DAO
Michelle Dacanay, DITA
Maria Finan, DAP

OAGS Panel Questions

Question: What is FDA's process for adding items to the HHS SBCX forecast?

Question: How does the FDA prioritize small business engagement in its contracting processes?

OAGS Panel Questions

Question: When is the best time to reach out for capabilities briefings? How to schedule capability meetings? How can we get in touch with CO's if we are not getting responses on calls and emails?

Question: What are unique attributes about FDA procurement practices that contractors should know?

Question: What makes a small business stand out to a contracting officer? What are some traits that you have seen in successful small businesses that make them a good fit for government?

OAGS Panel Questions

Question: Explain key stages of the contracting process, from proposal submission to contract award, for small businesses.

Question: What are your tips for successful matchmaking?



Federal Financial Assistance for Small Businesses

Facilitated by :
Stephanie Bogan
Grants Management Branch Chief

Agenda

- *Finding* Federal Financial Assistance
- *Applying* for Federal Financial Assistance

Finding Federal Financial Assistance

F - A - N - I - A - H



Finding Federal Financial Assistance

 An official website of the United States government [Here's how you know](#) ▼



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Search site content

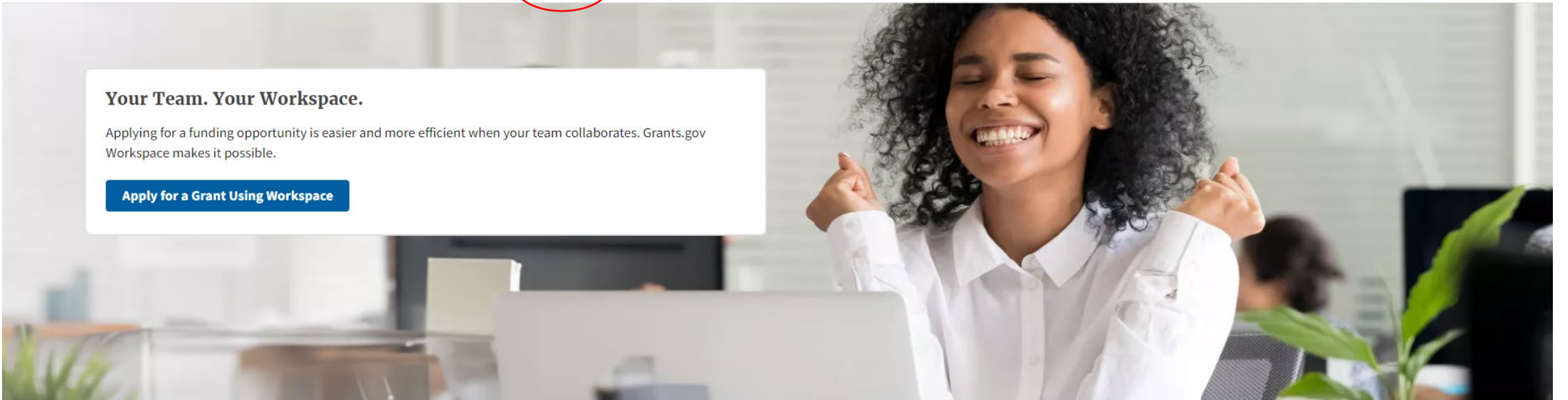


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Your Team. Your Workspace.

Applying for a funding opportunity is easier and more efficient when your team collaborates. Grants.gov Workspace makes it possible.

[Apply for a Grant Using Workspace](#)



Finding Federal Financial Assistance

Archived (13,571)

FUNDING INSTRUMENT TYPE:

- All Funding Instruments
- Cooperative Agreement (200)
- Grant (733)
- Other (11)
- Procurement Contract (5)

ELIGIBILITY:

- higher education (845)
- Public housing authorities/Indian housing authorities (818)
- Small businesses (912)

CATEGORY:

- All Categories
- Affordable Care Act (1)
- Agriculture (9)
- Arts (1)

AGENCY:

PAR-25-241	Tobacco, Alcohol, and Cannabis Policy Research for Health Equity (R21 Clinical Trial Optional)	HHS-NIH11	Posted	11/13/2024	01/07/2028
RFA-NS-25-025	Exploratory/Developmental Research on Guillain Barre Syndrome (GBS) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (R21 - Clinical Trial Not Allowed)	HHS-NIH11	Posted	11/13/2024	10/03/2025
PAR-25-081	National Cancer Institute's Investigator-Initiated Early Phase Clinical Trials for Cancer Treatment and Diagnosis (R01 Clinical Trial Required)	HHS-NIH11	Posted	11/12/2024	01/07/2027
PAR-25-167	Cancer Prevention and Control Clinical Trials Grant Program (R01 Clinical Trial Required)	HHS-NIH11	Posted	11/12/2024	01/07/2027
PAR-25-054	NINDS Exploratory Clinical Trials (UG3/UH3 Clinical Trial Required)	HHS-NIH11	Posted	11/12/2024	03/10/2025
PAR-25-108	Microbial-based Cancer Imaging and Therapy - Bugs as Drugs (R21 Clinical Trial Not Allowed)	HHS-NIH11	Posted	11/12/2024	05/07/2025
PAR-25-201	Integrating Mental Health Care into Health Care Systems and Non-Health Settings in Low- and Middle-Income Countries (R01 Clinical Trial Optional)	HHS-NIH11	Posted	11/12/2024	01/07/2028
PA-25-253	Exploratory Grants in Cancer Control (R21 Clinical Trial Optional)	HHS-NIH11	Posted	11/12/2024	09/07/2028
PAR-25-237	Improving Care and Outcomes for Cancer Survivors from Sexual and Gender Minority (SGM) Populations (R01 Clinical Trial Optional)	HHS-NIH11	Posted	11/12/2024	01/07/2027
PAR-25-027	NIDCR Dentist Scientist Career Transition Award for Intramural Investigators (K22 Clinical Trial Not Allowed)	HHS-NIH11	Posted	11/12/2024	01/07/2028
PAR-25-133	NeuroNEXT Small Business Innovation in Clinical Trials (U44 Clinical Trial Optional)	HHS-NIH11	Posted	11/12/2024	09/05/2027
F25AS00105	F25AS00105: Great Lakes Fish and Wildlife Restoration Act FY 2025	DOI-FWS	Posted	11/08/2024	01/08/2025
PA-25-172	Modular R01s in Cancer Control and Population Sciences (R01 Clinical Trial Optional)	HHS-NIH11	Posted	11/07/2024	01/07/2028
PAR-25-218	Research Infrastructure Development for Interdisciplinary Aging Studies (R61/R33 - Clinical Trial Optional)	HHS-NIH11	Posted	11/07/2024	12/02/2025

Finding Federal Financial Assistance

Opportunity Number ↕	Opportunity Title ↕	Agency ↕	Opportunity Status ↕	Posted Date ↕	Close Date ↕
RFA-FD-25-001	Clinical Trials Addressing Unmet Needs of Rare Neurodegenerative Diseases (R01) Clinical Trials Required	HHS-FDA	Posted	08/23/2024	10/21/2025
PAR-24-216	Minor Use Minor Species Development of Drugs (R01)	HHS-FDA	Posted	05/29/2024	01/29/2027
RFA-FD-24-030	Drug Development Tools Research Grants (U01) Clinical Trials Optional	HHS-FDA	Posted	02/12/2024	05/13/2025
PAR-23-202	Vet-LIRN Capacity-Building Project and Equipment Grants (U18)	HHS-FDA	Posted	05/18/2023	09/04/2028

Finding Federal Financial Assistance



SMALL BUSINESS FUNDING

24 NIH Institutes and Centers along with CDC, FDA, and ACL fund scientists & entrepreneurs working to bring their discoveries to patients.



Opportunity Number ↕	Opportunity Title ↕	Agency ↕	Opportunity Status ↕	Posted Date ↕	Close Date ↕
PA-24-245	PHS 2024-2 Omnibus Solicitation of the NIH, CDC and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44] Clinical Trial Not Allowed)	HHS-NIH11	Posted	07/03/2024	04/05/2025

Applying for Federal Financial Assistance



Learn

Go to the Grants Learning Center for an overview of grants.



Check

Make sure you are eligible before applying.



Search

Find federal grants that align with your work.



Register

Sign up with Grants.gov to apply using Workspace.



Apply

Complete and submit your application using Workspace.



Track

Enter your Grants.gov tracking number(s) for submission status.

Grants.gov

Thank You!

Contact Information:
Stephanie Bogan
Grants Management Branch Chief
Stephanie.bogan@fda.hhs.gov

Human Foods Program: Mission and Opportunities

Matt Baker

Director, HFP Division of Budget and Planning

Human Foods Program (HFP) Vision & Mission

FDA



Vision

The food supply is a vehicle for wellness.

Mission

Protect and promote the health and wellness of all people through science-based approaches to prevent foodborne illness, reduce diet-related chronic disease, and ensure chemicals in food are safe.



Human Foods Program Snapshot

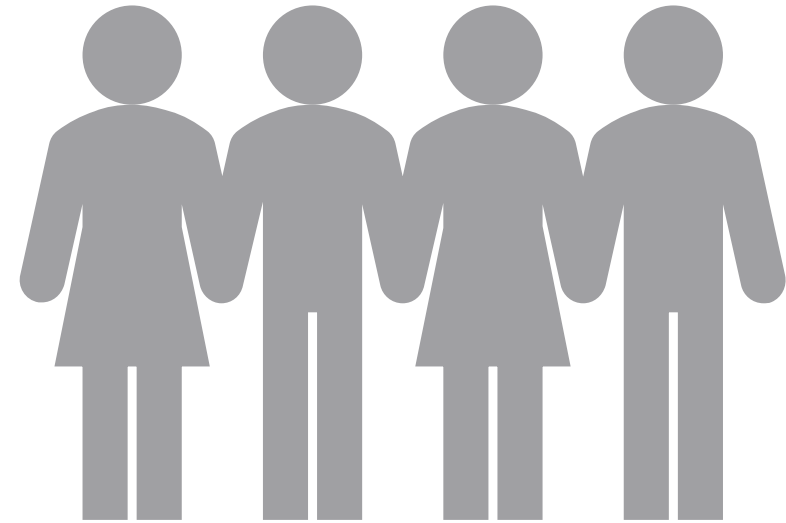
\$1 trillion+: The amount of food and dietary supplements we safeguard

91,000+: Domestic registered food facilities

35,000: Produce farms

128,000+: Foreign registered food facilities

2,200+: Employees



Vast array of products and programs

PRE-MARKET REVIEW

- ✓ Food & Color Additives
- ✓ Infant Formula
- ✓ New Dietary Ingredients
- ✓ Labeling Claims
 - ✓ Structure-Function Claims
 - ✓ Health Claims
 - ✓ Nutrient Content Claims

POST-MARKET REVIEW

- ✓ Manufactured / Processed Foods
- ✓ Non-Grade A Dairy
(cheese, ice cream, cream cheese)
- ✓ Canned Foods
- ✓ Acid/Acidified Foods
- ✓ Fresh Vegetables
- ✓ Fresh Fruits
- ✓ Processed Fruits & Vegetables
- ✓ Shell Eggs
- ✓ Bottled Water & Beverages
- ✓ Game Meat
- ✓ Food Labeling
- ✓ Dietary Supplements

Internal, Pre-Decisional

COOPERATIVE PROGRAMS

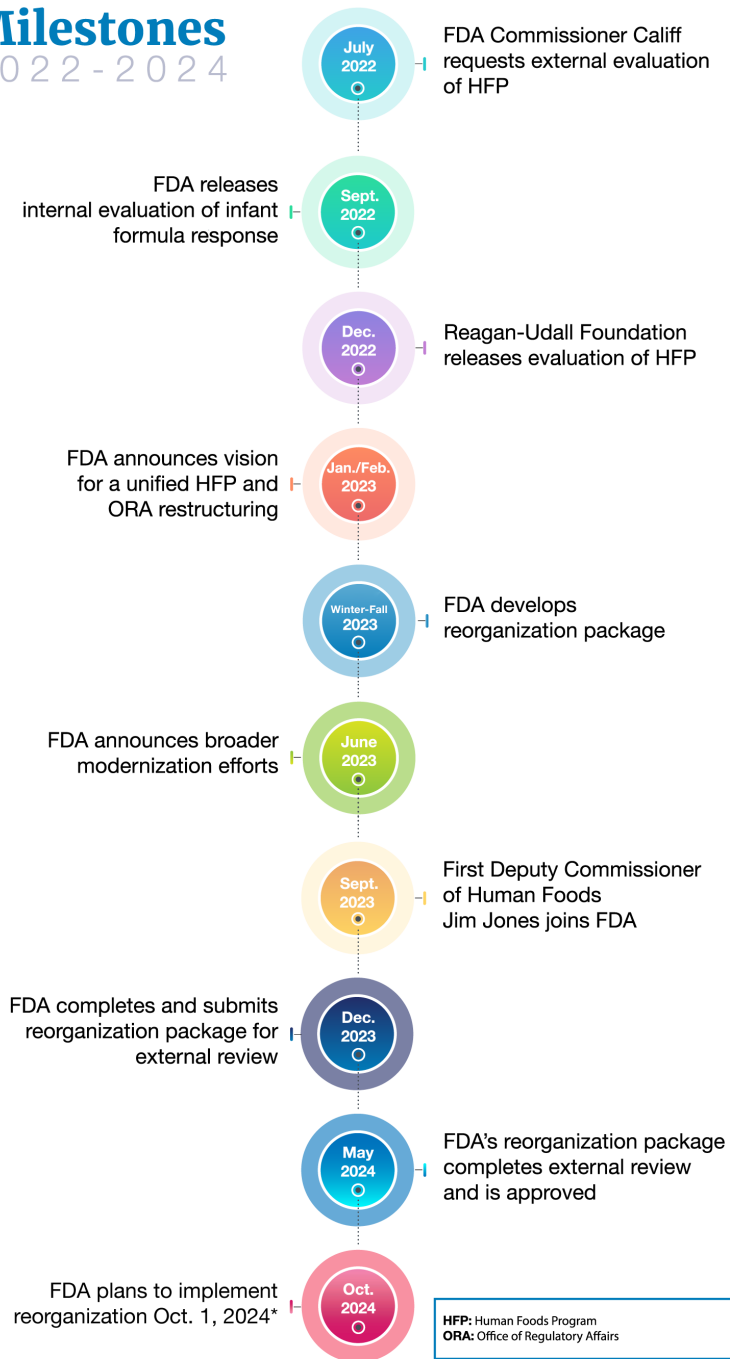
(Federal/State)

- ✓ Shellfish (NSSP)
- ✓ Milk Safety (NCIMS)
- ✓ Retail Food (Food Code)



Milestones

2022 - 2024



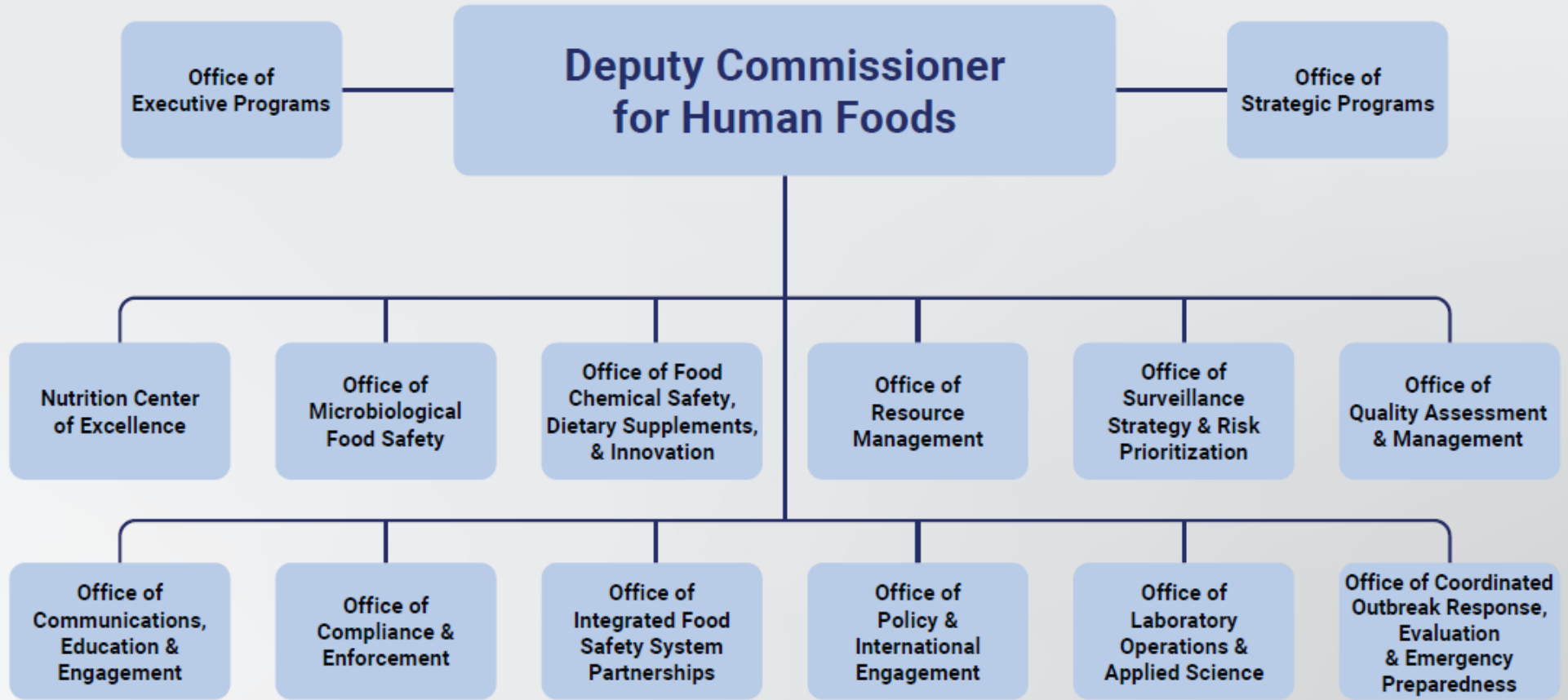
HFP: Human Foods Program
ORA: Office of Regulatory Affairs

* The reorganization will be implemented when all required reorganization steps have been met.

Legend:

Directly impacted by reorganization that took effect on Oct. 1, 2024 (i.e., shifts of functions, resources and/or personnel)

Department of Health and Human Services
Food and Drug Administration
Human Foods Program



HFP: FY 2025 Opportunity

Project Title: “Shipping, Receiving, & Laboratory Support Services”

Description Requirement: To obtain HFP mission support, including shipping and receiving support (internal delivery of packages, dangerous goods shipping); laboratory media preparation; laboratory storeroom operations (including hazardous chemical storage, handling and delivery); laboratory glassware decontamination and distribution; and medical/pathological waste (MPW) handling.

Current Award Details:

Current Contract Number	75F40121C00197
Current Contract Expiration Date	9/29/2025

Advance Procurement Plan Details:

NAICS	• 561210
Estimated Project Value	• \$3-5M



HFP: FY 2025 Opportunity

Project Title: “Leadership Development Board Support Services”

Requirement Description: To obtain leadership development support and coaching services to assist the Leadership Development Board in group coaching and implementation of an intentional, systematic, and effective leadership development program.

Current Award Details:

Current Contract Number	75F40121C00012
Current Contract Expiration Date	1/28/2025

Advance Procurement Plan Details:

NAICS	• 611710
Estimated Project Value	• \$1-3M

HFP: FY 2025 Opportunity

Project Title: “Scientific Desktop Publishing and Editing Services”

Requirement Description: To provide scientific writing services to support production of scientific publications and abstracts. Scientific writer support will help to facilitate the messaging efforts of research scientists.

Current Award Details:

**Current Contract
Number**

75F40120C00065

**Current Contract
Expiration Date**

7/15/2025

Advance Procurement Plan Details:

NAICS

• 541690

Estimated Project Value

• \$1-3M

HFP POC: LaQuia S. Geathers, laquia.geathers@fda.hhs.gov



HFP: FY 2025 Opportunity

Project Title: “Shipping, Receiving, & Laboratory Support Services”

Description Requirement: To obtain HFP mission support, including shipping and receiving support (internal delivery of packages, dangerous goods shipping); laboratory media preparation; laboratory storeroom operations (including hazardous chemical storage, handling and delivery); laboratory glassware decontamination and distribution; and medical/pathological waste (MPW) handling.

Current Award Details:

Current Contract Number

75F40121C00197

Current Contract Expiration Date

9/29/2025

Advance Procurement Plan Details:

NAICS

• 561210

Estimated Project Value

• \$3-5M

HFP POC: LaQuia S. Geathers, laquia.geathers@fda.hhs.gov

HFP: FY 2025 Opportunity

Project Title: “Training Support for HFP Staff College”

Requirement Description: To obtain the services of qualified personnel capable of providing instructional services and technical training courses on HFP regulated products including Manufactured Foods, Retail, Shellfish, Dairy and other areas under HFP’s authority.

Current Award Details:

Current Contract Number	N/A
Projected Start Date	8/01/2025

Advance Procurement Plan Details:

NAICS	• 611710
Estimated Project Value	• \$3-5M

HFP POC: LaQuia S. Geathers, laquia.geathers@fda.hhs.gov



U.S. FOOD & DRUG
ADMINISTRATION

FDA IT Acquisition Strategy





Mission

Serve as the leading force in technology and data to advance FDA's public health mission.



Vision

Unlock FDA's technology and data potential to improve health for all.

Our Journey

FDA's Technology Modernization Action Plan (TMAP)

September 18, 2019

2019

Data Modernization Action Plan

March 3, 2021

Introduction: Science-based regulation of evolving technologies will require FDA to develop new ways of interacting with data

Data have always formed the basis of science-based regulatory decision-making. These data may come from traditional sources—for example, measurements submitted to FDA from clinical trials or observations from FDA field inspections. As technology becomes more sophisticated and our world becomes more connected, data from many new sources can help us understand how medical products are performing, pinpoint the source of foodborne illness, or understand emerging public health threats.

At the same time, FDA's regulatory mission is growing more complex with the technological evolution of FDA-regulated products. New technologies hold enormous promise to patients and consumers—and unique challenges for responsible regulation. Without modern expertise and approaches to managing and analyzing data, FDA will miss critical opportunities to benefit patients and improve public health.

Data Modernization at FDA

In today's world, most interactions and processes are instrumented and digitized creating an abundance of data. Leveraging this data using modern data techniques will unlock new insights and value for public health.

Decades ago, much of the information submitted to FDA was not in digitized form—think of a hand-drawn graph representing the observations of an experiment. However, as digital technologies have become the norm over the past few decades, our society's ability to capture, analyze, and display data has created opportunities to analyze these data in powerful new ways.

2021

Enterprise Modernization Action Plan (EMAP)

May 2022

2022

Cybersecurity Modernization Action Plan

U.S. Food and Drug Administration

Office of Information Security
Office of Digital Transformation

November 2022

Leadership Modernization Action Plan (LMAP)

December 2022

Challenges

- Rapidly changing environment
- Aging systems and equipment
- Data sharing
- Budget and costs
- Talent turnover
- Cultural silos



“ We need the ability to create systems that **allow us to keep up** with the complexities of the industries and products we regulate, with **immense consequences** for the health of all Americans.

- **Robert M. Califf** M.D., MACC, FDA Commissioner

First Agency-Wide IT Strategy

Food and Drug Omnibus Reform Act of 2022



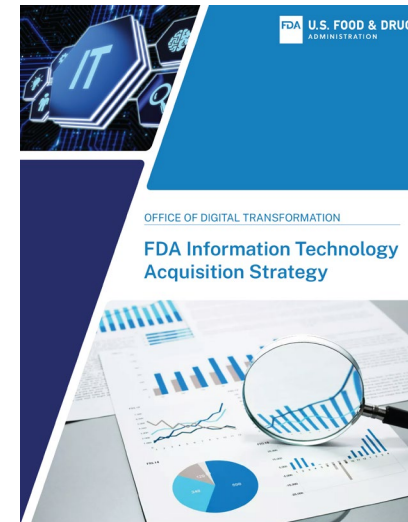
Published 9/2023



User Fee Commitment



Published 2/2024



GAO Assessment



Published 2/2024



IT Strategy Goals

1

Create a Shared OneFDA Ecosystem

2

Strengthen IT Infrastructure

3

Modernize Enterprise Services and Capabilities

4

Share Data for Mission Outcomes

5

Adopt Artificial Intelligence and Mission-Driven Innovations

6

Cultivate Talent and Leadership

IT Acquisition Strategy Goals

- **Strategic Procurement and Management**
- **Alignment with Enterprise Architecture**
- **Robust IT Vendor Management**

FDA IT Acquisition Challenges

- **Governance**
- **Meeting Socio-Economic goals**
- **Long acquisition timelines**
- **Redundant Business arrangement**
- **Business partners' performance management**
- **Enterprise licensing arrangement**
- **High O&M cost**
- **Get economies of scale across FDA**

Opportunities

- **Setting up large enterprise strategic acquisition vehicles**
- **Vendor management program- eSTAR**
- **Enterprise license management**
- **AI/ML for data mining and efficiencies**
- **Get economies of scale across FDA**
- **Robust processes and innovative techniques**
- **Enterprise Architecture**
- **Workforce development**

Questions

The background of the central section is a dark blue field with a network of glowing white lines and dots. A red location pin with the number "1" is positioned at the top left, with a white line pointing to the text. On the right side, there is a large, stylized compass rose with multiple white and blue needles pointing in various directions.

~~MPF Federal~~
Small Business
Journey in
Federal Contracting

702 Russell Avenue, Suite 400
Gaithersburg, MD 20877
Phone: (301) 265-2200
Email: info@mpffederal.com

Topics

1 Brief Overview of MPF Federal

2 Key Lessons Learned

3 Free Advice

4 Next Steps in Our Journey



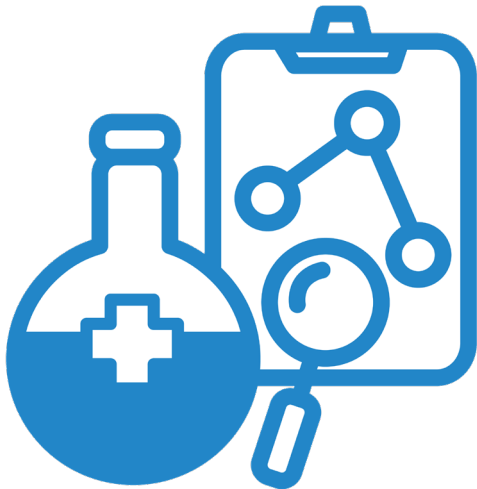
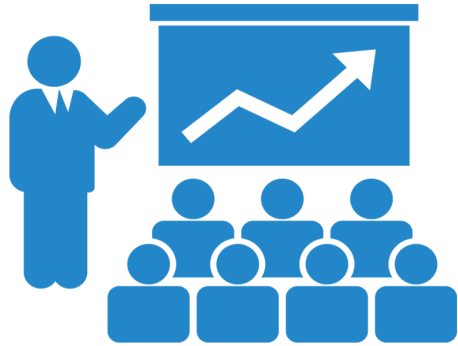


Brief Overview

- **Year Established:** 2012
- **Small Business Types:** SBA- Certified 8(a), HUBZone, Disadvantaged and Women-Owned Small Business
- **Facility clearance level:** Top Secret
- **Certifications:**
 - *CMMI Dev/3 and CMMI SVC/3*
 - *ISO 27001:2013*
 - *ISO/IEC 20000-1:2018*
 - *ISO 9001:2015 Certified*
 - *ISO 20001-1 (service management)*
 - *ISO 27001 (information security) certifications*

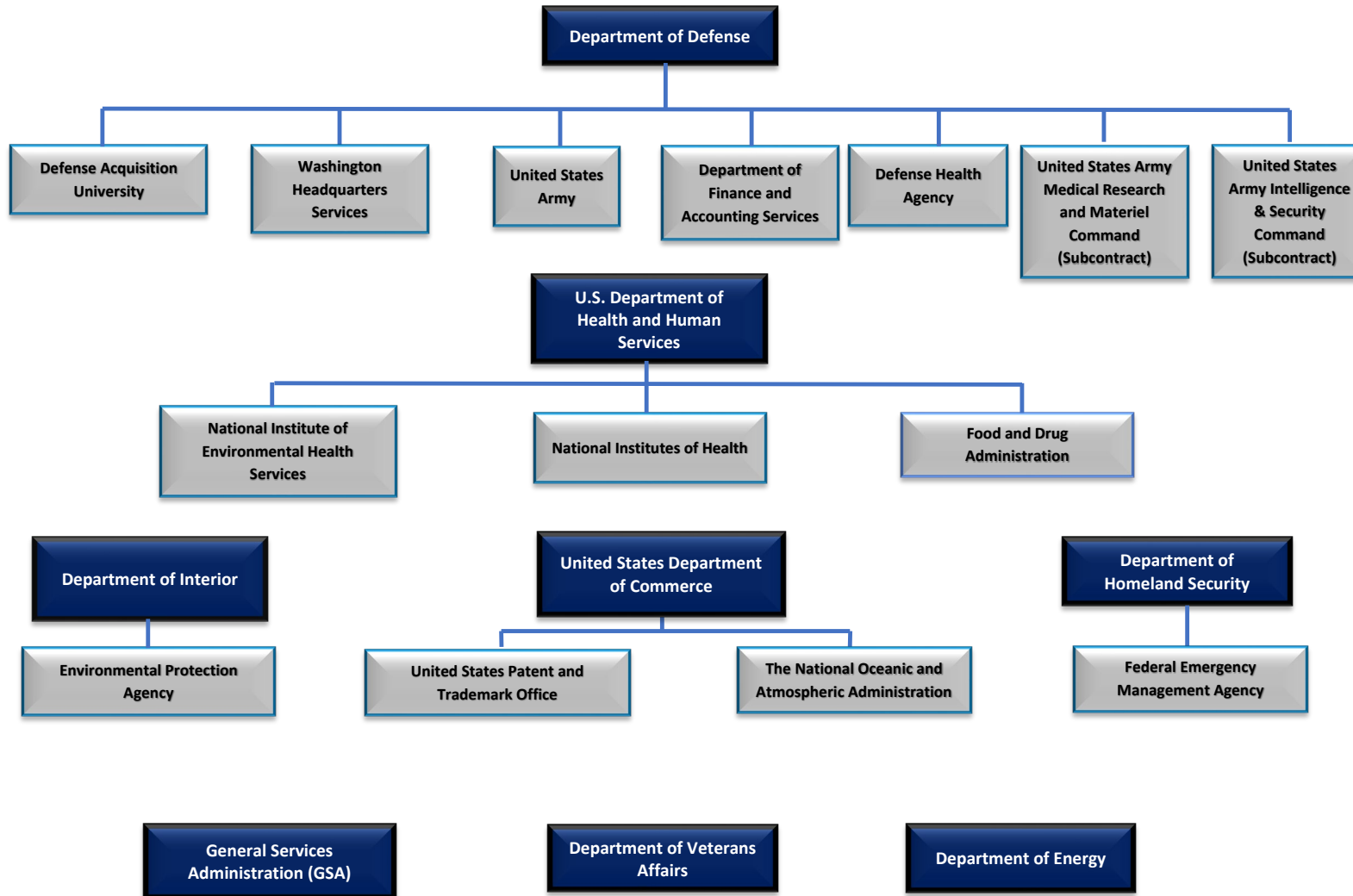


MPF CORE CAPABILITIES AND SERVICES



Training and Technical Services
Clinical Research and Evaluation
Life Sciences and Animal
Research Support
Systems Development and
Operations
Information Technology

Federal Agencies We Support



In the Beginning ...

- Contract at IRS
- Attending outreach events
- Talking to other companies



Key Lessons Learned

START



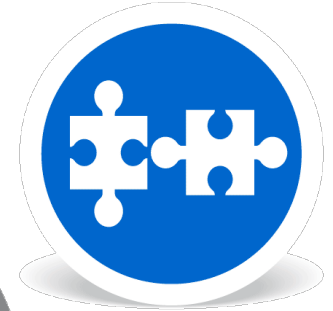
PREPARE

- Network
- Do Your Homework
- Know Your Customer
- Be Flexible and Listen



PEOPLE

- Right People
- Right Time
- Right Place



PARTNERSHIPS

- Leverage Partnerships



PERFORM

- Deliver Strategic Value
(Don't Simply Do Executive Tasks)

What is Your Plan



Identify a specific set of clients or contracts to go after — the government is too large to go after anything and everything



Spend the time developing (or partnering on) the right solution for the client that fits the way that they want to buy



Invest in understanding the client environment that you are going after — meet with people and *listen* to learn as much as you can



Differentiate yourself from others





Free Advice: Establish Meaningful Partnerships



- Government contracting is difficult for small business to get started. One important strategy is to partner for capability and past performance coverage
- Seek out partnerships that are complementary in terms of capabilities and experience
- Strategic partnerships can make the pie bigger for both parties — be careful not to destroy a potential long-term partnership over near-term workshare concerns
- Contract-access partnerships have their place — but recognize what you mean to the other partner

Relationships Matter

- Do you know the Small Business Rep?
- More importantly, do they know you?
- Do you know anyone in the Contracts Office?
- More difficult, but most important, do you know the Program Officials?



8(a) Certification Program



U.S. Small Business
Administration



Benefits from 8(a) Program

- Set aside contracts
- Sole Sourced contracts
- Receive one-on-one business development assistance for the nine-year term
- Pursue opportunities for mentorship from experienced and mature businesses
- Pursue joint ventures with established businesses to increase capacity

Graduation from 8(a)



- Leverage established customer relationships
- Leverage established business relationships
- Pay it forward with other small businesses through M/P relationships
- New Joint Ventures



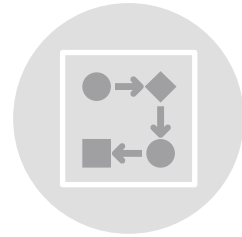
Next Steps in Our Journey: Internal Challenges



Managing growth
and evolution of
the company



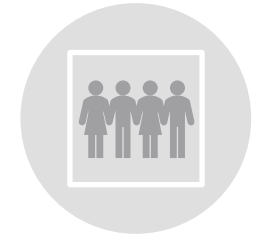
Building
infrastructure



Process Maturity



Expanding
headquarters
resources



Recruiting and
retaining staff

External Challenges



Expanding phase of proposal management -
PROTESTS



Increasing emphasis on
LPTA contracts

Make a Difference

- As an Employer
- As a Business
- As a Partner for the Government





EXIT 128 →

Thank You

Closing Remarks

*Benjamin Moncarz,
Chief Financial Officer*



FDA FY2025 Small Business Fair

Thursday, November 14, 2024
9:00 AM – 4:00 PM

FDA White Oak Campus Great Room
10903 New Hampshire Avenue, Building 31
Silver Spring, Maryland 20903



FDA U.S. FOOD & DRUG
ADMINISTRATION

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**THANK YOU FOR
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