

A complex network of blue lines and dots on a white background, representing a web of connections or a molecular structure.

# Welcome to the FISCAL YEAR 2026 FDA SMALL BUSINESS FAIR

---

November 20, 2025



# Opening Remarks

---

Dr. Barclay Butler  
Deputy Commissioner for Operations  
and Chief Operating Officer

# HCA Welcome

---

Leonard Grant  
Head of Contracting Activity

## ❑ FDA's Commitment to Small Business

- **Exceeded all FY24 and FY25 Small Business Goals**
- Hosting Small Business Events and Meet and Greets

## ❑ Resources and Support

- FDA OAGS Leadership Contact Information
- HHS Office of Small and Disadvantaged Business Utilization (OSDBU) Small Business Customer Experience ([SBCX](#))
- [FDA eBid Board](#)

## ❑ Action Items for Today

- Grow and develop your network - relationships drive opportunities in federal contracting.

# OAGS Contact Information

FDA

- **Ron Loube, Associate Director, 240-402-7539 / [ronald.loube@fda.hhs.gov](mailto:ronald.loube@fda.hhs.gov)**
- **Natalie Mitchell, Acting Director, Division of Information Technology Acquisitions (DITA) [All IT]  
301-796-8858, [Natalie.Mitchell@fda.hhs.gov](mailto:Natalie.Mitchell@fda.hhs.gov)**
- **Sandy Bellinger, Director, Division of Acquisition Programs (DAP) [Facilities and Lab Support, Services, and Supplies]  
240-402-7524 / [sandra.bellinger@fda.hhs.gov](mailto:sandra.bellinger@fda.hhs.gov)**
- **Kimberly Pendleton, Director, Division of Grants, Agreements, and Acquisition Support (DGAAS) [Grants]  
240-402-7610 / [kimberly.pendleton@fda.hhs.gov](mailto:kimberly.pendleton@fda.hhs.gov)**
- **Vidya Vish, Director, Division of Acquisition Operations (DAO) [Professional Services, Training, Research Services (BAA)]  
240-402-7576 / [vidya.vish@fda.hhs.gov](mailto:vidya.vish@fda.hhs.gov)**
- **Bryan Jones, Director, Division of Systems, Policy, and Program Support (DPSPS)  
240-402-7571 / [bryan.jones@fda.hhs.gov](mailto:bryan.jones@fda.hhs.gov)**



# **Doing Business with the FDA**

---

*Natalie Mitchell*

**OFBA | Office of Finance, Budget & Acquisitions**



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



- 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.



## Mission



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

## Vision



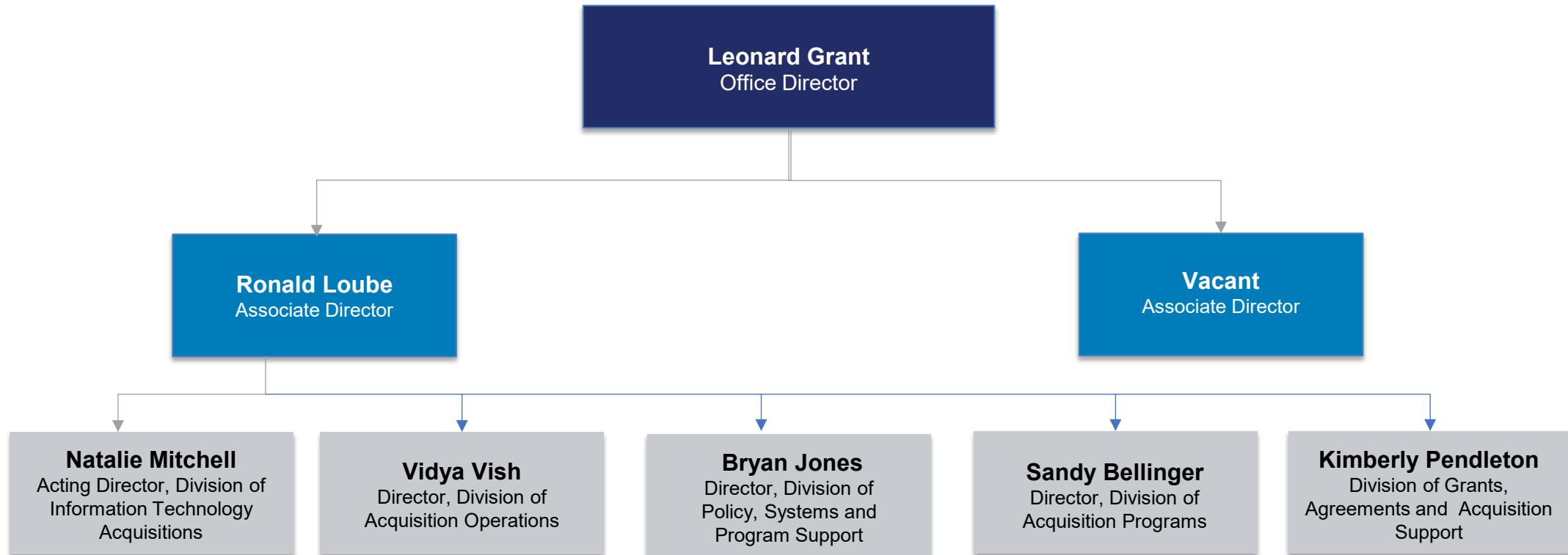
To be an acquisition center of excellence by **fostering strategic collaboration** with our partners and **empowering our workforce** to achieve results that protect and promote the health of all Americans while maintaining the public trust.

## 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

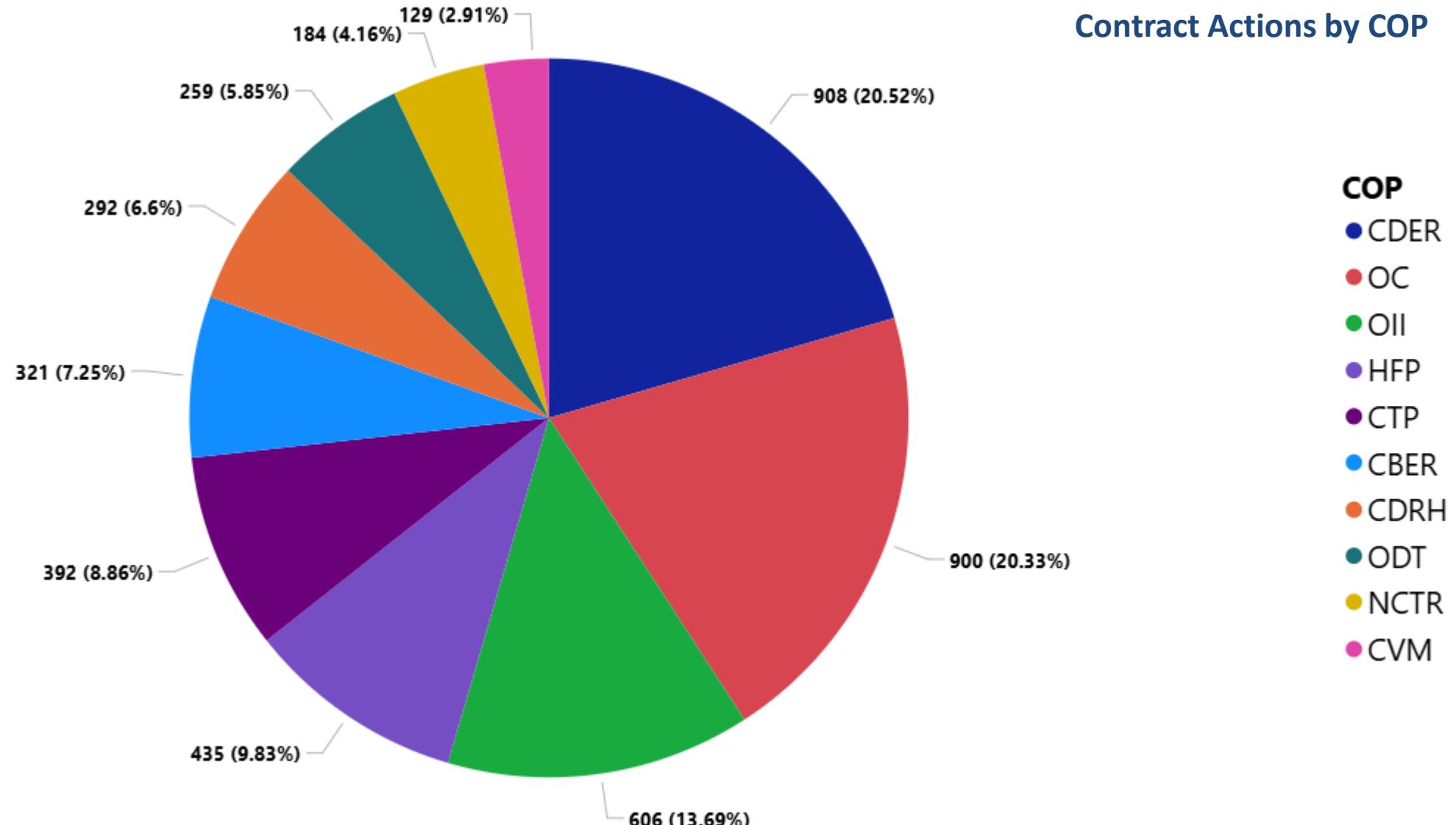


***Our staff provides the required depth of knowledge and experience to award and manage billions of dollars in contracts and grants to improve mission outcomes across the FDA***

# FY25 Statistics for OAGS



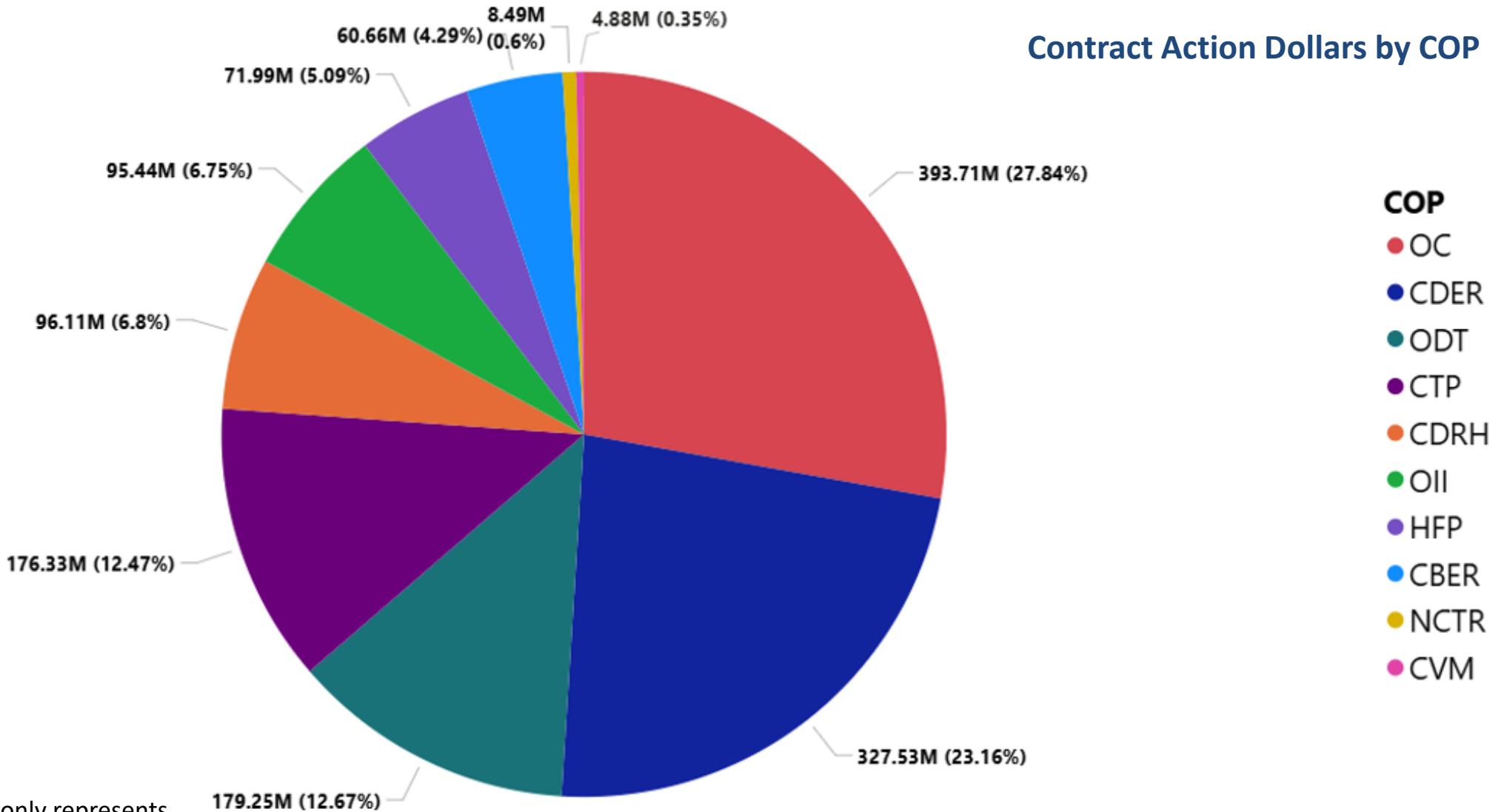
## Contract Actions by COP



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

## FY25 Statistics for OAGS

## Contract Action Dollars by COP



# FDA Socioeconomic Goals



Small Business Award Categories	FY Goal (FY15-21)	FY19	FY20	FY21	FY22	FY23	FY24 Goals	FY 24	FY25 Goals	FY 25
Small Businesses	38%	39.06%	40.09%	34.33%	33.49%	38.02%	33.06%	44.35%	38.50%	48.67%
Small Disadvantaged Businesses	5.00%	27.14%	26.96%	23.84%	23.96%	25.84%	26.50%	30%	9.87%	35.35%
Women-Owned Small Businesses	5.00%	14.13%	12.68%	10.33%	11.01%	11.58%	9%	12.12%	9.25%	9.69%
HubZone Businesses	3.00%	2.75%	4.09%	3.81%	4.48%	4.37%	4.34%	6.35%	5%	8.98%
Service-Disabled Veteran Owned	3.00%	2.81%	3.91%	2.29%	3.22%	3.79%	4.41%	5.43%	5%	5.39%

# Top 10 Contract Expenditure Categories for FY 2025

FDA

## Top 10 Vendors

Vendor Name	Sum of Dollars Obligated
DELOITTE CONSULTING LLP	\$115,282,728.83
PERATON ENTERPRISE SOLUTIONS LLC	\$66,809,091.66
BOOZ ALLEN HAMILTON INC	\$59,221,991.34
TRUE NORTH COMMUNICATIONS INC.	\$51,153,844.96
VETS SYNERGETIC GROUP LLC	\$42,996,272.32
REI SYSTEMS, INC.	\$42,244,582.83
KAIVA STRATEGIES, LLC	\$36,363,343.28
PRECISE SOFTWARE SOLUTIONS, INC.	\$31,044,539.66
INTERNATIONAL CONSULTING ASSOCIATES INC	\$29,572,362.91
FOUR POINTS TECHNOLOGY, L.L.C.	\$26,832,337.04
<b>Grand Total</b>	<b>\$501,521,094.83</b>

## Top 10 NAICS

Top 10 NAICS by Expenditures	Sum of Dollars Obligated
ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES – 541611	\$240,300,221.42
OTHER COMPUTER RELATED SERVICES – 541519	\$234,368,080.51
COMPUTER SYSTEMS DESIGN SERVICES - 541512	\$198,815,612.35
CUSTOM COMPUTER PROGRAMMING SERVICES – 541511	\$172,782,970.82
ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES – 541990	\$90,431,635.88
COMPUTING INFRASTRUCTURE PROVIDERS, DATA PROCESSING, WEB HOSTING, AND RELATED SERVICES - 518210	\$59,755,492.03
ADMINISTRATION OF PUBLIC HEALTH PROGRAMS - 923120	\$54,291,221.59
ADVERTISING AGENCIES - 541810	\$51,153,844.96
SOFTWARE PUBLISHERS - 511210	\$43,363,250.12
COMPUTER FACILITIES MANAGEMENT SERVICES - 541413	\$27,978,621.51
<b>Grand Total</b>	<b>\$1,173,240,951.19</b>

# Top 10 Small Business Contract Expenditure Categories for FY 2025

FDA

## Top 10 Small Business Vendors

Top 10 SB Contract Expenditures	Sum of Dollars Obligated
VETS SYNERGETIC GROUP LLC	\$ 42,996,272.32
KAIVA STRATEGIES, LLC	\$ 36,363,343.28
PRECISE SOFTWARE SOLUTIONS, INC.	\$ 31,044,539.66
INTERNATIONAL CONSULTING ASSOCIATES INC	\$ 29,572,362.91
FOUR POINTS TECHNOLOGY, L.L.C.	\$ 26,832,337.04
HUMANTOUCH LLC	\$ 17,664,916.23
SOFTWARE INFORMATION RESOURCE CORP.	\$ 16,308,182.12
PN-HEITECH, LLC	\$ 14,153,028.26
AKIMA DATA MANAGEMENT LLC	\$ 12,432,879.38
OBAN CORPORATION	\$ 12,371,179.98
<b>Grand Total</b>	<b>\$ 239,739,041.18</b>

## Top 10 NAICS (SB)

Top 10 NAICS (Small Business Contracts)	Sum of Dollars Obligated
OTHER COMPUTER RELATED SERVICES – 541519	\$ 199,989,623.90
ADMINISTRATIVE MANAGEMENT AND GENERAL MANAGEMENT CONSULTING SERVICES – 541611	\$ 93,316,596.05
"ALL OTHER PROFESSIONAL, SCIENTIFIC, AND TECHNICAL SERVICES" – 541990	\$ 82,538,426.03
CUSTOM COMPUTER PROGRAMMING SERVICES – 541511	\$ 61,709,210.77
COMPUTER SYSTEMS DESIGN SERVICES – 541512	\$ 55,133,907.04
COMPUTER FACILITIES MANAGEMENT SERVICES - 541513	\$ 27,978,621.51
FACILITIES SUPPORT SERVICES – 561210	\$ 18,050,294.90
COMPUTING INFRASTRUCTURE PROVIDERS, DATA PROCESSING, WEB HOSTING, AND RELATED SERVICES - 518210	\$ 17,530,745.64
COMPUTER AND COMPUTER PERIPHERAL EQUIPMENT AND SOFTWARE MERCHANT WHOLESALERS - 423430	\$ 13,240,942.00
SECURITY SYSTEMS SERVICES (EXCEPT LOCKSMITHS) - 561621	\$ 10,629,386.31
<b>Grand Total</b>	<b>\$ 580,117,754.15</b>

## Get your Business Ready

- Obtain a DUNS number from Dun & Bradstreet
- Register in System for Award Management (SAM).
- View Resources on [HHS OSDBU](#)

## Obtain a GSA Schedule or GWAC

- Being on schedule and/or a GWAC makes good “business sense” and will provide your company with multiple options.

## Develop Allies

- Find opportunities for mentorship, teaming, and partnering
- Participate in FDA and HHS [outreach events](#)

## 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

## Maintain High Ethical Standards

- Federal officials involved in the procurement process are limited in what information they can disclose.

## Own Your Future

- Review FDA [eBid Board](#)
- 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](#))

# OBISM and the OII IT Ecosystem

**Dr. Saumyendu Ghosh**



---

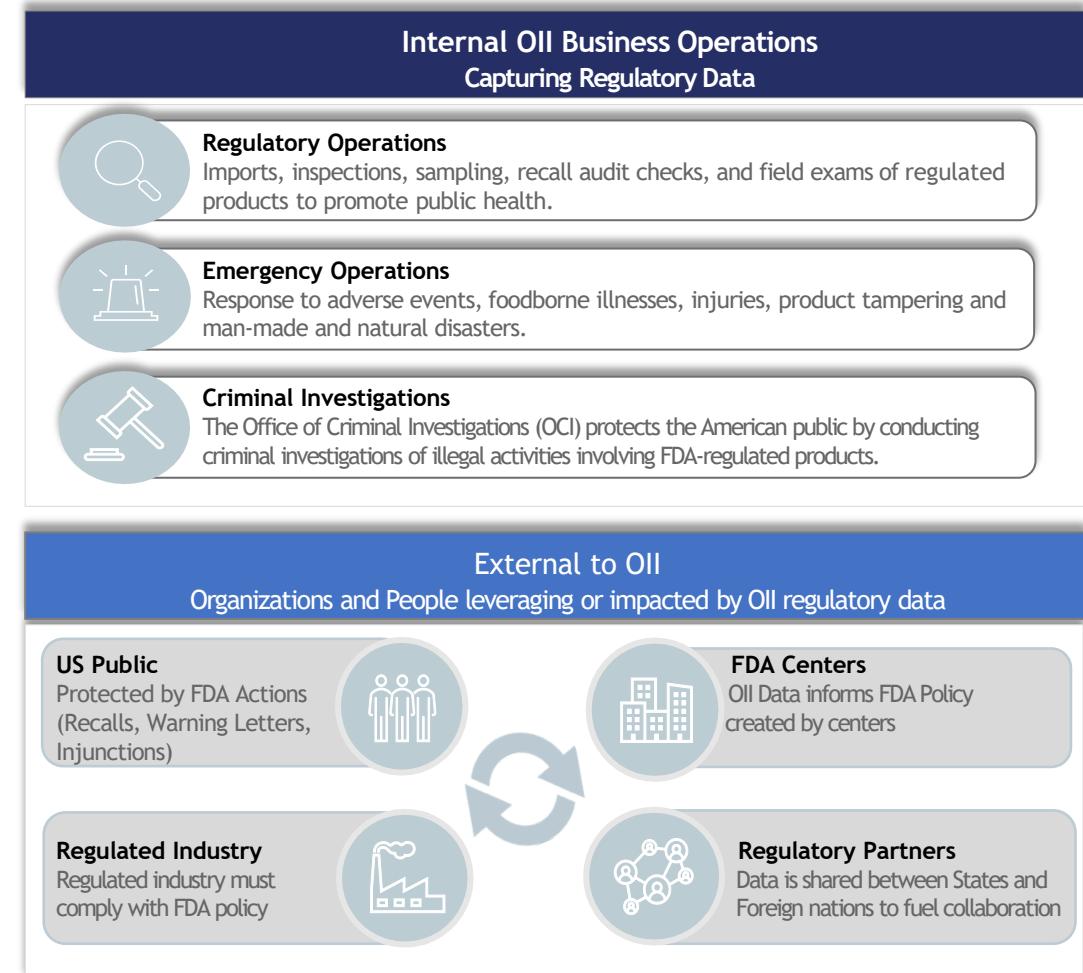
Office of Inspections and Investigations

# OBISM: Our Role and Mission

## Delivering IT Excellence for the American People

The Office of Business Informatics and Solutions Management (OBISM) plays a pivotal role within the Office of Inspections and Investigations (OII), providing strategic leadership and comprehensive support across multiple commodities and the agency's regulatory enforcement and import systems. Specializing in IT and data analytics, OBISM serves as the central hub for the development, implementation, and oversight of business informatics and solutions that drive operational efficiency and regulatory compliance for OII.

The office supports OII leadership and Centers by delivering expert counsel on business informatics needs, facilitating effective coordination with key partners within OII, contractor partners, and the FDA Office of Digital Transformation (ODT), where OBISM is currently detailed.



**Regulatory Enforcement Data Capture**  
 OII staff need tools to support enforcement operations like inspections and investigations. OII has recently implemented the Regulatory Operations Management System (ROMS), in Appian to improve Domestic Sample Collections and Field Exams and Recall Audit Checks.



# OII IT Ecosystem



## Enforcement and Operations Support Systems



Mobile Platform Solutions



Shared Services



Self Serve Releases  
Low/No-Code



## Infrastructure, Analytics, and Reporting



Enterprise Integrations



Leveraging AI and  
ML Platforms



Infrastructure &  
Cloud Migration  
Solutions

## Import Modernization

OII staff need cutting edge tools to predict risk and screen the import of millions of FDA-regulated products. FDA systems protect against possible bioterrorism threats and ensure imports that do not meet regulations are not admitted into commerce.



## Case Management

Case Management and Administrative Resource System (CMARS) is a new, modernized case management system that maintains the integrity of criminal investigations for legal proceedings through investigative reporting requirements, chain of custody management, intelligence support, and stakeholder reporting.

## Work Management

OII field work planners require innovative solutions to reduce time needed to create work plans, track operational activity targets, and determine workforce allocations in line with congressional mandates.

## Business Intelligence

Across the OII portfolio there are needs for cloud migration for data management, reporting, business intelligence, analytics, searching, and predictive analysis tools. Expertise is needed in managing hybrid cloud environments; internal (RHEV, VMWare, Citrix) & external (AWS, Google, Azure).



# Office of Translational Sciences (CDER/OTS)

Robert Gump  
Sr Research Biologist / COR II  
CDER/OTS/OCP/DARS

11/20/2025  
FDA Small Business Vendor Fair

# OTS Organizational Structure



# OTS Mission and Vision

## Mission

We empower a diverse, collaborative, and high-performing workforce to champion innovation and advance global human drug development

## Vision

Driving advancements in human health through scientific and regulatory innovation

# Office of Translational Sciences

## What We Do

OTS promotes and protects public health by assuring that safe and effective drugs are available to Americans by:

- Promoting scientific collaboration and innovation in drug regulatory review across CDER
- Assuring the validity of clinical trial design and analysis in regulatory decision making
- Developing and applying quantitative and statistical approaches to decision making in regulatory review process
- Ensuring alignment of CDER research with CDER goals
- Serving the CDER scientific community in establishing technology transfer agreements that are vital to collaboration with the broader scientific community
- Maintaining knowledge management databases that can be the basis of improvements in the regulatory review process
- Overseeing bioequivalence inspections to ensure the availability of safe and effective generic equivalents of investigational drugs

# OTS FY26 Priorities

## Empowering People

- Ensuring that our staff members have the support they need to thrive while continuing to meet our public health mission in a new hybrid work environment.
- Creating tools that help staff navigate and enhance communications, culture, technology, training, and mentorship, administrative updates, accountability, and equity.
- Enabling staff to quickly identify and partner with internal experts and subject matter expertise, even at a distance.

## Optimizing Processes

- Expanding the Administrative Operations Information System (AOIS)
- Refining strategies to improve inspections and remote tools while continuing work on advancing the surveillance of bioavailability/bioequivalence studies and good laboratory practice studies.
- Focusing on the enablement of automation to streamline work products and improve efficiency

## Enhancing Regulatory Review

- Emphasizing our critical core regulatory review activities to meet user fee deadlines and support thorough assessments of applications.
- Enhancing analytics environments and focusing on data quality.
- Accelerating Rare Cures (ARC), advancing innovation of medical products for underserved populations, alternative methods development, Complex Innovative Trial Designs, Model-Informed Drug Development, Patient Focused Drug Development, and Inspection Modernization.

THANK YOU



# **OAGS Contracting Officer Panel**

---

# Panel Introductions

---

Moderator: Jay O'Keefe

---

Ian Weiss, DAO  
Kim Davis, DAO  
Phillip Frame, DITA  
Maria Finan, DAP

# OAGS Panel Questions

**Question:** Will FDA be sharing an acquisition forecast for small business opportunities available in FY2026?

**Question:** Could you walk us through what a typical FDA procurement process looks like, from solicitation to award?

# OAGS Panel Questions

**Question:** What is your advice for a company new to government contracting to secure first contract within 6 months?

**Question:** How do FDA Contracting Officers plan to adapt to the proposed FAR changes, and what does it mean for small businesses?

# OAGS Panel Questions

**Question:** What do you wish more vendors understood about the internal decision-making process between technical teams and contracting officers when evaluating proposals?

**Question:** How heavily does FDA anticipate using government wide acquisition contracts (GWACs) for procurement in the coming year?

# OAGS Panel Questions

**Question:** What are the most common challenges or pitfalls you see companies encounter when bidding on FDA contracts, and what advice would you give to improve their chances of success?

**Question:** What are the current FDA priorities when it comes to acquisitions?



# Partnership, Purpose, and Perseverance

## A Small Business Journey With the FDA

### FDA Small Business Fair Keynote

Speaker: Anthony Adoremos, Chief Operating Officer  
Spatial Front Inc.



# Opening & Introduction

- Introduction to Spatial Front, Inc.
- Origins: Starting Small, Thinking Long Term
- Partnership: Listening Before Delivering
- Purpose: Why It Matters
- Perseverance: Building a Reputation for Reliability
- Modern Challenges: The Pace of Change
- Lessons for Small Businesses





# Origins: Starting Small, Thinking Long Term

- Began with a vision  
“Leading Geospatial  
Technologies  
to New Frontiers”
- Faced early challenges as an  
unknown business partner  
to the FDA
- Lesson: Success starts from  
understanding FDA’s mission  
and instilling trust





# Partnership: Listening Before Delivering

- Approach: Asking the FDA, 'What's holding you back?'
- Capability aligned with FDA's vision and mission
- Listening became our modus operandi
- Innovation was our pathway





# Purpose: Why It Matters

- Behind every contract there's a mission to serve people
- FDA's mission impacts millions
- Impact and innovation are at the heart of our culture





# Perseverance: Building a Reputation for Reliability

- Build reputation through capability
- Delivering on what we promise repeatably
- Eliminating single points of failure across the company
- Utilizing audits as an opportunity to coach



# Modern Challenges: The Pace of Change

- Rapid change: AI, cloud, cybersecurity, and data
- Accepting that change is always happening around us
- Balance innovation with relevance
- Remain agile, technically sharp, yet operationally grounded
- Adaptation as a small business advantage



# Lessons for Small Businesses

- Learn the Mission
- Invest in People
- Enhance Capability
- Build Repeatability
- Play the Long Game
- Every Large Contractor Started Small

# Questions and Answers



A complex network of blue lines and dots on a white background, representing a molecular or connectivity structure.

**Thank you for attending the  
Morning Speaker Session**

---

*LUNCH*